Policies and Procedures for the Pace University Human Research Protection Program

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Review History

Reviewed by HRPP Advisory Committee October, 2021 to April, 2022. Members:

Brian Evans, EdD, Professor, Mathematics Education, Dyson College of Arts and Sciences
Christopher Godfrey (co-chair), Clinical Associate Professor, Psychology - NYC, Dyson College of Arts and Sciences
Vishal Lala, PhD, Professor, Marketing, Lubin School of Business
Theresa K. Lant, PhD, Professor, Management and Management Sciences, Lubin School of Business
Eric Torres, Director for Sponsored Research
Lisa Valentino, JD, Associate University Counsel
Sharon Wexler (co-chair), PhD, Professor, PhD in Nursing, College of Health Professions
Anastasia Elizabeth Yasik, PhD, Professor, Psychology – NYC, Dyson College of Arts and Sciences
Zhan Zhang, PhD, Assistant Professor, Information Technology – NYC, Seidenberg School of Computer Sciences and Information Systems

Approved by Avrom Caplan, PhD, Associate Provost for Research, Institutional Official, April 28, 2022

1 Overview of the Human Research Protection Program (HRPP)

1.1. Ethical Principles for Protection of Human Subjects
(Dated 04/28/22)

When investigators carry out research involving human subjects, the investigators are treating the subjects as a means to an end, rather than an end in themselves. Consequently, there is an ethical obligation to protect the subjects' rights and welfare.

The Pace University Human Research Protection Program (HRPP) is guided by the principles established by The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report establishes three ethical principles for conducting research with human subjects: Respect for Persons, Beneficence, and Justice.

- Respect for Persons requires potential subjects to be treated as autonomous individuals capable of making an informed decision about whether or not to participate in research, and includes safeguards for those groups with less autonomy, such as children, prisoners, and adults with diminished capacity to consent.

- Beneficence requires that any risks to subjects are reasonable in relation to the benefits to subjects and to society at large from the knowledge to be gained by the research.

- Justice requires that the risks and benefits of the research be distributed fairly.

1.2. Requirements for Human Subjects Research Oversight
(Dated 04/28/22)

Pace University has established a Human Research Protection Program (HRPP) to oversee the conduct of human subjects research by Pace investigators and ensure the protection of the rights and welfare of human subjects. The three components of the HRPP are the Pace Institutional Review Board (IRB) (see Section 4.6.1), the HRPP communication program that provides education and training to investigators and others (see Section 4.6.2), and the HRPP auditing program (see Section 4.6.3).

1.3. Investigator Responsibilities
(Dated 04/28/22)

The Principal Investigator of human subjects research at Pace University is required to attest that they will comply with the following responsibilities:

1. Personally log into the electronic system using their individual username and password as the verification of their electronic signature.
2. Provide information to the IRB that is complete and accurate to the best of their knowledge.
3. Consult with the IRB if in doubt about which research activities are overseen by the IRB.
4. Design studies to protect individuals conducting the study, to adhere to ethical principles and standards appropriate to their discipline, to safeguard the rights and welfare of all human subjects, to minimize risks, to have adequate provisions to monitor the data for safety, to draw subjects from a population selected to distribute the risks and benefits fairly, to employ additional safeguards necessary to protect vulnerable populations, and to safeguard research

data.

5. Determine that adequate resources will be available to carry out the study, including facilities, access to an appropriate population, medical and psychological resources for subjects, and sufficient time and staff to conduct the research.
6. Ensure that prior to beginning work on the study, they and all members of the research team meet all applicable Pace University requirements for training and qualifications; disclose conflicts of interest; and are knowledgeable about study procedures.
7. Not initiate any human subjects research activities until an IRB final outcome letter has been received and any other required institutional approvals have been obtained.
8. Be responsible for execution and management of the study, including oversight and appropriate delegation of authority for all study personnel and any sub-awardees/subcontractors under their direction.
9. Comply with all applicable terms, conditions, assurances and certifications referenced in the application, award (grant or contract), and protocol; and with all applicable state, Federal, and local laws, rules, regulations, policies, and guidelines, as well as institutional policies (including those pertaining to IRB requirements, confidentiality, HIPAA, finances, and record retention) related to this study.
10. Follow the IRB-approved research plan by recruiting subjects in a fair and equitable manner; by adhering to the approved inclusion and exclusion criteria and maintaining appropriate documentation that demonstrates adherence; by employing the approved process for obtaining and documenting informed consent; by meeting all applicable HIPAA and other data security requirements; by maintaining the privacy of subjects and protecting the confidentiality of data; by responding appropriately to and documenting the response to subjects, prospective subjects, and family members who request information or have concerns or complaints; and by providing aggregate and/or individual study results to subjects if promised.
11. Maintain all required records and cooperate with any request for auditing by the IRB, sponsor, or government agency.
12. Comply with all requirements for identifying and reporting Unanticipated Problems, deviations, and safety monitors' reports, and any other new or significant information that might impact a subject's safety or willingness to continue in the study.
13. Ensure that IRB approval is obtained for non-exempt research prior to making any change to the approved study plan, consent form, or study personnel unless the change is immediately necessary for the safety of subjects; that IRB approval for continuation is obtained prior to the study expiration date; that a check-in is provided before the due date for studies without expiration dates; and that a closure report is submitted to close the study at the appropriate time.

2 Activities that Do Not Require Submission to the Pace IRB

2.1. Investigators Not Acting as Agents of Pace University

(Dated 04/28/22)

Submission to the Pace IRB is not required if a student, adjunct faculty member, or employee carries out human subjects research with no connection to Pace University. (Note that they must submit to a different IRB as appropriate.) For students, "no connection" means that the activity is not required by and will not be submitted for credit for any Pace University course or thesis requirement (e.g., the activity is performed as part of the student's outside employment). For adjunct faculty, "no connection" means that the activity has no association with any Pace educational or scholarly activity (e.g., the

activity is performed by an adjunct faculty member solely in connection with association with a non-Pace institution). For employees, "no connection" means that the activity is unrelated to any Pace job duties (e.g., the activity is required by a course taken by an employee at a non-Pace institution).

2.2. Pace Class Projects
(Dated 04/28/22)

Students who carry out projects involving intervention or interaction with living individuals or their identifiable data where the purpose of the project is to fulfill a class requirement, and not to develop or contribute to generalizable knowledge, are not required to submit the project to the IRB. However, the faculty member responsible for the class must have submitted to the IRB (see Section 3.2.1.6) and received an outcome letter from the IRB stating that the faculty's review process is acceptable (see Section 6.8.1).

2.3. Activities Other Than Class Projects that are Not Research with Human Subjects.
(Dated 04/28/22)

If an activity qualifies as either "Not Human Subjects Research" or "Not Engaged," submission to the IRB is not required.

Investigators may make their own determination using the algorithm below that their planned activity does not require submission to the IRB, either because it does not meet the definition of research, or because it does not involve human subjects. Investigators should submit a Not Human Subjects Research/Not Engaged request through the electronic system if they wish to check their evaluation or they need a formal Not Human Subjects Research/Not Engaged determination (see Section 3.1.2.5).

Algorithm for determining whether an activity requires IRB submission because it is human subjects research:

1. **Is the activity research**?
   Answer "No" if the activity is not designed to develop or contribute to generalizable knowledge. Also answer "No" if the activity is any of the following:
   (A) Scholarship or journalism focusing directly on the specific individuals about whom the information is collected (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship);
   (B) A clinical case study or case series that involves no more than three patients;
   (C) A non-clinical case study that investigates the processes, activities or operations at a single organization or event in non-treatment environment; or
   (D) Quality improvement or quality assurance that implements or evaluates a practice known to improve services.
   Yes ⇒ Continue to 2.
   No ⇒ End – IRB submission is NOT required

2. **Will the project involve any intervention or interaction with living individuals**?
   Answer "Yes" if there are any individuals who will do anything differently or have anything done to them differently because of this research, even if their identities are not known.
   Yes ⇒ IRB submission IS required, go to Section 3
   No ⇒ Continue to 3.

3. **Will the project involve obtaining biospecimens**?
   Answer "Yes" if blood, tissue, saliva, etc. will be obtained from a repository or pathology laboratory.
   Yes ⇒ IRB submission IS required, go to Section 3
   No ⇒ Continue to 4.

4. **Will the project involve obtaining information about living individuals** (any information pertaining to an individual's characteristics, opinions, or experiences)?
   Answer "Yes" even if you believe the information is anonymous – identifiability will be checked in questions 6-8.
   Yes ⇒ Continue to 5.
   No ⇒ End – IRB submission is NOT required

5. **Is the information Protected Health Information (PHI)?** Briefly, PHI is identifiable information from a health care provider.
   Yes ⇒ IRB submission IS required, go to go to Section 3
   No ⇒ Continue to 6.

6. **Will the information obtained be publicly available**?
   Answer "Yes" if no special access or permission is required to obtain the information.
   Yes ⇒ End – IRB submission is NOT required
   No ⇒ Continue to 7.

7. **Will anyone on the research team be able to identify who gave any of the information**?
   Answer "Yes" if anyone on the Pace research team could use personal knowledge or direct or indirect identifiers to deduce the identity of even one individual in the dataset.
   Yes ⇒ IRB submission IS required, go to go to Section 3
   No ⇒ Continue to 8.

8. **Will a key exist anywhere that links the information to the identity of individuals in the dataset**?
   Answer "Yes" even if the Pace research team does not have access to the key.
   Yes ⇒ Continue to 9.
   No ⇒ End – IRB submission is NOT required

9. **Will there be written documentation that the holder of the key will not disclose the key to the Pace research team**?
   Answer "Yes" only if the agreement is in writing.
   Yes ⇒ End – IRB submission is NOT required
   No ⇒ IRB submission IS required, go to go to Section 3

A "Not Engaged" determination is similar to a "Not Human Subjects Research" determination, except that the "Not Engaged" determination relates to one part of a larger project when that larger project is human subjects research. If Pace investigators are collaborating with outside researchers on a project, but the collaboration does not include having the Pace investigators interacting with human subjects or accessing their identifiable information or biospecimens, then the Pace investigators are not engaged in human subjects research.

The process of IRB review for "Not Human Subjects Research"/"Not Engaged" determinations is described in Section 6.2.1.

3 Activities that Do Require Submission to the IRB

3.1. Process for Submission to the IRB
(Dated 04/28/22)

Investigators must submit to the Pace IRB prior to beginning any project that involves research with human subjects, determined as described in Section 2. Submission to the IRB must occur through the electronic system. The IRB website provides information on how to access the electronic system.

Investigators should contact the IRB if they have any questions about the submission requirements.

3.2. Application Requirements

3.2.1. Basic Information

3.2.1.1. Project Title
(Dated 04/28/22)

The application requires a title that does not duplicate the title of any existing submission; allows the project to be readily identified by the investigators, by the subjects, and by the IRB; and spells out any non-standard acronyms.

3.2.1.2. Lay Summary
(Dated 04/28/22)

The application requires a lay summary that describes the project's purpose, subjects, design, procedures, and expected outcome in terms understandable to a lay audience.

3.2.1.3. Principal Investigator
(Dated 04/28/22)

The application requires the name of the Principal Investigator, who has the overall responsibility for ensuring that the conduct of the project is ethical and compliant (see Section 1.3). By submitting a research proposal, the Principal Investigator is attesting that they have sufficient training, education, and resources to fulfill these responsibilities.

The Principal Investigator must be a member of the Pace faculty, administration, or staff, or be a graduate student with a Faculty Advisor (see Section 3.2.1.9). An undergraduate may not be a Principal Investigator. The Faculty Advisor for a graduate student's project and the Principal Investigator for an undergraduate's project must be a member of the Pace faculty at the level of instructor or above.

3.2.1.4. Funding and Sponsorship
(Dated 04/28/22)

The application requires information about whether or not there is a sponsor or funding source for the project, and if so, identification of the source and of the status of the funding request.

3.2.1.5. Request for a 'Not Human Subjects Research'/'Not Engaged' Determination
(Dated 04/28/22)

Investigators are permitted to use the information in Section 2 to make their own assessments of whether they are engaged in human subjects research. However, investigators are able to request a formal "Not Human Subjects Research"/"Not Engaged" determination from the IRB.

The application for such requests requires the information in Sections 3.2.1.1, 3.2.1.2, 3.2.1.3, and 3.2.1.4, and, in addition, a description of the project and an explanation of why the project does not involve human subjects research at Pace University. Other sections are not required, except for Section 3.2.5 (Signatures).

3.2.1.6. Faculty Review of Class Projects
(Dated 04/28/22)

The faculty member responsible for a course that includes a requirement for students to complete projects that are not designed to develop or contribute to generalizable knowledge but that involve intervention or interaction with living individuals or their identifiable information must submit an application to the IRB. The application requires the information in Sections 3.2.1.1, 3.2.1.2, 3.2.1.3, and 3.2.1.4, and, in addition, the course number and title, a description of how students will be educated about human subjects protection, a description of the types of projects that students will be permitted to undertake, and a description of the faculty's review process for ensuring protection of the rights and welfare of individuals participating in the projects. Other sections are not required, except for Section 3.2.5 (Signatures).

3.2.1.7. Multi-Site Research

3.2.1.7.1. Involvement of Investigators who are not at Pace
(Dated 04/28/22)

The application requires information about whether the project involves any investigators who are not at Pace University. If not, no additional information is required.

If the investigators who are not at Pace will not be interacting with subjects or be obtaining identifiable information, then these investigators are not engaged in human subjects research and no additional information is required about the investigators who are not at Pace.

If the investigators who are not at Pace are engaged in the research, the Pace investigator must contact the Pace IRB at paceirb@pace.edu to discuss the arrangements for IRB oversight prior to submitting the application. The application requires the date of this discussion with the Pace IRB.

The options for IRB oversight of research are:

- The Pace IRB oversees the research of Pace investigators only – this option is available if the research qualifies for an exempt determination or if the project does not have a sponsor that

requires single IRB review, and if all involved investigators and IRBs agree to it. The application requires the information in Section 3.2.1.7.2.
- The Pace IRB extends its oversight to the investigators who are not at Pace – the Pace IRB will accept this arrangement if the project is low risk and if the Pace IRB considers that the necessary resources are available. The application requires the information in Section 3.2.1.7.3.
- An external IRB oversees the research of Pace investigators. The application requires the information in Section 3.2.1.7.4.

3.2.1.7.2. Investigators Who are not at Pace to be Overseen by their Own IRB
(Dated 04/28/22)

If any investigators involved in the project who are not at Pace will be overseen by their own IRB, and if the Pace Principal Investigator is the Lead Principal Investigator for the entire project, the application requires:
- A description of the process for communication with investigators who are not at Pace concerning IRB requirements and information relevant to the protection of participants, such as Unanticipated Problems, interim results, and protocol modifications; and
- A listing of the investigators who are not at Pace who will be overseen by their own IRBs.

This information is incorporated into the outcome letter for the submission (see Sections 6.8.2 and 6.8.3).

3.2.1.7.3. Investigators who are not at Pace to be Overseen by the Pace IRB
(Dated 04/28/22)

If the Principal Investigator is requesting the Pace IRB to oversee the research activities of investigators who are not at Pace, the application requires the following information:
- For each external institution with one or more investigators who are not at Pace:
  - Name of the external institution;
  - Name of the Principal Investigator at the external institution;
  - Position of the Principal Investigator at the external institution;
  - Biosketch, CV, or resume of the Principal Investigator at the external institution;
  - Names of any additional study personnel at the external institution;
  - Brief description of the activities to be carried out at the external institution; and
  - Name and contact information for the individual at the external institution who is responsible for IRB Authorization Agreements, or, if the individual is not from an institution that can execute an IRB Authorization Agreement, a signed Individual Investigator Agreement or Collaborating Institutional Investigator Agreement from the individual (see Section 4.6.7);
- A description of the process for communication with investigators who are not at Pace concerning IRB requirements and information relevant to the protection of participants, such as Unanticipated Problems, interim results, and protocol modifications;
- Information about whether the investigators who are not at Pace will use a separate agreement or consent form;
- Copies of completed local context review forms (see Section 4.6.7);
- Copies of IRB Authorization Agreement(s), Individual Investigator Agreement(s), or Collaborating Institutional Investigator Agreement(s) (see Section 4.6.7); and

- Confirmation by the Pace Principal Investigator that they will comply with their oversight responsibilities.

The process of IRB review for requests for the Pace IRB to extend oversight to investigators who are not at Pace is described in Sections 6.5.8. and 6.5.9.

3.2.1.7.4. Request to Rely on an External IRB
(Dated 04/28/22)

If the Principal Investigator is requesting that Pace agree to allow an external IRB to oversee the research of Pace investigators, the application requires the following information:

- Identification of the requested reviewing IRB;
- A description of the research activities that will be carried out by Pace investigators;
- Applicable project documents, including the protocol, consent forms, and IRB approval letters; and
- The reviewing IRB's local context review form, if required by the reviewing IRB.

The process of institutional review for requests to rely on an external IRB is described in Section 6.2.4.

3.2.1.8. Project Dates
(Dated 04/28/22)

The application requires the estimated project start date and completion date (the date when all analysis of identifiable information will be completed). No activities constituting research with human subjects may begin until the Principal Investigator has received an exempt determination or approval from the IRB.

3.2.1.9. Undergraduate or Graduate Student Research
(Dated 04/28/22)

The application requires the choice of whether the project is:

- Not student-led research;
- Undergraduate student research, in which case the Faculty Advisor must be the Principal Investigator, and the application requires the name of the undergraduate student; or
- Graduate student research, in which case the graduate student must be the Principal Investigator and the application requires the name of the Faculty Advisor, who must be a member of the Pace faculty at the level of instructor or above.

3.2.1.10. Study Personnel
(Dated 04/28/22)

The application requires the name and role of all individuals who will interact with subjects or have access to their identifiable information. All study personnel must have a current certificate of training from the Collaborative Institutional Training Initiative (CITI) in either the Social & Behavioral Research – Basic/Refresher Course or the Biomedical Research – Basic/Refresher Course. The IRB may impose additional requirements regarding the training and experience of study personnel for projects that involve special populations, sensitive topics, or experimental procedures.

The application allows the Principal Investigator to identify individuals who will not interact with subjects or have access to their identifiable information but who require access to the electronic system as "Administrative" personnel. Administrative personnel are not required to have CITI training.

3.2.1.11. Conflict of Interest Disclosure and Management Requirements
(Dated 04/28/22)

The application requires a statement as to whether or not any investigator has a significant conflict of interest with the research, and if so, must identify the investigator(s) and describe the conflict. The process for managing investigator conflicts of interest is described in Section 4.6.5.

3.2.1.12. In-Person Interactions
(Dated 04/28/22)

The application requires a statement as to whether any study personnel will have in-person interactions with any subjects or potential subjects, and if so, the circumstances of the interaction. The research must comply with applicable institutional policies concerning in-person interactions.

3.2.1.13. Assessment of Whether the Research is Greater than Minimal Risk
(Dated 04/28/22)

The application requires an assessment by the Principal Investigator as to whether the project is greater than minimal risk.

Investigators are responsible for identifying all risks to human subjects that are caused by their research. An important distinction is whether or not these risks are greater than minimal. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Risks of research always include potential loss of confidentiality and often include discomfort with study questions or procedures. Such risks are generally classified as no greater than minimal. Study procedures that may be greater than minimal risk include treatments for physical and mental health conditions, invasive interventions, use of drugs or devices, or uncommon interactions.

3.2.2. Assessment of Whether the Research Might Meet Exempt Criteria
(Dated 04/28/22)

The Federal regulations classify human subjects research as either exempt or non-exempt. The three categories of research listed below are classified as exempt and are not required to meet all of the criteria for IRB approval (for example, agreement to participate can be obtained using an information sheet rather than a full consent form). Exempt research must be submitted to the IRB prior to conducting any study activities. The IRB makes the determination about whether the project qualifies as exempt (see Section 6.3).

The application requires an assessment by the Principal Investigator as to whether the research might meet the criteria of one of the following exempt categories used by the Pace IRB:

Educational Research (Exempt Category 1) Criteria
In order for a project to meet the criteria for Exempt Category 1, the research must:

- Plan to obtain agreement from the subjects, and from their parents if subjects are children, before they participate in any research interactions or interventions;
- Be conducted in established or commonly accepted educational settings;
- Only involve normal educational practices;
- Provide adequate privacy and confidentiality protections, either by only collecting anonymous data or by employing appropriate data security measures for identifiable data; and
- Not be likely to adversely impact either:
  - students' opportunity to learn required educational content; or
  - the assessment of educators who provide instruction.

Surveys/Interviews with Adults (Exempt Category 2) Criteria
In order for a project to meet the criteria for Exempt Category 2 (surveys and interviews), the research must:

- Plan to obtain agreement from the subjects before they participate in any research interactions or interventions;
- Only involve subjects who are adults;
- Only involve collecting data by surveys, interviews, or focus groups (group interviews); and
- Provide adequate privacy and confidentiality protections, either by only collecting anonymous data or by employing appropriate data security measures for identifiable data.

Benign Behavioral Interventions with Adults (Exempt Category 3) Criteria
In order for a project to meet the criteria for Exempt Category 3 (benign behavioral interventions), the research must:

- Plan to obtain agreement from the subjects before they participate in any research interactions or interventions;
- Only involve subjects who are adults;
- Only involve collecting data from the verbal or written responses of subjects experiencing a behavioral intervention (such as playing online games or solving puzzles) when the intervention is:
  - Brief in duration;
  - Harmless:
  - Painless;
  - Not physically invasive;
  - Not designed to involve deception;
  - Not likely to have a significant adverse lasting impact on the subjects; and
  - In the opinion of the Principal Investigator, not likely to offensive or embarrassing to subjects; and
- Provide adequate privacy and confidentiality protections, either by only collecting anonymous data or by employing appropriate data security measures for identifiable data.

The process of IRB review for exempt determinations is described in Section 6.3.

3.2.3. Information for Exempt and Non-Exempt Research

3.2.3.1. Information in a Separate Protocol
(Dated 04/28/22)

If a project has a protocol separate from the IRB application, the information requirements in Section 3.2.3 can be satisfied by a brief summary of the information with a reference to the protocol pages where the full details may be found. The protocol must be attached to the submission.

3.2.3.2. Study Purpose
(Dated 04/28/22)

The application requires a description of the purpose of the research. The description should provide information on the knowledge expected to be gained by performing the study.

3.2.3.3. Special Classes of Subjects

3.2.3.3.1. Identification of Special Classes
(Dated 04/28/22)

Investigators must identify whether their subjects will include any individuals in the following special classes:

- Children (see Section 3.2.3.3.2)
- Adults with diminished capacity to consent (see Section 3.2.3.3.3)
- Pace University students (see Section 3.2.3.3.4)
- Employees of any member of the study team (see Section 3.2.3.3.4)
- Patients (past or current) of any member of the study team (see Section 3.2.3.3.4)
- Pregnant women specifically recruited because they are pregnant (see Section 3.2.3.3.5)
- Subjects or parents of child subjects who understand spoken English but have limited ability to read English (see Section 3.2.3.3.6)
- Subjects or parents of child subjects who do not speak English (see Section 3.2.3.3.7)
- Subjects who are outside the United States, unless the only interactions with subjects are anonymous surveys (see Section 3.2.3.3.8)
- Prisoners and others involuntarily institutionalized (see Section 3.2.3.3.9)

Projects that will include any special classes of subjects must fulfill the requirements for that class.

3.2.3.3.2. Requirements for Children as Subjects
(Dated 04/28/22)

Children are individuals who have not attained the legal age of consent, which is 18 years old in New York State, as well as in the rest of the United States except Alabama and Nebraska (19 years) and Mississippi (21 years). Investigators are responsible for determining the age of majority in the jurisdiction in which they are conducting the research.

Children may be subjects of exempt research only in Exempt Category 1 (Educational Research), in which case their assent and their parent's permission must meet the requirements of exempt agreement in Section 3.2.3.8.1.

For non-exempt research with children, the application requires information according to Section 3.2.3.8.2 about consent from the child's parent or guardian (termed "parental permission"), and, if any child subjects will have the capacity to understand what participation will entail, about how children will

be asked to agree (assent) to participate. If children will assent, the application requires a script for the assent discussion with the child and the parent permission form must include a statement from the parent that their child appears to understand what is involved in participation and has agreed to participate.

For research with children that is greater than minimal risk, the application requires information about whether or not any of the child subjects will be wards of the state or wards of any or any other agency, institution, or entity, and if so, requires a description of the extra protections for wards in accordance with Section 6.5.7.2.

3.2.3.3.3. Requirements for Adults with Diminished Capacity as Subjects
(Dated 04/28/22)

Diminished capacity means a cognitive condition where an adult is not capable of providing informed consent. Adults with diminished capacity must not be used as subjects of convenience, meaning that the research must investigate a condition of importance to the population represented by the subjects. No exempt research may include adults with diminished capacity as subjects.

Consent must be obtained according to the requirements in Section 3.2.3.8.2 from the subject's legally authorized representative, defined as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by Pace HRPP policy as acceptable for providing consent in the noresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

If any subjects are not able to provide informed consent but do have the capacity to understand what participation will entail, the project must be described to the potential subject and the subject must be asked to agree (assent) to participate. If assent will be obtained, the Principal Investigator must provide a script for the discussion with the subject and the consent form must include a statement from the person conducting the consent discussion that the subject for whom the legally authorized representative provided consent appears to understand what is involved in participation and has agreed to participate.

The application requires a description of how the person conducting the consent discussion will assess the capacity of potential subjects to consent or assent and ensure that the person signing on behalf of the subject is a legally authorized representative in the jurisdiction where the research will occur.

3.2.3.3.4. Requirements for Students, Employees, and Patients of Study Personnel as Subjects
(Dated 04/28/22)

Inclusion of individuals who are students, employees, or patients of any member of the study team requires special safeguards to ensure that participation is truly voluntary, without coercion or undue influence, in both exempt and non-exempt research.

The application requires a description of the protections against the risk that the decision about whether or not to participate and that the information obtained by participating might affect the

assessment of the student's or employee's performance or might affect a patient's treatment. Possible approaches include:

- Collecting data with no link to the identity of the subjects;
- Including a statement in the exempt information sheet or approved consent form that the subject's participation in the study will have no impact on their relationship with the investigators (for students, their grades; for employees, their evaluations; and for patients, their care);
- Excluding subjects who are students, direct reports, or patients of any member of the study team;
- Establishing written procedures to assure that study team members will not have access to the identities of any subjects who are their students, direct reports, or patients;
- Assigning someone other than the professor, supervisor, or clinician to describe the research or obtain consent; or
- Waiting until after course grades or employee evaluations have been submitted for the professor or supervisor to know who has and has not consented to participate.

3.2.3.3.5. Requirements for Pregnant Women as Subjects
(Dated 04/28/22)

Investigators should identify pregnant women as subjects if women will be recruited specifically because they are pregnant. The application requires a description of how the pregnancy status of the potential subjects will be determined and why it would not be unexpected to the potential subjects that they were approached for the research. If the risks of the research are greater than minimal, the additional protections in Section 6.6.10.4 are required.

3.2.3.3.6. Subjects Who Understand Spoken English but Have Limited Ability to Read English
(Dated 04/28/22)

If the study includes subjects who understand spoken English but have limited or no ability to read English, the application requires a description of how the person conducting the agreement or consent discussion will assess whether their agreement (for exempt research) or their consent (for non-exempt research) is truly informed.

3.2.3.3.7. Subjects Who Do Not Speak English
(Dated 04/28/22)

If the study includes subjects or parents of child subjects who do not speak English, the application requires a description of how their agreement (for exempt research) or their consent (for non-exempt research) will be obtained. The preferred approach is to translate the written material into a language that the subject understands and to conduct discussions with the subject using an interpreter if no member of the study team is fluent in the subject's or parent's language. If the study provides the prospect of direct benefit to subjects, the Principal Investigator may request approval of the use of the "short-form" process described in Section 6.6.5.2 instead of using a translated consent form. The application form requires the investigator to acknowledge their responsibility to assure that the individuals who will translate the written materials and who will interpret discussions are appropriately qualified.

3.2.3.3.8. Subjects Outside the United States
(Dated 04/28/22)

If the study includes subjects from outside the United States, the application requires:

- Identification of the country or countries where the subjects are located;
- The roles of the Pace investigators in the study;
- How the appropriateness of the research for the local context has been evaluated;
- The arrangements for local IRB review;
- How local study personnel will be trained; and
- Copies of relevant documents such as local IRB outcome letters, a local context review, and plans for human subjects training of international investigators.

3.2.3.3.9. Prisoners as Subjects Requirements
(Dated 04/28/22)

A prisoner is an individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Extensive safeguards are required to assure the protection of the rights and welfare of prisoner subjects (see Sections 6.5.7.6 and 6.6.11.5). Investigators should contact the IRB at paceirb@pace.edu for assistance in ensuring their research plan fulfills all requirements applicable to prisoner research.

3.2.3.4. Number of Subjects
(Dated 04/28/22)

The application requires the approximate anticipated number of subjects who will participate in the research.

3.2.3.5. Inclusion and Exclusion Criteria
(Dated 04/28/22)

The application requires specifying a minimum age for subjects, and, if any subjects will be in Alabama, Nebraska, Mississippi or outside the United States, an explanation of how the project will ensure that no subjects will be younger than the age of majority in their jurisdiction. The application also requires a listing of any other characteristics that will be used to include or exclude any subjects, such as sex or health status.

3.2.3.6. Recruitment Process
(Dated 04/28/22)

The application requires a description of how the study team will identify individuals who are potentially eligible to participate in the study, unless the study will be requesting a waiver of consent (see Section 3.2.3.8.2), as a choice of one or more of the following:

- Potential subjects will see a description of the study (flyer, electronic ad, listing on a survey panel, etc.) with information on how to contact the study team or click on the survey if interested – this requires a description of how and where the study will be publicized;

- Potential subjects will receive unsolicited emails, texts, or postal letters – this requires a description of how the emails, phone numbers, or postal addresses of potential subjects will be obtained and why they would not be surprised or upset to receive the unsolicited message;
- Potential subjects will hear a presentation during an in-person or remote class or other gathering – this requires a description of who will make the presentation and where;
- Potential subjects will hear about the study from other participants – this requires a description of how participants will be asked to recruit others for the study; and/or
- Another method will be used to recruit subjects – this requires a description of how the research population will be identified, and how potential subjects will be contacted and provided with information about the study.

The recruitment plan should draw subjects from a population selected to distribute the risks and benefits of the research in an equitable manner. The recruitment procedures should employ adequate confidentiality protections for potentially embarrassing or damaging information; for example, if potential subjects are being recruited because they have a psychiatric disorder, the recruitment process should ensure that this will not be revealed to anyone other than the potential subject.

If the study includes screening subjects for eligibility by obtaining information from the potential subjects before obtaining full consent, the application requires a description of the information provided to the potential subjects that includes:

- A statement that the questions will be asked to determine whether the individual may qualify for a research study;
- A statement that answering the questions is voluntary and does not obligate the individual to participate in the study even if they are eligible;
- A brief description of the study; and
- A statement about what will be done with their answers, including confidentiality protections.

3.2.3.7. Recruitment Materials
(Dated 04/28/22)

The application requires the Principal Investigator to upload all written recruitment materials and oral scripts.

Recruitment materials should include the following information, as applicable, and not include any exculpatory language (statements waiving or appearing to waive any legal rights or providing a release from liability for negligence):

- A clear statement that this is research and not treatment
- A statement about the purpose of the research
- The eligibility criteria (summary form)
- Time commitments and other commitments for subjects
- If there will be any audio or video recording, a statement that this will occur
- The location of the research
- The name and telephone number or email address of a contact person or office – Note that a @pace.edu email addresses must be used for communicating with subjects and potential subjects; gmail addresses do not provide sufficient security.
- Any reimbursement or payments provided to subjects, with the following restrictions:
  - The amount may be specified by stating, for example, “up to $xxx”; and
  - The amount may NOT be emphasized by using large, bold, underlined, italicized font or

by putting this information first in the ad before the study purpose, procedures, and time commitment.

Requirements of the institutions where the recruitment materials are distributed or posted must be followed.

3.2.3.8. Agreement or Consent Requirements

3.2.3.8.1. Agreement to Participate in Exempt Research
(Dated 04/28/22)

If the research qualifies as exempt, the application requires:

- A description of the process for obtaining agreement; and
- A written information sheet, as an alternative to a full consent form, which must include:
  - The title of the study;
  - A statement that the project involves research;
  - A statement that participation is voluntary;
  - Identification of the Principal Investigator;
  - Identification of the sponsor of the study, if any;
  - A brief explanation of the purpose of the study;
  - A brief description of study procedures;
  - An estimate of the time required for participation;
  - If any of the questions or procedures might be upsetting, a statement covering the ability to stop the study and available support resources;
  - A statement about confidentiality protections, including any limits to confidentiality because of the study team's obligation to report suspected child abuse or neglect or intent to harm self or others;
  - If any of the participants might be a student, employee, or patient of anyone on the study team, a statement covering the lack of consequences of participation or choosing not to participate;
  - A statement about subject payment, including any conditions on the subject receiving full payment;
  - Contact information of the investigator using a Pace email account for answering subject questions; and
  - Specification of the action potential subjects will take if they agree to participate.

A template for the information sheet is available in the electronic system. A written or electronic signature is required for agreement to participate in exempt research only if the subjects will be audio or video recorded or will be identified in published accounts of the research.

3.2.3.8.2. Consent to Participate in Non-Exempt Research
(Dated 04/28/22)

For non-exempt research, the application requires the Principal Investigator to indicate whether or not consent will be obtained.

If consent will be obtained, the application requires:

- A description of how informed consent will be sought, how the study team will approach individuals to seek consent, and the members of the study team who will be conducting the informed consent discussion, including any provisions required for special classes of subjects (see Section 3.2.3.3). The consent process must provide the prospective subject with sufficient opportunity to discuss and consider whether or not to participate and must minimize the possibility of coercion or undue influence;
- A description of how subjects will be provided with a copy of the consent form;
- Either a description of the signature process or a justification for not obtaining a signature. In general, a signature is required for subjects to be video or audio recorded or for subjects to be identified in published accounts of the research.;
- If the project involves deception (misleading subjects or omitting information):
  - A description of the deception;
  - Why the research could not be practicably carried out without the deception;
  - Why the deception will not adversely affect the rights and welfare of subjects; and
  - Whether subjects will be debriefed, and if so, how, where, and when, including whether subjects will be given the option to withdraw their data.
- The consent form(s) to be used in the project, based on the IRB consent template and including all required elements (see Section 6.6). If the project involves groups of subjects who will have different experiences in the research, each group should have a separate consent form, unless the differences in the experience are minor enough to be clearly explained in a combined consent form.

If consent will not be obtained, the application requires a description of:

- Why the research could not be practicably carried out if subjects were required to consent;
- Why not obtaining consent will not adversely affect the rights and welfare of subjects;
- Whether subjects will be provided with additional information after participation, and if so, how, where, and when, including whether subjects will be given the option to withdraw their data; and
- If the project involves the use of identifiable private information or biospecimens, why the research could not practicably be carried out without using such information in an identifiable format.

3.2.3.9. Study Methods
(Dated 04/28/22)

The application requires a description of the study design and procedures related to subjects. The description must provide a complete account of the experience of the subjects, including all interventions and interactions and the duration of a subject's participation, and must specify the survey or interview platform, if applicable.

If the project involves audio or video recording of subjects, the application requires a description of whether written permission for the recording will be obtained by having the recruitment material contain instructions for the subject to email their permission to the investigator; by having the subjects sign the consent form or information sheet, which contains the statement that the subject is permitting recording; or by another described method.

If any of the study procedures (survey or interview questions, tests, procedures, etc.) are potentially upsetting to subjects, the application requires a description of how subjects will be provided with a list

of resources to support their mental health and wellbeing, in the information sheet or consent form, at the end of the survey form, in a separate sheet provided to the subjects, or another method.

If the project might obtain any information concerning child abuse or intent to harm self or others, the application requires a description of how the subjects will be notified of the study team's reporting obligations.

If information about suicide ideation is obtained, the description must include how such information will be evaluated and acted upon.

If the study is exempt, the description must include why the study qualifies for the indicated exempt category.

The application requires all study documents to be uploaded that related to study procedures, such as surveys, interviews, and focus group outlines.

3.2.3.10. Costs Incurred by Subjects
(Dated 04/28/22)

The application requires a description of any costs that subjects will incur by participating in the research.

3.2.3.11. Payments to Subjects
(Dated 04/28/22)

The application requires a description of whether subjects will be paid (including payments, incentives, raffles, compensation, and reimbursements), and if so, a description of the value, method, and timing of payments, including any conditions on payments.

3.2.3.12. Confidentiality of the Project Data
(Dated 04/28/22)

Confidentiality refers to the protection of identifiable private information collected by the research.

The application requires:

- A description of how subjects will be identified in the research data (anonymous, identified by name or code number, or other); and
- A description of the data security measures, which must at a minimum comply with Pace University Information Technology data security standards. Special protections are required if the research data includes Protected Health Information under HIPAA or includes Social Security numbers, driver's license numbers, or financial account information; and
- A description of when and how subject identifiers will be removed from the research data.

3.2.3.13. Privacy Protections
(Dated 04/28/22)

Privacy refers to an individual's control over who has access to them or to information about them. The application requires either:

- A statement that subject privacy is protected by obtaining the minimum information necessary to conduct the study and by carrying out interventions and interactions with subjects and potential subjects in private settings; or
- A description of alternative methods to protect subject privacy.

3.2.3.14. Information with Potential Health Importance to Individual Subjects
(Dated 04/28/22)

If the project includes collecting information that has the potential to be important to the physical or mental health of an individual subject, the application requires a description of the plan for either communicating the information to the subject and/or their primary care providers or an explanation of why no such information will be communicated.

3.2.4. Information for Non-Exempt Projects

3.2.4.1. Screening Procedures
(Dated 04/28/22)

If a non-exempt project involves collecting screening information by direct contact with potential subjects prior to obtaining their full consent, the application requires:

- The procedures that will be used for screening to determine subject eligibility;
- What eligibility data will be collected, how these data will be stored, who will have access to these data, and when these data will be destroyed;
- For screening failures, how and what data will be retained, if any, along with when these data will be destroyed, including whether identifiers are being retained from those who screen out and whether contact information is being retained for future research;
- How oral or written agreement to participate in the screening will be obtained, which must include a short summary of the study, a description of the screening procedures, and a statement that participation in the screening and in the study are voluntary; and
- Any screening scripts, surveys, or forms and other screening related documents.

3.2.4.2. Risks to Subjects
(Dated 04/28/22)

For non-exempt research, the application requires a description of all potential risks to subjects including physical, psychological, social, legal, or other. The description must include the probability, severity, potential duration, and reversibility of each risk, as well as the procedures utilized to prevent and/or minimize any actual and/or potential risk.

Investigators should not state that there are no risks. There is always at least the risk of breach of confidentiality and often discomfort with study procedures which must be mitigated.

3.2.4.3. Benefits to Subjects and Others
(Dated 04/28/22)

For non-exempt research, the application requires a description of any potential benefits to the subject as well as benefits that may accrue to society in general as a result of the study.

3.2.4.4. Data Safety and Monitoring
(Dated 04/28/22)

For non-exempt research that is no greater than minimal risk, the application requires confirmation that the Principal Investigator will report all Unanticipated Problems involving risks to subjects and others and all study deviations to the IRB according to IRB requirements (see Section 6.9).

For non-exempt research that is greater than minimal risk, the application requires a description of a formal Data Safety and Monitoring plan that establishes an independent committee to monitor and analyze risks to subjects (see Section 6.5.5).

3.2.4.5. Biospecimens
(Dated 04/28/22)

If the project involves the collection or use of any biological samples such as saliva, skin or nasal swabs, or blood, the application requires:

- The methods of sample collection;
- How the samples will be identified and analyzed; and
- How the samples will be maintained, including any genetic analysis and any release outside of the study team of either identified or anonymous samples and the plans for eventual destruction of the samples.

3.2.4.6. Use of Protected Health Information
(Dated 04/28/22)

If the project involves use of Protected Health Information (PHI), the application requires either a statement that authorization will be obtained from the subjects or a request for a waiver of authorization, including:

- The purpose of accessing PHI without authorization;
- The selection criteria for the records to be accessed;
- The date range for the records to be accessed;
- The data fields that are needed from the medical record;
- How research personnel will access the records;
- Which HIPAA identifiers are included in the data accessed;
- Why the research cannot be conducted without accessing PHI without authorization;
- Why it is not practical to obtain authorization from the participants;
- The methods to protect any identifiable information from use and disclosure by unauthorized parties;
- When and how identifiers linked to the data will be destroyed (identifiers should be destroyed at the earliest opportunity as consistent with the design of the research);
- Confirmation that the PHI will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the Privacy Regulation (45 CFR 164.512); and
- Confirmation that the requested information constitutes the minimum necessary data to accomplish the goals of the research.

3.2.4.7. Data Analysis
(Dated 04/28/22)

For non-exempt research, the application requires a description of the plans for analysis of the study data to support the purpose of the research. If the project is greater than minimal risk, the application requires a description of how the sample size was chosen and how the Principal Investigator will have access to a population that will allow recruitment of the necessary number of subjects

3.2.4.8. Clinical Trials
(Dated 04/28/22)

If the project is a clinical trial, the application requires:

- The NCT number identifying the project in the governments website, ClinicalTrials;
- A description of how the registration and posting requirements will be fulfilled;
- Confirmation that the consent form includes the statement: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."; and
- Confirmation that the study does not involve bonus payments, finders feed, or any other direct or indirect remuneration that constitutes an inducement for recruiting or enrolling subjects, or coupons good for a discount on the purchase price of the product once it has been approved for marketing.

3.2.4.9. Food and Dietary Supplements
(Dated 04/28/22)

If the project involves food or dietary supplements (see Section 7.5.1), the application requires identification of the food or dietary supplement and a description of its use in the project. If the project is evaluating the use of the food or dietary supplement for the diagnosis, cure, mitigation, treatment, or prevention of a disease (as opposed to evaluating the effect on a structure or function of the body), the application requires the information in Section 3.2.4.10 about the food or dietary supplement.

3.2.4.10. Research with Drugs
(Dated 04/28/22)

If the project involves the use of any drug or biologic agent (see Section 7.1.3), the application requires:

- The trade, generic, and/or investigational name of the drug(s);
- For each drug, whether the study involves an approved or new use of an approved drug or an experimental drug;
- The status of the Investigational New Drug (IND) application or reason why no IND is required;
- How the drug will be dispensed; and
- The investigator's brochure or drug package insert.

3.2.4.11. Research with Devices
(Dated 04/28/22)

If the project involves the use of any device (see Section 7.1.4), the application requires:

- The trade, generic, and/or investigational name of the device
- For each device, whether the study involves an approved or new use of an approved device, an experimental device, or an in vitro diagnostic test;

- The status of the Investigational Device Exemption (IDE); confirmation that the device is a non-significant risk device and the Principal Investigator will comply with abbreviated IDE requirements; confirmation that the Principal Investigator will comply with the requirements for the research use of an in vitro diagnostic device; or an explanation of why the device is used for its FDA approved or cleared indication in one of the applicable IDE exemption categories;
- The use of the device in the project; and
- The investigator's device brochure or Instructions for Use.

3.2.4.12. Research Involving Exposure to Ionizing Radiation
(Dated 04/28/22)

If the project involves exposure to ionizing radiation, the application requires a description of the purpose and amount of the subjects' exposure.

3.2.5. Signature Requirements
(Dated 04/28/22)

All submissions must be electronically signed by the Principal Investigator. For Not Human Subject determination requests, the Principal Investigator certifies that the information provided is complete and accurate. For Class Projects, the Principal Investigator certifies that they understand their overall responsibility for ensuring that the conduct of class projects is ethical. For all other submissions, the Principal Investigator is certifying that they accept the responsibilities described in Section 1.3. For undergraduate research, the undergraduate certifies that they accept the responsibilities under the supervision and with the assistance of their Faculty Advisor who is the Principal Investigator and who also certifies that they will supervise and assist the undergraduate. For graduate student research, the Faculty Advisor certifies that they will supervise and assist the graduate student who is the Principal Investigator in ensuring that the conduct of the study is ethical and compliant.

3.3. Requirements After Initial Submissions

3.3.1. Study Modifications, Check-Ins, Renewals, and Closures
(Dated 04/28/22)

The IRB provides oversight of a research project until it qualifies for closure; that is, as long as any activities are occurring that constitute human subjects research. A project may be closed when all interventions or interactions with subjects and analysis of identifiable information have ceased.

The requirements for submitting information about reportable events (Unanticipated Problems and major deviations) according to Section 3.3.2 apply to all projects.

The requirements for modifications, renewals, check-ins, and closures are different for projects that received an exempt determination, for projects that received approval with a check-in due date, and for projects that received approval with an expiration date. Some requirements also depend on the status of the study (enrollment is continuing / enrollment has ended but study interventions are continuing / study interventions have ended but analysis of identifiable information is continuing / the study qualifies for closure).

For studies that have received an exempt determination, the Principal Investigator must:

- Submit an exempt study modification form if changes to the project might affect the exempt determination. (For example, a study involving interviews with adults would require a study modification form to be submitted and approved prior to interviewing children.) The exempt study modification form requires a description of the reason for the proposed changes and why they might affect the exempt determination, and requires the Principal Investigator to make appropriate changes to the information provided in the initial application, including uploading revised versions of any changed study materials; and
- Submit an exempt check-in/closure form that requires information about whether the project will continue; whether any subject complaints or deviations have occurred; and, if the study qualifies for closure, confirmation that no further interactions with subjects or analysis of identifiable information will take place and that study data will be retained for at least three years:
    - If the study will continue after the due date, no later than 45 days prior to the check-in due date; or
    - When the study qualifies for closure.

For studies that have received approval with a check-in due date, the Principal Investigator must:

- Submit a non-exempt study modification form that must be approved before any changes to the project may be made, including to the protocol, application, consent form, recruitment material, and other study materials, unless the change is immediately necessary for the safety of subjects. The non-exempt study modification form requires the status of the study; a description of the reason for the proposed changes; an assessment of whether the changes relate to a subject's willingness to remain in the study and therefore require changes to the consent form and if so, the re-consenting plan; and requires the Principal Investigator to make appropriate changes to the information provided in the initial application, including uploading revised versions of any changed study materials; and
- Submit a non-exempt check-in/closure form that requires information about whether the project will continue; the number of subjects enrolled; any new information pertaining to the risks or benefits of the project; any subject withdrawals or complaints; any deviations; and, if the study qualifies for closure, confirmation that no further interactions with subjects or analysis of identifiable information will take place and that study data will be retained for at least three years:
    - If the study will continue after the due date, no later than 45 days prior to the check-in due date; or
    - When the study qualifies for closure.

For studies that have received approval with an expiration date, the Principal Investigators must:

- Submit a non-exempt study modification form that must be approved before any changes to the project may be made, including to the protocol, application, consent form, recruitment material, and other study materials, unless the change is immediately necessary for the safety of subjects. The non-exempt study modification form requires the status of the study; a description of the reason for the proposed changes; an assessment of whether the changes relate to a subject's willingness to remain in the study and therefore require changes to the consent form and if so, the re-consenting plan; and requires the Principal Investigator to make appropriate changes to the information provided in the initial application, including uploading revised versions of any changed study materials; and
- Submit a renewal/closure form that requires information about the status of the study; the number of subjects enrolled; any new information relevant to the risks or benefits of the project including any reports from a safety monitor even if no new safety concerns are identified; any

subject withdrawals or complaints; any deviations; and, if the study qualifies for closure, confirmation that no further interactions with subjects or analysis of identifiable information will take place and that study data will be retained for at least three years:
  - If the study will continue after the expiration date, no later than 45 days prior to the expiration date; or
  - When the study qualifies for closure.

3.3.2. Reportable Events Requirements
(Dated 04/28/22)

A reportable event either (1) provides *new information about subject welfare* or (2) constitutes a *major deviation* from IRB or other requirements.

The following events meet the criteria of providing *new information about subject welfare*:
- An Unanticipated Problem involving risks to subjects or others as described in Section 6.9.1;
- A report from a safety monitoring body that recommends changes to the protocol as described in Section 6.9.2;
- A complaint from a subject this is not resolved by the Principal Investigator (see Section 4.6.4.1); and
- A change that was made prior to or without IRB approval because the change was immediately necessary for the safety of subjects.

A deviation is any inconsistency with the approved project plan, IRB requirements, institutional policies, or applicable regulations. A deviation is a *major deviation* if the event could harm the subject's rights or welfare or substantially damage the overall reliability of the study information.

Note that deviations that are not major are considered minor deviations and are reported on the study renewal/closure or check-in/closure form. Examples of major and minor deviations are found in Section 6.9.5.

Principal Investigators must submit a Reportable Events form to the IRB no later than seven days after the Principal Investigator become aware of the event that provides new information about subject safety or is a major deviation.

The Reportable Event form requires:
- The date of the event;
- The date the Principal Investigator became aware of the event;
- A description of the event (without personal identifiers of any subjects);
- A description of any immediate actions taken to mitigate the consequences of the event; and
- Planned changes in response to the event (the Corrective and Preventative Action Plan), including the cause(s) of the event, required new processes, and the plans for implementing, evaluating, and reporting on the new processes.

IRB actions in response to reportable events are described in Section 6.9.7.

3.3.3. Recordkeeping and Audit Requirements
(Dated 04/28/22)

Investigators are required to maintain complete records of all study materials for at least 3 years after the study is closed, and when the consent form incorporates an authorization under HIPAA, the signed consent forms must be retained for at least 7 years after the study is closed. Investigators are responsible for complying with Pace University record retention requirements and with any sponsor record retention policies.

Investigators must make their records available for inspection and copying to representatives of the Office of Research for for-cause and not-for-cause audits (see Section 4.6.3).

4 Operations of the Human Research Protection Program

4.1. Structure of the HRPP

4.1.1. Organizational Structure

(Dated 04/28/22)

The Human Research Protection Program (HRPP) is a function of the Office of Research at Pace University. The Office of Research provides support, resources and assistance for research-related activities at Pace University, helping faculty, staff, and students who are seeking grants and external funding for their research, scholarship, and creative activities. The Office of Research houses the Institutional Review Board (IRB) and IACUC committees, and administers research compliance and integrity programs for funded projects and the university community.

The three components of the HRPP are the Pace Institutional Review Board (IRB) (see Section 4.6.1), the HRPP communication program that provides education and training to investigators and others (see Section 4.6.2), and the HRPP auditing program (see Section 4.6.3).

4.1.2. Institutional Official

(Dated 04/28/22)

The Institutional Official for the HRPP is the Associate Provost for Research, who is responsible for the overall operations of the HRPP, including assuring that the HRPP has sufficient resources, including staffing, space, and technology, to support the HRPP's responsibilities.

The Institutional Official appoints a standing HRPP Advisory Committee that meets on an as-needed basis to provide advice on the conduct of the HRPP program, including reviewing and making recommendations on significant changes to policies and procedures. The HRPP Advisory Committee is chaired by the IRB chairs and includes the HRPP Director, faculty who are representative of the disciplines of Pace University investigators and of the Faculty Council, and legal counsel to the IRB. IRB administrators assist the chairs in the operation of the HRPP Advisory Committee.

The Institutional Official has full access to the electronic system, and periodically reviews reports of IRB findings and actions.

Reference:

§46.108(a) In order to fulfill the requirements of this policy each IRB shall:

§46.108(a)(1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties;

§46.108(a)(3) Establish and follow written procedures for:

§46.108(a)(3)(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

4.1.3. Independence and Authority of the HRPP
(Dated 04/28/22)

The HRPP operates independently of other Pace University functions and makes decisions and determinations according to these policies and procedures without being influenced by other institutional or external considerations. The Institutional Official is responsible for assuring this independence and investigates any allegations of attempts to influence HRPP actions.

The IRB has the authority to decide whether a proposed activity requires IRB review, to issue exempt determinations, and to approve, require modifications in (to secure approval), or disapprove research activities. The IRB has the authority to observe or have a third party observe the consent process and the research.

If an activity requires IRB review, there are no other institutional offices or entities that have the ability to allow the activity to begin before the IRB has issued an exempt determination or an approval. Certain other institutional offices and entities do have the authority to stop an activity from occurring even if the activity has received an exempt determination or an approval from the IRB.

Nothing in this policy limits the authority of a physician or other licensed healthcare professional to provide emergency medical care, to the extent that the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

References:

§46.109(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption (under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

§46.109(g) An IRB shall have authority to observe or have a third party observe the consent process and the research.

§46.116(j) *Emergency medical care.* Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

§46.112: Review by institution: Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

4.2. Assurances and Certifications
(Dated 04/28/22)

Pace University maintains an active Federal-Wide Assurance (FWA) FWA00023526 in compliance with all Federal requirements. Pace U IRB #1 is linked to this assurance as OHRP IRB#00004707.

For research involving human subjects that is supported by a Federal department or agency, Pace University provides a certification that the research has been determined to be exempt, determined to be exempt with limited IRB review, or reviewed and approved by the IRB according to these policies. No

human subjects may be involved in any project supported by a Federal department or agency until the project has been determined to be exempt, determined to be exempt with limited IRB review, or reviewed and approved by the IRB, and until Pace University has provided certification to the Federal department or agency component supporting the research.

Reference:

§46.101(a) Except as detailed in §46.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.

§46.101(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.

§46.101(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Federal department or agency but not otherwise covered by this policy comply with some or all of the requirements of this policy.

§46.101(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, or to the equivalent office within the appropriate Federal department or agency, and shall also publish them in the Federal Register or in such other manner as provided in department or agency procedures. The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report.

§46.103: *Assuring compliance with this policy – research conducted or supported by any Federal department or agency.*

§46.103(a) Each institution engaged in research that is covered by this policy, with the exception of research eligible for exemption under §46.104, and that is conducted or supported by a Federal department or agency, shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for Federal-wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office. Federal departments and agencies will conduct or support research covered by this policy only if the institution has provided an assurance that it will comply with the requirements of this policy, as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB (if such certification is required by §46.103(d)).

§46.103(b) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

§46.103(c) The department or agency head may limit the period during which any assurance shall remain effective or otherwise condition or restrict the assurance.

§46.103(d) Certification is required when the research is supported by a Federal department or agency and not otherwise waived under §46.101(i) or exempted under §46.104. For such research, institutions shall certify that each proposed research study covered by the assurance and this section has been reviewed and approved by the IRB. Such certification must be submitted as prescribed by the Federal department or agency component supporting the research. Under no condition shall research covered by this section be initiated prior to receipt of the certification that the research has been reviewed and approved by the IRB.

§46.119: *Research undertaken without the intention of involving human subjects*: Except for research waived under §46.101(i) or exempted under §46.104, in the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted by the institution to the Federal department or agency component supporting the research, and final approval given to the proposed change by the Federal department or agency component.

4.3. Statutory and Regulatory Requirements for Human Subjects Research

(Dated 04/28/22)

The HRPP complies with the Federal regulatory requirements of the Department of Health and Human Services at 45 CFR Part 46 (*Federal Policy for the Protection of Human Subjects*). Research approved or given an exempt determination prior to January 21, 2019 will continue to comply with the requirements with an effective date of July 14, 2009 in 45 CFR 46 unless the IRB makes and documents a determination that the research will comply with the requirements with an effective date of January 21, 2019 in 45 CFR 46.

For clinical investigations involving products under the jurisdiction of the Food and Drug Administration (FDA), the HRPP complies with the FDA regulations at 21 CFR Parts 50 and 56.

The New York State law Chapter 45, Article 24-A (*Protection of Human Subjects*) provides in §2445 (*Applicability*) that compliance with Federal human subjects protection regulations constitutes compliance with Article 24-A. Pace University submits an attestation of its compliance to the Commissioner of Public Health on an annual basis.

In the case of differences between applicable federal, state, and local laws governing the conduct of human subjects research, the Office of the University Counsel is consulted for guidance on resolving the conflict.

Reference:

§46.101(e) Compliance with this policy requires compliance with pertinent federal laws or regulations that provide additional protections for human subjects.

§46.101(f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

§46.101(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research.

§46.116(i) *Preemption.* The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

Food and Drugs – Protection of Human Subjects 21 CFR Part 50

Food and Drugs – Institutional Review Boards 21 CFR Part 56

NY Pub Health L §2445(1): The provisions of this article shall not apply to the conduct of human research which is subject to, and which is in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.

NY Pub Health L §2445(2): Upon attestation, satisfactory to the commissioner, by an institution or agency that such institution or agency (a) conducts human research that is subject to and is in compliance with policies and regulations promulgated by any agency of the federal government for the protection of human subjects, and (b) conducts or proposes to conduct or authorize human research, which is not subject to but does or shall comply with federal policies and regulations, the commissioner may deem, subject to conditions, such institution or agency's human research in compliance with this article. Such attestation shall be submitted annually on or before January first to the department on a form prescribed by the commissioner. See Section 2445 of the NY State legislation.

4.4. Written Plan for the HRPP

(Dated 04/28/22)

The HRPP written plan consist of this document, including all referenced supporting materials. The written plan constitutes Pace University policy that applies to all Pace investigators, and not following the policy is considered noncompliance (see Section 6.9.6). Exceptions to these policies and procedures are permitted if consistent with applicable Federal, State, and local requirements and if the IRB chairs (for IRB policies) or the HRPP Director (for other HRPP policies) approves the exception and documents the rationale in writing.

The Institutional Official is responsible for the written plan. Additions or revisions to the plan are approved by the Institutional Official, after consulting with the HRPP Director, IRB chairs, legal representatives, and the HRPP Advisory Committee as appropriate to the scope of the proposed changes. The HRPP Director reviews the written plan at least every two years.

The current approved version of this document is maintained on the Office of Research website and is available to sponsors, investigators, research staff, other members of the research community, IRB members, and research participants. Changes to the policies and procedures are communicated through articles on the Office of Research website, instructions and help text in the electronic submission system, training materials, and, if warranted, emails to the Pace research community.

Specific topics covered by these policies and procedures required by the Federal regulations are:

- Procedures for conducting initial and continuing review of research – Section 6
- Procedures for conducting continuing review of research and determining which projects require review more often than annually – Section 6.7;
- Procedures for reporting IRB findings and actions to the investigator – Section 6.8;
- Procedures for reporting IRB findings and actions to the institution – Section 4.1.2;
- Procedures for determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review – Section 6.9;
- Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with IRB approval – Sections 1.3 and 6.8;
- Ensuring prompt reporting to the IRB of unanticipated problems involving risks to subjects or others – Section 6.9.1; and
- Ensuring prompt reporting to appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of any unanticipated problems

involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval – Section 6.9.7.

Reference:

§46.108(a) In order to fulfill the requirements of this policy each IRB shall:

§46.108(a)(3) Establish and follow written procedures for:

§46.108(a)(3)(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

§46.108(a)(3)(ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

§46.108(a)(3)(iii) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

§46.108(a)(4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of

§46.108(a)(4)(i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and

§46.108(a)(4)(ii) Any suspension or termination of IRB approval.

4.5. Quality Improvement of the HRPP

(Dated 04/28/22)

The HRPP Director, in conjunction with the Institutional Official, is responsible for quality improvement of the HRPP. The budgeting process incorporates an assessment of the adequacy of the HRPP resources. In consultation with the Institutional Official, IRB chairs, and others as appropriate, the HRPP Director establishes on an annual basis one or more initiatives to measure and improve the quality, effectiveness, and efficiency of the HRPP, based on findings from for-cause and not-for-cause audits (see Section 4.6.3), concerns or complaints (see Section 4.6.4), and operational metrics.

4.6. HRPP Operations

4.6.1. Institutional Review Board

(Dated 04/28/22)

The Pace Institutional Review Board (IRB) operates according to the requirements in Sections 5, 6, and 7.

4.6.2. HRPP Communication Program

4.6.2.1. Education and Training for Investigators

(Dated 04/28/22)

All investigators performing research with human subjects are required to complete training through the Collaborative Institutional Training Initiative (CITI), the Social & Behavioral Research – Basic/Refresher Course or the Biomedical Research – Basic/Refresher Course. Training must be renewed every three years.

Additional training and education for investigators is provided by live sessions at the beginning of the academic year for student researchers and their faculty mentors, by guest lectures as requested by faculty for research-focused courses, by presentations to faculty councils and departmental meetings, and by the Office of Research newsletter.

The electronic system contains instructions, help text, and links to the website and to this document to provide targeted information as investigators are completing IRB forms. The quality assurance program uses not-for-cause audits as described in Section 4.6.3 as a mechanism to educate investigators on requirements for carrying out research. IRB chairs, the HRPP Director, and IRB administrators are available to any member of the Pace research community to discuss human subjects protection issues.

4.6.2.2. Community Outreach
(Dated 04/28/22)

The HRPP website contains information for prospective subjects explaining what is involved in participating in research and providing resources where more information may be found.

4.6.3. HRPP Auditing Program
(Dated 04/28/22)

The HRPP auditing program encompasses for-cause and not-for-cause audits.

For-cause audits are initiated when the IRB or the Institutional Official provides a written request specifying the reason that an audit is needed. The Institutional Official approves an auditing plan that specifies the scope and conduct of the audit. The results of for-cause audits are reported to the Institutional Official, and to the IRB if the IRB requested the audit.

Not-for-cause audits are initiated by the HRPP according to the Quality Assurance plan developed on an annual basis and approved by the Institutional Official to assess the compliance of the research with applicable terms, conditions, assurances and certifications referenced in the application, award (grant or contract), and protocol; and with applicable state, Federal, and local laws, rules, regulations, policies, and guidelines, as well as institutional policies. Prioritization of studies for not-for-cause audits considers the potential for problems with subject safety or data integrity, based on characteristics including greater than minimal risk and first-time Principal Investigators. The results of not-for-cause audits are communicated to the Principal Investigator and to the IRB if there are any audit findings of deviations that may represent serious or continuing noncompliance (see Section 6.9.7).

For both for-cause and non-for-cause audits, the individuals carrying out the audit must not have any conflict of interest with the research or program that they audit.

The IRB process for responding to compliance concerns is described in Section 6.9.7.

Allegations of research misconduct (fabrication, falsification, or plagiarism) are investigated by the Office of the University Counsel. The HRPP notifies the Office of the University Counsel of any information indicating possible research misconduct and works with the Office of the University Counsel to the extent possible in coordinating investigations.

4.6.4. Concerns and Complaints Related to Human Subjects Research

4.6.4.1. Human Subject Concerns and Complaints
(Dated 04/28/22)

Information sheets for exempt research and consent forms for approved research include contact information for the Principal Investigator for subject questions, concerns, and complaints. Consent forms for approved research also include contact information for the Pace IRB.

When anyone on the study team receives a communication from subjects, the Principal Investigator is responsible for responding. If the subject's issue is resolved, the Principal Investigator is required to provide a summary of resolved subject communications at the time of renewal, check-in, or closure. If the subject's issue is not resolved, the Principal Investigator must submit a Reportable Events form (see Section 3.3.2) within seven days of determining that their attempts to resolve the issue have not satisfied the subject.

When the IRB receives information from a Principal Investigator about an unresolved concern or complaint or the IRB receives a communication directly from a subject, the IRB, in consultation with the Institutional Official, investigates the issue and formulates a plan for response. The plan takes into account the wishes of the subject concerning further communication. The IRB follows up as described in Section 6.9 if the circumstances raise compliance concerns.

4.6.4.2. Investigator Concerns and Complaints
(Dated 04/28/22)

When any member of the Pace HRPP receives a concern or complaint from investigators about any aspect of the Human Research Protection Program, that member notifies the HRPP Director and the IRB chairs. The HRPP Director and the IRB chairs will decide who will take the lead in responding to the issue and will communicate with the Institutional Official on an ongoing basis.

Responses to concerns or complaints may include re-opening or revising the review of a submission, education of the investigator or the Pace research community, changes to the HRPP policies or procedures, for-cause audits of the HRPP, and providing additional support or oversight to the HRPP.

All communications concerning investigator concerns and complaints are retained in the electronic system.

4.6.5. Managing Conflicts of Interest in the Conduct of Research
(Dated 04/28/22)

Investigators must disclose to the IRB whether any member of the study team has significant financial interest at the time of initial application and if a new significant financial interest arises during the course of the project.

For NIH and NSF externally sponsored projects, investigators must also disclose significant financial interests to the Office of Sponsored Research. Such disclosures are evaluated according to Pace University requirements (PDF), with the University Reviewing Official developing a management plan for conflicts of interest. For projects without NIH or NSF funding, the University Reviewing Official follows

the same process for financial conflicts of interest that are disclosed to the IRB or for institutional conflicts of interest disclosed to the Office of Research.

When a project involves an investigator with a financial conflict of interest or an institutional conflict of interest, the project must be reviewed by the full board, and the IRB evaluates the management plan and determines whether or not additional protections are needed to protect the rights and welfare of human subjects.

4.6.6. Sponsor Expectations for Human Subjects Research
(Dated 04/28/22)

Contracts and funding agreements should contain provisions to contribute to the protection of human subjects in sponsored research. The Office of Sponsored Research negotiates contracts and funding agreements to ensure that the following requirements are addressed:

- The provisions for medical care for research subjects with a research-related injury, if applicable;
- The responsibility to communicate findings that could affect the safety of the subjects or influence the conduct of the study, including findings from site monitoring, data and safety monitoring, and study results; and
- The ability to publish results.

4.6.7. Reliance Relationships for Human Subjects Research
(Dated 04/28/22)

Use of a single IRB is required for research that is funded by the NIH or NSF and involves more than one institution and that requires IRB approval or limited IRB review. The reviewing IRB is identified by the funding agency or proposed by the lead institution subject to the acceptance of the funding agency.

The Pace IRB acts as the single IRB when Pace is the lead institution if the project is low risk and if the Institutional Official determines that appropriate IRB resources are available, based on information about the project provided by the Pace Principal Investigator as described in Section 3.2.1.7.3. If the Institutional Official determines that the Pace IRB does not have sufficient resources, the Pace Principal Investigator will be advised to arrange for single IRB review by an external IRB, which may be a commercial IRB or an IRB at an academic institution engaged in the research.

When the Pace IRB agrees to act as a single IRB for the involvement of one or more external investigators who are affiliated with an institution with an FWA, Pace University enters into a written IRB Authorization Agreement with the relying institution(s) that specifies the allocation of responsibilities between the Pace IRB and the external institution(s).

For external investigators who are not affiliated with an institution with an FWA, the Pace IRB will extend oversight if the IRB determines that the investigator is sufficiently qualified and that the Pace Principal Investigator has the training, experience, and resources to oversee the conduct of the external investigator. External investigators with no institutional affiliation must complete an Individual Investigator Agreement and external investigators with an affiliation with an institution that does not have an FWA must complete a Collaborating Institutional Investigator Agreement. These agreements confirm the training and experience of the investigator in conducting research with human subjects and the investigator's responsibility to protect the rights and welfare of human subjects and to comply with all relevant requirements.

A Pace Principal Investigator who wishes to use an external IRB must submit an application as described in Section 3.2.1.7.4 which is reviewed as described in Section 6.2.4. The Pace Principal Investigator for a study with an external IRB of record is responsible for complying with all requirements of the IRB of record, and in addition, for notifying the Pace IRB about Unanticipated Problems that occur during the study, for submitting study personnel changes for approval prior to submitting them to the IRB of record, and for submitting check-in/closure reports.

When Pace University relies on an external IRB, Pace University enters into a written IRB Authorization Agreement with the institution of the IRB of record that specifies the allocation of responsibilities between Pace University and the external IRB.

Reference:

§46.103(e) For nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (*e.g.,* in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).

§46.114(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

§46.114(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

§46.114(b)(2) The following research is not subject to this provision:

§46.114(b)(2)(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

§46.114(b)(2)(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

§46.114(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

4.6.8. Emergency Preparedness and Response for Human Subjects Research

(Dated 04/28/22)

Responses to emergencies for the human research protection program are coordinated with the overall Pace University emergency response effort. The lead individual for the human research response is the Institutional Official, if available, then the IRB chairs, then the HRPP Director, then the IRB administrators. The IRB electronic system is cloud-based and so should be accessible with minimal delays even if the emergency disrupts electricity or travel.

The top priority in an emergency is the protection of the wellbeing of human subjects: first, contacting investigators of any greater than minimal risk research to assess whether the emergency is affecting

personnel, communication, travel, supplies, water, electricity, or any other resources needed to protect subjects and if so, how investigators are responding, and second, contacting investigators of any research holding out the prospect of direct benefit to subjects to assess whether and how the direct benefit can continue to be provided. The second priority is formulating a plan to support the continuation of research given the constraints of the emergency, which may involve pausing certain types of research such as face-to-face interactions and utilizing external contractors to assist with HRPP functions.

If the IRB were to be unable to continue oversight of one or more studies, the HRPP Director would determine whether to close the studies or to arrange for the transfer of the oversight to an external IRB, depending on the available resources of Pace and the external IRB, based on the protection of the rights and welfare of the subjects and the expected benefits of the study.

5 Composition of the IRB

5.1. Number, Qualifications, and Diversity of IRB Members
(Dated 04/28/22)

The IRB has a minimum of five members, qualified by their varying backgrounds to promote complete and adequate review of the acceptability of proposed research activities conducted by Pace investigators. The IRB ensures that its advice and counsel in safeguarding the rights and welfare of human subjects is respected because of its members' professional competence and diversity of race, gender, and cultural backgrounds. The IRB includes persons knowledgeable about institutional commitments, policies, and resources; regulations; applicable law; standards of professional conduct; and practice, and community attitudes. The IRB also includes at least one member who is knowledgeable about and experienced in working with children and at least one member who is a prisoner representative with appropriate background to provide insight into the special protections required when prisoners are research subjects (see Section 6.5.7.6)

At least one member of the IRB is considered a nonscientist because their primary concerns are in nonscientific areas, at least one member is considered a clinical scientist because their primary concerns are in clinical scientific areas, and at least on member is considered a non-clinical scientist because their primary concerns are in non-clinical scientific areas.

At least one member of the IRB is considered unaffiliated because they are not affiliated with Pace University except for their membership on the IRB and they are not part of the immediate family of a person who is affiliated with Pace University. The unaffiliated members are considered to represent the perspectives of research subjects.

No members of the IRB are permitted to have any responsibility for business development at Pace University, such as grant administration, finance, or technology development.

IRB members may be designated as alternates who may attend a meeting and vote in place of any member in the same category (nonscientist, clinical scientist, or non-clinical scientist). If a member and their alternate are both present during a meeting, only the member may be counted towards quorum and vote.

The IRB has two equal co-chairs. IRB chairs have all the same responsibilities as IRB members and in addition, chair the IRB meetings according to parliamentary procedures, designate experienced IRB members as expedited reviewers (see Section 6.4.1.1), chair the HRPP Advisory Committee (see Section 4.1.2), and work closely with IRB administrators, the HRPP Director, and the Institutional Official to protect the rights and welfare of human subjects.

The IRB ensures that appropriate expertise is available to review research, and arranges for the assistance of consultants who are not IRB members if expertise is required beyond or in addition to that available from IRB members. Such consultants do not vote with the IRB.

Reference:

§46.107(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

§46.107(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

§46.107(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

§46.107(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

5.2. Appointment of IRB Members

(Dated 04/28/22)

The Institutional Official appoints IRB members and chairs for two-year terms every other August. There is no maximum term limit for IRB members or chairs. New IRB members or chairs are appointed to fill vacancies or to provide necessary expertise, with the same re-appointment cycle as existing members. The IRB chairs evaluate the performance of members and may recommend to the Institutional Official that a member be changed to alternate status, be removed during their term, or not be reappointed if the member substantially fails to meet expectations (see Section 5.3).

The IRB administrator maintains a roster of IRB members identified by name, earned degrees, representative capacity (nonscientist, clinical scientist, non-clinical scientist), experience relevant to their contribution to the IRB review, and affiliation with Pace University. The roster is updated within 90 days of any change in IRB membership.

Reference:

§46.108(a) In order to fulfill the requirements of this policy each IRB shall:

§46.108(a)(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to

describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;

5.3. Expectations of IRB Members
(Dated 04/28/22)

IRB members are responsible for ensuring that the rights and welfare of research subjects are protected by reviewing and approving human research in a manner consistent with Federal regulations, state and local laws, and Pace University guidelines and policies. Regular IRB members are expected to attend at least 75% of scheduled meetings and alternates are expected to attend at least 75% of meetings to which they have been invited. All members must avoid voting on any matter in which they have a conflict of interest according to the process described in Section 6.4.2.1. When a member has been assigned as a primary or secondary reviewer (see Section 6.4.2.2), they are expected to submit their reviews prior to the meeting in the electronic system. When a member is an expedited reviewer and is assigned a submission, they are expected to communicate with an IRB administrator if they are not able to submit their review within one week of assignment.

All IRB members must complete the CITI training for IRB members and renew the training every three years. Education of IRB members is provided at full board meetings. A new IRB member is assigned as a secondary reviewer after attending at least two meetings, and is assigned as a primary reviewer after completing at least two secondary reviews.

5.4. IRB Registration
(Dated 04/28/22)

The HRPP Director maintains the registration of the Pace University IRB using electronic submission system on the OHRP website. The registration is updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairs, and is renewed prior to the expiration of the 3-year effective period.

The registration information contains:

- The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.
- The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.
- The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.
- The name, phone number, and electronic mail address of the IRB chairs.
- The approximate numbers of all active protocols and active protocols conducted or supported by HHS. An “active protocol” is any protocol for which the IRB conducted an initial review or a continuing review at a full board meeting or under an expedited review procedure during the preceding twelve months.
- The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

The decision to disband a registered IRB would be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

Reference:

Section **46.501**: *What IRBs must be registered?*

Each IRB that is designated by an institution under an assurance of compliance approved for federal wide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

Section **46.502**: *What information must be provided when registering an IRB?*

The following information must be provided to HHS when registering an IRB:

§46.502(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

§46.502(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

§46.502(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

§46.502(d) The name, phone number, and electronic mail address of the IRB chairperson.

§46.502(e)(1) The approximate numbers of:

§46.502(e)(1)(i) All active protocols; and

§46.502(e)(1)(ii) Active protocols conducted or supported by HHS.

§46.502(e)(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

§46.502(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

Section **46.503**: *When must an IRB be registered?*

An IRB must be registered before it can be designated under an assurance approved for federal wide use by OHRP under §46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

Section **46.504:** *How must an IRB be registered?*

Each IRB must be registered electronically through the efile system unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

Section **46.505**: *When must IRB registration information be renewed or updated?*

§46.505(a) Each IRB must renew its registration every 3 years.

§46.505(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with §46.504.

§46.505(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

§46.505(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

5.5. IRB Administrators

(Dated 04/28/22)

IRB administrators support the IRB members and chairs in fulfilling their responsibilities for protection of human subjects. The HRPP Director ensures that IRB administrators are provided with appropriate training and education to fulfill their responsibilities.

Specific duties of IRB administrators include:

- Managing communicating with investigators;
- Processing IRB submissions (see Section 6.1), including completing pre-review, performing administrative review, and assigning reviewers for exempt, expedited and full board submissions;
- Managing IRB meetings (see Section 6.4.2), including developing agendas, distributing meeting materials, tracking attendance and quorum, following up on required actions, and preparing minutes;
- Maintaining the electronic system and IRB records (see Section 6.10).

IRB administrators who are appointed as alternate IRB members and as expedited reviewers also fulfill the responsibilities of IRB members (see Section 5.3).

6 IRB Review of Submissions

6.1. General Review Procedures

(Dated 04/28/22)

When a submission is made to the IRB, an IRB administrator evaluates whether all study personnel have fulfilled their training requirements and whether the submission is complete and internally consistent (e.g., the proposed exempt category matches the study procedures; the information in the consent form matches the information in the application; a waiver is requested if no consent form is attached). The IRB also checks whether a Principal Investigator or Faculty Advisor on a new submission has any studies that have expired or passed their check-in due date and requires the Principal Investigator to make the appropriate submission to renew or close the study before the new submission is reviewed. An IRB administrator notifies the Principal Investigator of any needed clarifications or corrections.

The four review paths for submission are:

1. Administrative review
2. Exempt review (including limited IRB review)
3. Expedited review
4. Full-board review

Experienced IRB administrators may perform administrative reviews. Expedited reviewers (see Section 6.4.1.1) may perform administrative, exempt, or expedited reviews.

Submissions that are eligible for administrative review are:

- Initial and revised requests for “Not Human Subjects Research”/”Not Engaged” determinations;
- Initial and revised submissions for class projects;
- Initial and revised requests for “118 determinations” for proposals lacking definite plans for involvement of human subjects;
- Initial and revised requests to rely on an external IRB;
- Reportable events submissions only if the chairs conclude that the event that was described in the report is clearly not a compliance concern (see Section 6.9.7); and

- Study closures.

Submissions that are eligible for exempt review are initial submissions, study modification forms, and check-in forms for projects that qualify for an exempt determination (all submissions for exempt projects except reportable events forms). If the reviewer determines that an initial or revised project does not qualify for an exempt determination, the reviewer communicates to the Principal Investigator that a resubmission for non-exempt review is required.

For submissions that are not eligible for administrative or exempt review, an IRB administrator, after consulting with expedited reviewers or chairs if appropriate, assesses whether the project requires full board or expedited review. The expedited review process may be used, except for the following categories of submissions that require full-board review:

- Initial submissions for projects:
  - That are greater than minimal risk;
  - That involve procedures that are not in a Pace IRB expedited category (see Section 6.4.1.2);
  - That include an investigator with a conflict of interest management plan (see Section 4.6.5);
  - That involve interventions or interactions with prisoners (see Section 6.5.7.6); or
  - That involve a food or dietary supplement, drug, or device (see Section 7.1);
- Modifications to projects initially reviewed by the full board, unless the expedited reviewer makes the determination that the requested change qualifies as a minor change (see Section 6.4.1.2);
- Continuing review for study renewals, unless at the time of initial submission or a previous continuing review the full board has determined and documented that the project is no greater than minimal risk and that subsequent continuing reviews may be carried out by the expedited process;
- Reportable events submissions;
- Any submission where the expedited reviewer recommends disapproval; and
- Any submission that raise significant ethical, regulatory, or policy issues.

6.2. Administrative Review Process

6.2.1. Not Human Subjects Research/Not Engaged Determinations

(Dated 04/28/22)

Investigators are permitted to make their own determinations that their planned activity does not constitute research with human subjects or engagement in research, using the information in Section 2. An investigator is also permitted to submit an application to the IRB to request a formal not human subjects research or not engaged determination (see Section 3.2.1.5).

Research is a systematic investigation designed to develop or contribute to generalizable knowledge. A systematic investigation is considered to be a collection or analysis of data that uses a predetermined method to gain information. Generalizable knowledge is considered to be conclusions that can be applied to circumstances outside of the specific instances of the investigation.

The definition of research specifically excludes scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

Additional activities that are not considered research by Pace University policy are:

- Clinical case studies or case series that involve no more than three patients. Note that HIPAA authorizations (see Section 6.6.4) may be needed for clinical case studies or case series.
- Non-clinical case studies that investigates the processes, activities or operations at a single organization or event in non-treatment environment.
- Quality improvement and quality assurance activities that implement or evaluate a practice known to improve services.

A human subject is a living individual about whom an investigator obtains or analyzes information or biospecimens through intervention or interaction with the individual or obtains or analyzes identifiable private information or identifiable biospecimens.

An intervention can be either a physical procedure to gather information or biospecimens (e.g., measuring blood pressure, collecting saliva) or manipulation of the subject or the subject's environment. An interaction is any communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., an educational or medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

"Engagement" is defined in the OHRP Guidance on Engagement. Pace University is considered to be engaged in a particular human subjects research project when its employees or any other individuals who act on behalf of, exercises authority or responsibility for, or perform activities designated by Pace University for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about or identifiable biospecimens from the subjects of the research; or (3) the informed consent of human subjects for the research. Pace University is considered to be engaged when it receives an award directly through a grant, contract, or cooperative agreement for the human subjects research (i.e., Pace is the awardee institution), even where all activities involving human subjects are carried out by employees or agents of a non-Pace institution.

If the reviewer needs clarifications or additional information, or concludes that the submitted activity is human subjects research or is engagement, the reviewer notifies the Principal Investigator how to modify the application and resubmit to the IRB.

If the reviewer makes the determination that the submitted activity is not human subjects research or does not constitute engagement in research, the reviewer provides an outcome letter through the electronic system (see Section 6.8.1).

6.2.2. Review of Class Projects

(Dated 04/28/22)

The review of submissions describing class projects that will involve intervention or interaction with living individuals or their identifiable information involves assessing whether the process described in Section 3.2.1.6 for ensuring the protection of the rights and welfare of individuals participating in the projects is acceptable.

If the reviewer needs clarifications or additional information, the reviewer notifies the Principal Investigator how to modify the application and resubmit to the IRB.

If the faculty's review process is acceptable, the reviewer provides an outcome letter through the electronic system (see Section 6.8.1).

6.2.3. Proposals Lacking Definite Plans for Involvement of Human Subjects
(Dated 04/28/22)

The Principal Investigator of a project submitted for funding where the involvement of human subjects is planned but the Principal Investigator is unable to describe the details of the project until a later date is permitted to submit a request to the IRB for a formal determination that the research qualifies as a proposal lacking definite plans for involvement of human subjects under 45CFR46.118 (a "118 determination.")

The required information for a 118 determination is a description of the entire project and a detailed timeline for development of plans for activities involving human subjects.

If the reviewer needs clarifications or additional information, or concludes that the Principal Investigator is able to provide enough details for IRB review, the reviewer notifies the Principal Investigator how to modify the application and resubmit to the IRB.

If a submitted activity is determined to meet the criteria for a 118 determination, the reviewer provides an outcome letter through the electronic system (see Section 6.8.1).

Reference:
Section **46.118**: Applications and proposals lacking definite plans for involvement of human subjects.
Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under §46.101(i) or exempted under §46.104, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

6.2.4. Requests to Rely on an External IRB
(Dated 04/28/22)

The review of a request to rely on an external IRB (see Section 3.2.1.7.4) involves assessing the quality of the proposed IRB of record and, with the assistance of the chairs or HRPP Director as needed, determining whether the reliance is appropriate based on the study activities that will take place at Pace

University. For research that is greater than minimal risk, the proposed IRB of record must be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) or in the process of obtaining AAHRPP accreditation. For research that is no greater than minimal risk, if the proposed IRB of record participates in SMART IRB, this will be considered sufficient evidence of quality, because participation in SMART IRB requires being AAHRPP accredited, being in the process of obtaining accreditation, or having undergone an OHRP Quality Assessment Program within the past 5 years. If the proposed IRB of record does not participate in SMART IRB, the IRB Director or HRPP Director will contact the proposed IRB of record to ask for access to their policies on how they conduct review of external sites (including provisions for local context review) and any letters or findings within the past five years from OHRP or FDA as a result of investigations or inspections of the IRB.

If the reviewer needs clarifications or additional information, the reviewer notifies the Principal Investigator how to modify the application and resubmit to the IRB. If the reviewer is unable to determine that the reliance is appropriate, the reviewer refers the application to the full board.

If the reviewer determines that the reliance is appropriate, the reviewer contacts the reviewing IRB and, together with the Pace Principal Investigator, completes all required documentation (see Section 4.6.7). The reviewer provides an outcome letter through the electronic system (see Section 6.8.1).

6.2.5. Events that are Not Reportable
(Dated 04/28/22)

If the chairs conclude that the events described in a reportable events submission do not constitute a reportable event or compliance concern (see Section 6.9.7), the reviewer communicates this determination as an acknowledgement through the electronic system.

6.2.6. Study Closures
(Dated 04/28/22)

The review of check-in/closure forms that request study closure (see Section 3.3.1) involves following up for compliance purposes according to Section 6.9 on any reported subject withdrawals or complaints, enrollment of more subjects than approved by the IRB, deviations, or new information about risks or benefits. The reviewer processes the closure and provide an outcome letter through the electronic system (see Section 6.8.1).

6.3. Review of Exempt Research
(Dated 04/28/22)

Exempt research is reviewed by an expedited reviewer (see Section 6.4.1.1) who verifies that:

- All proposed project activities satisfy the criteria for the three exempt categories used by the Pace IRB (see Section 3.2.2);
- The provisions to protect the privacy of subjects and to maintain the confidentiality of data described in Sections 3.2.3.12 (Confidentiality of the Project Data) and 3.2.3.13 (Privacy Protections) are adequate, either because only truly anonymous information is collected or because appropriate data security measures are in place for identifiable data. (Note that the Pace IRB requires this determination for all exempt research, while the Federal regulations only require it for certain types of exempt research);

- If any students, employees, or patients of any study team members will be subjects, that the protections against coercion and undue influence described in Section 3.2.3.3.4 are adequate (see Section 6.6.11.3);
- If any subjects will have limited or no ability to read or understand English, that the arrangements for obtaining agreement described in Sections 3.2.3.3.6 and 3.2.3.3.7 are adequate; and
- Prospective agreement to participate will be obtained for any research involving intervention or interaction with subjects, including providing the potential subject with the following information:
  - The title of the study;
  - A statement that the project involves research;
  - A statement that participation is voluntary;
  - Identification of the Principal Investigator;
  - A brief explanation of the purpose of the study;
  - A brief description of study procedures;
  - An estimate of the time required for participation;
  - If any of the questions or procedures might be upsetting, a statement covering the ability to stop the study and available support resources;
  - A statement about confidentiality protections;
  - If any of the participants might be a student, employee, or patient of anyone on the study team, a statement covering the lack of consequences of participation or choosing not to participate;
  - A statement about subject payment, including any conditions on the subject receiving full payment;
  - Contact information for the Principal Investigator for answering subject questions; and
  - Specification of the action potential subjects will take if they agree to participate;
- If the subject will be audio- or video-recorded or will be named in publication of results, the researchers will obtain a paper or electronic record of their agreement to be recorded or named; and
- If Pace IRB oversight will be extended to investigators who are not at Pace, that the investigators are qualified based on information in Section 3.2.1.7.3 (Investigators who are not at Pace to be Overseen by the Pace IRB).

If a project that would otherwise meet the criteria for an exempt determination seeks to waive or alter the prospective agreement requirement, the reviewer notifies the Principal Investigator that the project should be submitted for non-exempt review.

If the reviewer needs clarifications or additional information, or concludes that the submitted activity does not qualify for an exempt determination, the reviewer notifies the Principal Investigator how to modify the application and resubmit to the IRB. For exempt check-in/closure forms, if the forms report subject complaints or deviations, the reviewer follows up for compliance purposes according to Section 6.9.

If the reviewer makes the determination that the submitted activity qualifies for an exempt determination, the reviewer provides an outcome letter through the electronic system (see Section 6.8.2). If the project involves obtaining information that is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and disclosure of the human subjects' responses outside the research might place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation, the expedited reviewer will document in the

electronic system that they carried out a limited IRB review and determined that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Note that the Federal regulations have additional exempt categories that are not used by the Pace IRB. Five of these research activities require approval, rather than an exempt determination, from the Pace IRB: observations of public behavior; educational tests (if not eligible in exempt category 1); benign behavioral interventions that involve deception; certain secondary research (because the category 4 exemption criteria are very narrow and unlikely to apply to any projects carried out by Pace investigators); and taste and food quality evaluation. The remaining three are not applicable to Pace investigators: Federal research and demonstration projects; broad consent for obtaining information or biospecimens; and broad consent for analyzing information or biospecimens.

Reference:

§46.104(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

§46.104(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

§46.104(b)(1) S*ubpart* B. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

§46.104(b)(2) *Subpart* C. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

§46.104(b)(3) S*ubpart* D. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

§46.104(d)(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

§46.104(d)(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

§46.104(d)(2)(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

§46.104(d)(2)(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

§46.104(d)(2)(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

§46.104(d)(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

§46.104(d)(3)(i)(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

§46.104(d)(3)(i)(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

§46.104(d)(3)(i)(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

§46.104(d)(3)(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

§46.104(d)(3)(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

§46.104(d)(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

§46.104(d)(4)(i) The identifiable private information or identifiable biospecimens are publicly available;

§46.104(d)(4)(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

§46.104(d)(4)(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

§46.104(d)(4)(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for noresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

§46.104(d)(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

§46.104(d)(5)(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

§46.104(d)(5)(ii) [Reserved]

§46.104(d)(6) Taste and food quality evaluation and consumer acceptance studies:

§46.104(d)(6)(i) If wholesome foods without additives are consumed, or

§46.104(d)(6)(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

104(d)(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

104(d)(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

104(d)(8)(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

104(d)(8)(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

104(d)(8)(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

104(d)(8)(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

6.4. Review of Non-Exempt Research

6.4.1. Expedited Review Process

6.4.1.1. Appointment and Authority of Expedited Reviewers

(Dated 04/28/22)

The chairs are expedited reviewers and appoint additional expedited reviewers who are considered experienced board members based on their knowledge, training, performance of reviews, and participation in IRB meetings. Expedited reviewers receive additional training concerning the expedited review categories and the expedited review procedure in the electronic system.

Expedited reviewers exercise full IRB authority except they may not disapprove submissions. Expedited reviewers may obtain assistance with their reviews from the chairs or HRPP Director and may refer a submission for full board review if appropriate.

Reference:

§46.110(b)(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In

reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non expedited procedure set forth in §46.108(b).

6.4.1.2. Expedited Review Categories
(Dated 04/28/22)

For a submission to be eligible for expedited review (see Section 6.1), the project must be no greater than minimal risk and involve only procedures in an established expedited category.

The categories of expedited review used by the Pace IRB, numbered according to the Federal regulations, are:

110(b)(1)(i) #5 Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for noresearch purposes (such as medical treatment or diagnosis or educational purposes).

110(b)(1)(i) #6 Collection of data from voice, video, digital, or image recordings made for research purposes.

110(b)(1)(i) #7 Non-exempt research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or non-exempt research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

110(b)(1)(i) #8 Continuing review of research previously approved by the full board as follows (note that in most cases, such projects do not require continuing review, see Section 6.7):

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(b) where no subjects have been enrolled and no additional risks have been identified; or
(c) where the remaining research activities are limited to data analysis.

110(b)(1)(i) #9 Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories five to eight do not apply but where the IRB has determined and documented at a full board meeting that the research involves no greater than minimal risk and that subsequent continuing review may be carried out by the expedited review process.

110(b)(1)(ii): Changes in previously approved research that are determined by the expedited reviewer to qualify as minor changes, meaning that the change does not increase the risk of the project and, for projects initially reviewed by the full board, has no effect on the aspect of the study that required full board review (see Section 6.1).

110(b)(1)(iii): Research for which limited IRB review is a condition of exemption (see Section 6.3).

If the expedited reviewer determines that a project appearing in one of the expedited categories is greater than minimal risk or requires a check-in period of less than 36 months, the expedited reviewer refers the project for full board review and documents this determination in the electronic system.

Note that the Pace IRB does not use all of the expedited categories from the Federal regulations, because Federal expedited categories 1, 2, 3, and 4 represent types of research that Pace investigators do not commonly undertake and would warrant full board consideration.

Reference:

§46.110(a) The Secretary of HHS has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the FEDERAL REGISTER for public comment. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

§46.110(b)(1) An IRB may use the expedited review procedure to review the following:

§46.110(b)(1)(i) Some or all of the research appearing on the list described in paragraph (a) of this section, unless the reviewer determines that the study involves more than minimal risk;

§46.110(b)(1)(ii) Minor changes in previously approved research during the period for which approval is authorized; or

§46.110(b)(1)(iii) Research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8).

OHRP Expedited Review Categories (1998) 63 FR 60364-60367

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for noresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
   (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   (b) where no subjects have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

6.4.1.3. Communication of Expedited Review Actions to Board
(Dated 04/28/22)

The agendas for full board meetings provide the board members with the location in the electronic system of the listing of all expedited actions.

Reference:
§46.110(c) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.

6.4.2. Full Board Review Process

6.4.2.1. Schedule, Quorum, and Voting Requirements for IRB Meetings
(Dated 04/28/22)

The IRB meets monthly on a schedule set by the chairs on an annual basis. The chairs may call special IRB meetings if necessary.

Quorum requires a majority (>50%) of board members to be present, including at least one nonscientist and at least one scientist (clinical or non-clinical scientist) (see Section 5.1). The possible motions on an agenda item are approval, conditions required to secure approval, tabling, acknowledgement, or disapproval. In order for the motion to pass, a majority (>50%) of the members present (including those who have abstained) must vote in favor.

Each member has one vote. If the member is unable to vote (absent or recused), then one appropriately designated alternate member may vote in place of the member. No proxy votes (written or telephone) are allowed. If quorum is lost, no business may be conducted.

At the beginning of each meeting, the chairs remind the attendees that the proceedings are confidential and that members must disclose any conflicts of interest they have in any of the items on the agenda for the meeting, either because they or an immediate family member is a member of the study team or is otherwise involved in the design, conduct, or reporting of the research, or because they or an immediate family member has any financial interest in the sponsor, product, or service being tested. Members with a conflict of interest may be present at the meeting to provide information, but must leave the meeting prior to the final discussion and vote on the item. An alternate member for the recused member may vote on the item. The minutes record the presence of a conflict, the recusal from voting, and, if applicable, voting by the alternate.

Members who attend the meeting via teleconference must have received all pertinent information prior to the meeting and be able to participate actively and equally in all discussions.

Individuals who are not IRB members may attend IRB meetings but may not vote. IRB administrators, Pace legal representatives, and alternates who are not in voting status routinely attend IRB meetings. Others such as consultants and investigators whose projects are being reviewed may attend as visitors if

invited by the chairs and must acknowledge the confidentiality of the meeting proceedings. The minutes reflect the attendance of all individuals at the meetings.

Reference:

§46.107(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

§46.108(b) Except when an expedited review procedure is used (as described in §46.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

6.4.2.2. Distribution of IRB Meeting Materials and Assignment of Reviewers

(Dated 04/28/22)

An IRB administrator prepares and distributes the agenda at least one week prior to the meeting. At the discretion of the chairs, additional material may be added to the agenda if there is a need for rapid review and the members would have adequate time to review the new material. The agenda contains links to all meeting materials, which are available to IRB members in the electronic system. All members are expected to review the meeting materials prior to the meeting.

Pace IRB uses a primary reviewer process for all agenda items. An IRB administrator, in consultation with the chairs, assigns a primary reviewer for each agenda item, based on the expertise of the members and equitable distribution of work. Consultants may be engaged to provide necessary expertise. For initial submissions and any items presenting complex issues, a secondary reviewer is also assigned. The primary and secondary reviewers provide written reviews in the electronic system prior to the meeting and lead the discussion of the item at the meeting, providing a summary of the submission and their reviews and recommendations.

6.4.2.3. Minutes of IRB Meetings

(Dated 04/28/22)

IRB administrators prepare minutes which include:

- The date, time, and location of the meeting;
- A listing of members, by board role, who are present (including alternate members replacing absent or recused members); members who are absent; board members who have a conflict of interest; members who are recused; and all other individuals who are present;
- When a member joins or leaves the meeting, and any loss of quorum;
- Educational materials distributed/discussed;
- For each agenda item, a listing of separate actions and controverted issues and their resolution;
- All votes on actions, including number of members voting for, against, those recusing themselves from voting (and/or from discussion) and those abstaining from voting on actions;
- If a submission is approved, that the criteria for approval in Section 6.5 were met;
- The approval period for each approved initial submission or study renewal;
- If changes to a submission are required or if a submission is disapproved, a reference to the basis for requiring the changes or for the disapproval in the electronic system;
- A reference to study-specific justifications in the electronic system for any waivers or alterations of the requirement for informed consent or for any waivers of informed consent documentation;

- Any determinations regarding regulatory categories and references to study-specific justifications in the electronic system for research involving children; adults with diminished capacity; pregnant women; or prisoners;
- If revised consent forms are approved, whether and how already-consented subjects will be re-consented;
- Any determinations related to IND Exemptions under 21 CFR 312.2(b), IDE exemptions under 21 CFR 812.2, or abbreviated IDEs for non-significant risk device studies under 21 CFR 812.2(b);
- Any determinations related to management plans of Financial Conflicts of Interest (see Section 4.6.5);
- The determinations and board actions pertaining to any for-cause audits or Reportable Events reports considered by the board, including any urgent actions previously approved by the chairs in response to unanticipated problems or deviations. Determinations include whether or not an event reported as an Unanticipated Problem meets the definition in Section 6.9.1 and whether or not the report provides evidence of serious or continuing noncompliance;
- If research is suspended or terminated, the reasons for the suspension or termination; and
- Any determinations required by HIPAA and its regulations and references to study-specific justifications in the electronic system, including determinations related to waivers of HIPAA authorization for research uses and disclosures of subjects' PHI (see Section 6.6.8).

The IRB reviews, correct, and approves minutes of the previous meeting at a subsequent meeting.

Reference:

§46.115(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

§46.115(a)(2) Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

6.5. Criteria for Approval of Non-Exempt Human Subjects Research

6.5.1. Risks are Minimized Criterion

(Dated 04/28/22)

To approve non-exempt research, the IRB must determine that risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

The IRB assesses the risks of the research and whether they are minimized using information in Sections 3.2.1.13 (Assessment of Whether the Research is Greater than Minimal Risk), 3.2.3.5 (Inclusion and Exclusion Criteria), 3.2.3.9 (Study Methods), 3.2.3.12 (Confidentiality of the Project Data), 3.2.3.13 (Privacy Protections), 3.2.4.2 (Risks to Subjects); and 3.2.4.5 (Biospecimens).

Reference:

§46.111(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

§46.111(a)(1) Risks to subjects are minimized:

§46.111(a)(1)(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

§46.111(a)(1)(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

6.5.2. Risks are Reasonable in Relation to Benefits Criterion

(Dated 04/28/22)

To approve non-exempt research, the IRB must determine that risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

In evaluating the risks and benefits of the research, the IRB assesses whether the research design is scientifically appropriate, and uses consultants to ensure that the appropriate expertise is available to determine the scientific merits of the project.

The IRB assesses whether the risks are reasonable in relation to anticipated benefits using information in Sections 3.2.3.2 (Study Purpose), 3.2.4.2 (Risks to Subjects), and 3.2.4.3 (Benefits to Subjects and Others).

Reference:

§46.111(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

§46.111(a)(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (*e.g.,* the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

6.5.3. Selection of Subjects is Equitable Criterion

(Dated 04/28/22)

To approve non-exempt research, the IRB must determine that selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

The IRB assesses whether the selection of subjects is equitable and whether the recruitment, payment, and consent processes are adequate to protect against coercion and undue influence using information in Sections 3.2.3.3 (Special Classes of Subjects), 3.2.3.5 (Inclusion and Exclusion Criteria), 3.2.3.6

(Recruitment Process), 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.9 (Study Methods), 3.2.3.10 (Costs Incurred by Subjects); 3.2.3.11 (Payments to Subjects), 3.2.4.2 (Risks to Subjects), and 3.2.4.3 (Benefits to Subjects and Others).

Reference:

§46.111(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

§46.111(a)(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

6.5.4. Consent Process is Acceptable Criterion

(Dated 04/28/22)

To approve non-exempt research, the IRB must determine either that informed consent will be obtained and documented from each prospective subject or the subject's legally authorized representative in accordance with applicable requirements in Section 6.6 or that the project qualifies for a waiver or alteration of consent in Section 6.6.7 or a waiver of documentation of consent in Section 6.6.6.2. The IRB may require that information, in addition to that specifically mentioned in Section 6.6.3, be given to the subjects if the IRB determines that the information would meaningfully add to the protection of the rights and welfare of subjects.

Note that the Pace IRB goes beyond the Federal regulations in regards to some screening activities. The Pace IRB requires that for non-exempt projects that involve contacting potential subjects prior to obtaining their full consent in order to collect information for screening, recruiting, or determining eligibility, the potential subjects must agree to participate in the screening and the screening data must be adequately protected (see Section 3.2.4.1). The Federal regulations do allow an IRB to approve a research proposal in which an investigator will obtain information by contacting subjects for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without informed consent.

The IRB assesses whether the consent process is acceptable using information in Sections 3.2.2.3 (Special Classes of Subjects), 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), and 3.2.4.1 (Screening Procedures).

Reference:

§46.109(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

§46.109(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

§46.111(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

§46.111(a)(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §46.116.

§46.111(a)(5) Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.

§46.116(g) *Screening, recruiting, or determining eligibility.* An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

§46.116(g)(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

§46.116(g)(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

6.5.5. Data Safety Monitoring is Acceptable Criterion

(Dated 04/28/22)

To approve non-exempt research, the IRB must determine that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

The IRB assesses whether the monitoring is adequate using information in Sections 3.2.4.2 (Risks to Subjects) and 3.2.4.4 (Data Safety and Monitoring).

Reference:

§46.111(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

§46.111(a)(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

6.5.6. Privacy and Confidentiality Protections are Acceptable Criterion

(Dated 04/28/22)

To approve non-exempt research and exempt research requiring limited IRB review, the IRB must determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. For research that is no greater than minimal risk, an individual subject's identifiable data may be made public if the subject has provided written agreement on paper or electronically for the publication of their identifiable data.

The IRB assesses whether the privacy and confidentiality protections are adequate using information in Sections 3.2.3.12 (Confidentiality of the Project Data), 3.2.3.13 (Privacy Protections), and 3.2.3.8.2 (Consent to Participate in Non-Exempt Research).

Reference:

§46.111(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

§46.111(a)(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

§46.111(a)(7)(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

6.5.7. Protections of Vulnerable Subjects are Acceptable Criterion

6.5.7.1. Protections Against Coercion or Undue Influence

(Dated 04/28/22)

To approve non-exempt research, the IRB must determine that when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, adults with diminished capacity, economically or educationally disadvantaged persons, or students, employees, or patients of the investigators, additional safeguards have been included in the study to protect the rights and welfare of these subjects. The IRB ensures that adequate expertise from members or consultants is available to consider the appropriate additional protections for special populations.

The IRB assesses whether the recruitment, payment, and consent processes are adequate to protect special populations against coercion and undue influence using information in Sections 3.2.2.3 (Special Classes of Subjects), 3.2.3.6 (Recruitment Process), 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.10 (Costs Incurred by Subjects), and 3.2.3.11 (Payments to Subjects).

Reference:

§46.111(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

6.5.7.2. Protections for Children

(Dated 04/28/22)

To approve non-exempt research involving children, the IRB:

- Must determine that the research satisfies the criteria in one of the following categories:
  1. Research presenting no more than minimal risk to children;
  2. Research presenting more than minimal risk to children when the risk is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being; when the risks are justified by the anticipated benefits to the subject; and when the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches;
  3. Research presenting more than minimal risk to children when the risk is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject; when the risk represents a minor increase over minimal risk; when the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; and when the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; or
  4. Research not meeting the criteria for any of categories 1-3 when the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and when the project is referred to the Secretary of HHS for further review.
- Must determine that unless the project qualifies for a waiver or alteration of consent in Section 6.6.7 or a waiver of documentation of consent in Section 6.6.6.2, that adequate provisions are

made for obtaining and documenting the assent of the children and the permission of their parents or guardians according to Section 6.6.11.1.

To approve research that is greater than minimal risk involving children who are wards of the state or any other agency, institution, or entity, the IRB must determine either that:

- The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards; or
- The research is related to the subject's status as wards and there is an adequate plan for appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization. Note that the Pace IRB requires an advocate for wards in studies in child research category 2 (greater than minimal risk with the prospect of direct benefit), even though the Federal regulations only require an advocate for studies in child research categories 3 and 4.

The IRB assesses whether the inclusion of children meets the criteria in this section using information in Sections 3.2.3.2 (Study Purpose), 3.2.3.3 (Special Classes of Subjects), 3.2.3.6 (Recruitment Process), 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.5 (Inclusion and Exclusion Criteria), 3.2.3.9 (Study Methods), 3.2.4.2 (Risks to Subjects), and 3.2.4.3 (Benefits to Subjects and Others).

Reference:

Section **46.403**: *IRB duties*

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

Section **46.404**: *Research not involving greater than minimal risk*

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

Section **46.405**: *Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects*

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

405(a) The risk is justified by the anticipated benefit to the subjects;

405(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

405(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

Section **46.406**: *Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition*

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

406(a) The risk represents a minor increase over minimal risk;

406(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

406(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

406(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

Section **46.407**: *Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children*

HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

407(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

407(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

407(b)(1) That the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or

407(b)(2) The following:

407(b)(2)(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

407(b)(2)(ii) The research will be conducted in accordance with sound ethical principles;

407(b)(2)(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§46.409(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

§46.409(a)(1) Related to their status as wards; or

§46.409(a)(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

§46.409(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

6.5.7.3. Protections for Adults with Diminished Capacity

(Dated 04/28/22)

To approve non-exempt research involving adults with diminished capacity to provide informed consent, the IRB:

- Must determine that the research investigates a condition of importance to the population represented by the subjects;
- Must determine that the research satisfies the criteria in one of the following categories:
  1. Research presenting no more than minimal risk to adults; or
  2. Research presenting more than minimal risk to adults when the risk is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being; when the risks are justified by the anticipated benefits to the subject; and when the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- Must determine that unless the project qualifies for a waiver or alteration of consent in Section 6.6.7 or a waiver of documentation of consent in Section 6.6.6.2, that adequate provisions are

made for assessing the capacity of potential subjects to consent or assent, for verifying the status of the legally authorized representative, and for obtaining and documenting the assent of the adults and the consent of their legally authorized representatives according to Section 6.6.11.2.

The IRB assesses whether the inclusion of adults with diminished capacity to consent meets the criteria in this section using information in Sections 3.2.3.2 (Study Purpose), 3.2.3.3 (Special Classes of Subjects), 3.2.3.5 (Inclusion and Exclusion Criteria), 3.2.3.6 (Recruitment Process), 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.9 (Study Methods), 3.2.4.2 (Risks to Subjects), and 3.2.4.3 (Benefits to Subjects and Others).

6.5.7.4. Protections for Students, Employees, and Patients of Study Personnel
(Dated 04/28/22)

To approve non-exempt research or to issue an exempt determination for research involving students, employees, or patients of any member of the study team, the IRB must determine that there are adequate safeguards to ensure that participation is truly voluntary, without coercion or undue influence. There must be no perceived or actual advantage to agreeing to participate and study data must not affect the evaluation of students or employees. The agreement or consent discussion should be performed by a member of the study team other than the person with the relationship with the student, employee, or patient if the IRB determines that this would provide additional protection against coercion or undue influence.

The IRB assesses whether the inclusion of students, employees, or patients of any member of the study team meets the criteria in this section using information in Sections 3.2.3.3 (Special Classes of Subjects), 3.2.3.5 (Inclusion and Exclusion Criteria), 3.2.3.6 (Recruitment Process), 3.2.3.8.1 (Agreement to Participate in Exempt Research), 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.9 (Study Methods), 3.2.4.2 (Risks to Subjects), and 3.2.4.3 (Benefits to Subjects and Others).

6.5.7.5. Protections for Pregnant Women
(Dated 04/28/22)

To approve non-exempt research involving pregnant women, even if the investigators will not be aware of the subject's pregnancy status, the IRB:

- Must determine that:
  - Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
  - The study falls into one of the following categories:
    1. The risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means; or
    2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman but not to the fetus;
    3. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the fetus but not to the woman;
    4. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman and to the fetus;
  - Any risk is the least possible for achieving the objectives of the research;

  - No inducements, monetary or otherwise, will be offered to terminate a pregnancy; and
  - Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- Must determine that unless the project qualifies for a waiver or alteration of consent in Section 6.6.7 or a waiver of documentation of consent in Section 6.6.6.2, that adequate provisions are made for obtaining and documenting the consent of the pregnant women and the father of the fetus, if applicable, according to Section 6.6.11.4.

The IRB assesses whether the inclusion of pregnant women meets the criteria in this section using information in Sections 3.2.3.2 (Study Purpose), 3.2.3.3 (Special Classes of Subjects), 3.2.3.5 (Inclusion and Exclusion Criteria), 3.2.3.6 (Recruitment Process), 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.9 (Study Methods), 3.2.4.2 (Risks to Subjects), and 3.2.4.3 (Benefits to Subjects and Others).

Note that the Pace IRB does not approve research involving nonviable neonates and neonates of uncertain viability, or research involving fetal material.

Reference:
Section **46.203**: *Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates*
In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.
Section **46.204**: *Research involving pregnant women or fetuses*
Pregnant women or fetuses may be involved in research if all of the following conditions are met:
§46.204(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
§46.204(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
§46.204(c) Any risk is the least possible for achieving the objectives of the research;
§46.204(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
§46.204(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
§46.204(j) Individuals engaged in the research will have no part in determining the viability of a neonate.
§46.206(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.
§46.206(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

6.5.7.6. Protections for Prisoners
(Dated 04/28/22)

To approve research involving prisoners, the IRB:

- Must include a prisoner representative in the review of the project;

- If the project involves any interventions or interactions with prisoners, must review at a full board meeting the initial submission and any modifications that affect those interactions and must provide continuing review at least annually;
- Must not include a majority of members with an association with the prison(s) involved in the project;
- Must determine that:
  - Any possible advantages accruing to the prisoner through their participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
  - The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
  - Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
  - The information is presented in language which is understandable to the subject population;
  - Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on their parole; and
  - Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.
- Must determine that the research satisfies the criteria in one of the following categories:
  1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the HHS Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of their intent to approve such research; or
  4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of their intent to approve such research; and
- Must determine that unless the project qualifies for a waiver or alteration of consent in Section 6.6.7 or a waiver of documentation of consent in Section 6.6.6.2, that adequate provisions are

made for obtaining and documenting the consent of prisoner subjects according to Section 6.6.11.5; and
- If the research is sponsored by the Department of Health and Human Services (HHS), must certify to the HHS Secretary, in such form and manner as the HHS Secretary may require, that the duties of the IRB under this section have been fulfilled.

Epidemiological research may involve prisoners as subjects only if all three of the following criteria are met:
- The sole purposes of the research are either (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease;
- The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects; and
- Prisoners are not a particular focus of the research.

If a subject already enrolled in a research study that was not approved for the inclusion of prisoners becomes incarcerated, all study-related activities for the subject must cease until the continued participation of the subject has been approved by the IRB according to the requirements in this Section, unless the Principal Investigator believes that continuation of study interventions is in the best interest of the subject. The Principal Investigator must provide information to the IRB that will allow the IRB to determine whether the subject meets the definition of a prisoner and whether it is appropriate for the subject to remain in the study and any risks associated with terminating participation in the study. If the subject's participation cannot be terminated because of health or safety reasons, study-related activities may resume or continue after the IRB has followed the procedures in this Section for review of the research. If the IRB determines that some the requirements cannot be met, but that the Principal Investigator is correct that it is in the best interests of the subject to remain in the study, study activities may resume or continue and the IRB will inform OHRP of the decision along with the justification. The IRB may consider the alternative of providing the subject with the study intervention through some other mechanism such as compassionate use or off label use, etc.

The IRB assesses whether the inclusion of prisoners meets the criteria in this section using information in Sections 3.2.3.2 (Study Purpose), 3.2.3.3 (Special Classes of Subjects), 3.2.3.5 (Inclusion and Exclusion Criteria), 3.2.3.6 (Recruitment Process), 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.9 (Study Methods), 3.2.4.2 (Risks to Subjects), and 3.2.4.3 (Benefits to Subjects and Others).

Reference:
Section **46.302**: *Purpose*
Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.
Section **46.304**: *Composition of Institutional Review Boards where prisoners are involved*
In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:
§46.304(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
§46.304(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

Section **46.305**: *Additional duties of the Institutional Review Boards where prisoners are involved*

§46.305(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

§46.305(a)(1) The research under review represents one of the categories of research permissible under §46.306(a)(2);

§46.305(a)(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

§46.305(a)(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

§46.305(a)(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

§46.305(a)(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

§46.305(b) The Board shall carry out such other duties as may be assigned by the Secretary.

§46.305(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§46.306(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

§46.306(a)(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

§46.306(a)(2) In the judgment of the Secretary the proposed research involves solely the following:

§46.306(a)(2)(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

§46.306(a)(2)(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

§46.306(a)(2)(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

§46.306(a)(2)(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects (PDF)

6.5.8. Study Personnel are Qualified

(Dated 04/28/22)

To approve non-exempt research, the IRB must determine that all study personnel satisfy the training requirements and that the Principal Investigator has the experience and resources to fulfil their responsibilities (see Section 1.3).

The IRB assesses whether the study personnel are qualified using information in Sections 3.2.1.3 (Principal Investigator), 3.2.1.7.3 (Investigators who are not at Pace to be Overseen by the Pace IRB), 3.2.1.9 (Undergraduate or Graduate Student Research), 3.2.1.10 (Study Personnel), 3.2.3.2 (Study Purpose), 3.2.3.9 (Study Methods), and 3.2.4.2 (Risks to Subjects).

6.5.9. Local Context is Considered
(Dated 04/28/22)

The review of research conducted outside the Greater New York City area includes consideration of the local context in evaluating whether the study qualifies for an exemption determination or is approved.

The IRB assesses the local context using information in Sections 3.2.1.7.3 (Investigators who are not at Pace to be Overseen by the Pace IRB) and 3.2.3.3.8 (Subjects Outside the United States).

6.6. Consent Requirements

6.6.1. Applicability of Consent Requirements
(Dated 04/28/22)

The requirements of Section 6.6.2 apply to all non-exempt research unless the IRB determines that the project qualifies for a waiver of consent according to Section 6.6.7. The requirements of Sections 6.6.3, 6.6.10, and 6.6.11 apply to all non-exempt research unless the IRB determines that the project qualifies for a waiver or alteration of consent according to Section 6.6.7. The requirements of Section 6.6.5 and 6.6.11.3 apply to all exempt and non-exempt research unless the IRB determines that the project qualifies for a waiver or alteration of consent according to Section 6.6.7. The requirements of Section 6.6.6.1 apply to all non-exempt research unless the IRB determines that the project qualifies for a waiver of documentation of consent according to Section 6.6.6.2.

The requirements of Section 6.6.4 apply whenever a project involves Protected Health Information unless the IRB determines that the project qualifies for a waiver of authorization according to Section 6.6.8.

The requirements of Section 6.6.9 apply to all clinical trials and cannot be waived.

The Pace IRB does not approve research that requests an exception from informed consent for emergency research under FDA regulations 21CFR56.24.

The IRB assesses whether the agreement or consent process meets the criteria in this section using information in Sections 3.2.3.8.1 (Agreement to Participate in Exempt Research) and 3.2.3.8.2 (Consent to Participate in Non-Exempt Research).

6.6.2. General Requirements for Consent

6.6.2.1. Circumstances of Consent Requirements
(Dated 04/28/22)

An investigator is required to seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Reference:

§46.116(a)(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

6.6.2.2. Understandable Language Requirements
(Dated 04/28/22)

The information that is given to the subject or the legally authorized representative must be in language understandable to the subject or the legally authorized representative.

Reference:

§46.116(a)(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

6.6.2.3. Organization and Content of Information Provided to Prospective Subjects Requirements
(Dated 04/28/22)

The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. If the text of the consent form, exclusive of signature pages, is three pages or less, the entire consent form is considered to serve as the concise and focused presentation.

Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

Reference:

§46.116(a)(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

§46.116(a)(5)(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

§46.116(a)(5)(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

6.6.2.4. Absence of Exculpatory Language Requirements
(Dated 04/28/22)

No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Reference:

§46.116(a)(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

6.6.3. Required and Additional Elements of Consent

6.6.3.1. Purpose, Procedures, Duration, and Number of Subjects Consent Element
(Dated 04/28/22)

Informed consent must include:

- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the subject's participation;
- A description of the procedures to be followed;
- The approximate number of subjects involved in the study; and
- Identification of any procedures that are experimental.

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(6) The approximate number of subjects involved in the study;

6.6.3.2. Risks Consent Element
(Dated 04/28/22)

Informed consent must include a description of any reasonably foreseeable risks or discomforts to the subject.

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(2) A description of any reasonably foreseeable risks or discomforts to the subject;

6.6.3.3. Benefits Consent Element

(Dated 04/28/22)

Informed consent must include a description of any benefits to the subject or to others that may reasonably be expected from the research.

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

6.6.3.4. Alternatives Consent Element

(Dated 04/28/22)

Informed consent for any research that involves treatment must include a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

6.6.3.5. Confidentiality Consent Element

(Dated 04/28/22)

Informed consent must include a statement describing the extent to which confidentiality of records identifying the subject will be maintained and obtain specific agreement from the subject if any identifiable information from the research will be made public. The statement must describe any limits to confidentiality because of the study team's obligation to report suspected child abuse or neglect or intent to harm self or others;

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6.6.3.6. Compensation for Injury Consent Element

(Dated 04/28/22)

Informed consent for research that is greater than minimal risk must include an explanation as to whether any compensation if injury occurs and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

6.6.3.7. Study Contact Information Consent Element

(Dated 04/28/22)

Informed consent must include an explanation of whom to contact:

- For answers to pertinent questions about the research and research subjects' rights; and
- In the event of a research-related injury to the subject if the research is greater than minimal risk.

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

6.6.3.8. Voluntariness of Participation Consent Element

(Dated 04/28/22)

Informed consent must include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

6.6.3.9. Use of Private Information and Biospecimens Consent Element

(Dated 04/28/22)

Informed consent for any research that involves the collection of identifiable private information or identifiable biospecimens must include a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the

information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

If the Principal Investigator believes that this statement might hinder recruitment, the Principal Investigator may describe a plan to ensure that de-identified data will never be used or shared and may instead include a statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Reference:

§46.116(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

§46.116(b)(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

§46.116(b)(9)(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

§46.116(b)(9)(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

6.6.3.10. Unknown Risks Consent Element

(Dated 04/28/22)

Informed consent for any research that is greater than minimal risk must include a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

Reference:

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

6.6.3.11. Termination of Participation Consent Element

(Dated 04/28/22)

Informed consent for any research that involves treatment or subject payment must include disclosure of anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.

Reference:

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

6.6.3.12. Costs Consent Element
(Dated 04/28/22)

Informed consent for any research that involves additional costs to subjects from participation in the research must include a description of the costs.

Reference:

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(3) Any additional costs to the subject that may result from participation in the research;

6.6.3.13. Payment Consent Element
(Dated 04/28/22)

Informed consent must include either a statement that subjects will not be paid or a description of the value, method, and timing of payments (including incentives, raffles, compensation, and reimbursements), and specify any conditions on whether the subject will receive the payments.

6.6.3.14. Orderly Termination after Withdrawal Consent Element
(Dated 04/28/22)

Informed consent for any research that involves treatment must include the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

Reference:

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

6.6.3.15. Significant New Findings Consent Element
(Dated 04/28/22)

Informed consent for any research that involves treatment must include a statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

Reference:

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

6.6.3.16. Commercial Profits Consent Element
(Dated 04/28/22)

Informed consent for any research involving biospecimens must include a statement regarding whether or not the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and, if so, whether the subject will or will not share in this commercial profit.

Reference:

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

6.6.3.17. Return of Research Results Consent Element

(Dated 04/28/22)

Informed consent for any research involving collection of clinically relevant research results must include a statement regarding whether or not clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

Reference:

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

6.6.3.18. Whole Genome Sequencing Consent Element

(Dated 04/28/22)

Informed consent for any research involving biospecimens must include a statement regarding whether or not the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Reference:

§46.116(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

§46.116(c)(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

6.6.4. Authorizations Under HIPAA

(Dated 04/28/22)

Informed consent for any research involving the use or disclosure of Protected Health Information (PHI), where authorization is not waived according to Section 6.6.8, must be written in plain language and must include:

- A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;

- The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
- The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure;
- A description of each purpose of the requested use or disclosure;
- An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of PHI for research, including for the creation and maintenance of a research database or research repository;
- A place for the signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided; and
- Statements adequate to place the individual on notice of all of the following:
    - The individual's right to revoke the authorization in writing, and any exceptions to the right to revoke and a description of how the individual may revoke the authorization;
    - The consequences to the individual of a refusal to sign the authorization and assurance to the subject that the provision of treatment will not be conditioned on signing the authorization (and clarifying that participation in the research project and any procedures that are solely research-related are conditioned on the subject signing the authorization); and
    - The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by HIPAA.

Investigators are encouraged to combine the authorization with the consent form, so that subjects will sign a single form. If a separate authorization form is used, this form does not have to be reviewed by the IRB, but it is the responsibility of the Principal Investigator to ensure that the form of authorization is acceptable to the entity providing the PHI and to provide the subject with a copy of the authorization.

The IRB assesses whether the authorization meets the criteria in this section using information in Sections 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.9 (Study Methods), 3.2.3.12 (Confidentiality of the Project Data), and 3.2.4.6 (Use of Protected Health Information).

Reference:

§164.508(b)(3)(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same or another research study.

§164.508(b)(4)(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

§164.508(b)(5)(i) Revocation of authorizations. An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that the covered entity has taken action in reliance thereon;

§164.508(b)(6) Documentation. A covered entity must document and retain any signed authorization under this section as required by § 164.530(j): for six years from the date of its creation or the date when it last was in effect, whichever is later.

§164.508(c)(1) Core elements. A valid authorization under this section must contain at least the following elements:

§164.508(c)(1)(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

§164.508(c)(1)(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

§164.508(c)(1)(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

§164.508(c)(1)(iv) A description of each purpose of the requested use or disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

§164.508(c)(1)(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

§164.508(c)(1)(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

§164.508(c)(2) Required statements. In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

§164.508(c)(2)(i)(A) The individual's right to revoke the authorization in writing, and … the exceptions to the right to revoke and a description of how the individual may revoke the authorization;

§164.508(c)(2)(ii)(B) (ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating … the consequences to the individual of a refusal to sign the authorization ….

§164.508(c)(2)(iii) iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

§164.508(c)(3) Plain language requirement. The authorization must be written in plain language.

§164.508(c)(4) Copy to the individual. If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

6.6.5. Special Consent Requirements

6.6.5.1. Agreement or Consent from Limited- and Non-Readers
(Dated 04/28/22)

If the study includes subjects or parents of child subjects who understand spoken English but have limited or no ability to read English, the IRB approves the study or issues an exempt determination if the IRB determines that the study has an adequate process, as described in the application (see Section 3.2.3.6), for ensuring that the subject's agreement (for exempt research) or their consent (for non-exempt research) is truly informed.

6.6.5.2. Agreement or Consent from Non-English-Speakers
(Dated 04/28/22)

If the study includes subjects or parents of child subjects who are not fluent in English, the IRB approves the study or issues an exempt determination if the IRB determines that the study has an adequate process, as described in the application (see Section 3.2.3.7), for ensuring that the subject's or parent's agreement (for exempt research) or their consent (for non-exempt research) is truly informed.

The agreement or consent process must use translated written materials, unless the study provides the prospect of direct benefit to subjects, in which case, the IRB may approve the "short-form" process described in Section 6.6.5.1 instead. Discussions with subjects or parents must either be conducted by a member of the study team who is fluent in the subject's or parent's language or use an interpreter. The

investigator is responsible for assuring that the individuals who will translate the written materials and who will interpret discussions are appropriately qualified.

6.6.6. Documentation of Consent Requirements

6.6.6.1. Methods of Documentation of Consent Requirements
(Dated 04/28/22)

Informed consent for non-exempt research must be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative and a written copy must be given to the person signing the informed consent form, unless the IRB determines that the project qualifies for a waiver of documentation of consent according to Section 6.6.6.2.

The informed consent form may be either of the following:

- A written informed consent form that meets the requirements of Sections 6.6.2 and 6.6.3. The person conducting the consent discussion must give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative; or
- A short-form written informed consent form in the language understood by the subject or legally-authorized representative stating that the English-language consent form has been orally presented to the subject or the subject's legally authorized representative using an interpreter, and that the key information required by Section 6.6.2.3 was presented first to the subject, before other information, if any, was provided. When this method is used, there shall be a witness to the oral presentation who is not otherwise associated with the study and who is fluent in English and in the language understood by the subject or legally-authorized representative. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the English-language consent form, and the person actually obtaining consent shall sign a copy of the English-language consent form. A copy of the English-language consent form shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

Reference:

§46.117(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

§46.117(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following:

§46.117(b)(1) A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

§46.117(b)(2) A short form written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a

witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

6.6.6.2. Waiver of Written Documentation of Consent Requirements
(Dated 04/28/22)

The IRB may waive the requirement for obtaining an informed consent form that is signed on paper or electronically for some or all subjects if the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, such as for audio- or video-recording or publicizing research information that identifies individuals.

The IRB requires the person conducting the consent discussion to provide subjects or legally authorized representatives with a written statement regarding the research when written documentation is waived unless the IRB accepts the Principal Investigator's justification not providing this information.

Note that the Pace IRB does not include two circumstances allowed in the Federal regulations for waiving documentation of consent: the waiver for when the principal risk is from a breach of confidentiality, because the IRB expects confidentiality protections must reduce this risk to no more than minimal; and the waiver for a distinct cultural community because such research must be no greater than minimal risk and which would already meet the criteria for a waiver, unless the project involved publicizing identifiable information which would require signed permission.

Reference:

§46.117(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- **§46.117(c)(1)(i)** That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- **§46.117(c)(1)(ii)** That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- **§46.117(c)(1)(iii)** If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

§46.117(c)(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

6.6.7. Waivers and Alterations of Consent Requirements
(Dated 04/28/22)

The IRB may waive or alter consent for non-exempt research that meets the following criteria, except that a waiver rather than an alteration is required if the consent process omits or alters the requirements in Section 6.6.2:

- The research involves no more than minimal risk to the subjects;

- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. This is typically required for studies involving deception, in which case the subject should be offered the opportunity to withdraw their data.

Reference:

§46.116(a)(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

§46.116(f) *General waiver or alteration of consent*—**§46.116(f)(1)** *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

§46.116(f)(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

§46.116(f)(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

§46.116(f)(3)(i) The research involves no more than minimal risk to the subjects;

§46.116(f)(3)(ii) The research could not practicably be carried out without the requested waiver or alteration;

§46.116(f)(3)(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

§46.116(f)(3)(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

§46.116(f)(3)(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

6.6.8. Waiver of HIPAA Authorization

(Dated 04/28/22)

The IRB may waive or alter the requirement for HIPAA authorization for use and disclosure of Protected Health Information for non-exempt research that meets the following criteria:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
  - An adequate plan to protect the identifiers from improper use and disclosure;
  - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of

the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart; and

- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to and use of the protected health information.

The IRB assesses whether the waiver or alteration of authorization meets the criteria in this section using information in Sections 3.2.3.8.2 (Consent to Participate in Non-Exempt Research), 3.2.3.9 (Study Methods), 3.2.3.12 (Confidentiality of the Project Data), and 3.2.3.14 (Use of Protected Health Information). The determination that the research qualifies for the waiver is included in the outcome letter and recorded in the electronic system, including a brief description of the protected health information for which use or access has been determined to be necessary by the IRB.

Reference:

§164.512(i)(1)(i)(A) Permitted uses and disclosures. A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that … The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by … an Institutional Review Board (IRB), established in accordance with … 45 CFR 46.107…

§46.164.512(i)(2) Documentation of waiver approval. For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

46.164.512(i)(2)(i) Identification and date of action. A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

§46.164.512(i)(2)(ii) Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

§46.164.512(i)(2)(ii)(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

§46.164.512(i)(2)(ii)(A)(1) An adequate plan to protect the identifiers from improper use and disclosure;

§46.164.512(i)(2)(ii)(A)(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

§46.164.512(i)(2)(ii)(A)(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

§46.164.512(i)(2)(ii)(B) The research could not practicably be conducted without the waiver or alteration; and

§46.164.512(i)(2)(ii)(C) The research could not practicably be conducted without access to and use of the protected health information.

§46.164.512(i)(2)(iii) Protected health information needed. A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;

§46.164.512(i)(2)(iv) Review and approval procedures. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

§46.164.512(i)(2)(iv)(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (… 45 CFR 46.108(b)…) or the expedited review procedures (…45 CFR 46.110…);…

§46.164.512(i)(2)(v) Required signature. The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

6.6.9. Posting of Clinical Trial Consent Forms Requirements
(Dated 04/28/22)

For clinical trials supported by a Federal department or agency that are approved on or after January 21, 2019, if the Pace Principal Investigator is the responsible party, the Principal Investigator must ensure that one IRB-approved informed consent form used to enroll subjects is posted on ClinicalTrials.gov after the trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

Reference:

§46.116(h) *Posting of clinical trial consent form.* **§46.116(h)(1)** For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

§46.116(h)(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

§46.116(h)(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

6.6.10. Reconsenting Process
(Dated 04/28/22)

If a modification to an approved study includes approval of revised consent forms, the IRB makes the determination as to whether or not the change would affect the subjects' willingness to continue in the study or otherwise should be communicated to already-consented subjects, and if so, the IRB approves the study only if the IRB determines that the reconsenting process is adequate to protect the rights and welfare of already-consented subjects.

6.6.11. Consent Requirements for Special Populations

6.6.11.1. Assent from Children and Permission from Parents Requirements
(Dated 04/28/22)

The child assent and parental permission requirements for projects that involve children as subjects are:

- Assent from children:
  - Assent must be obtained from child subjects who are capable of providing assent, based on their ages, maturity, and psychological state, unless the project qualifies for a waiver of consent according to Section 6.6.7 or unless the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research;
  - Assent is the affirmative agreement to participate in the research, not the absence of objection; and
  - The assent of the child must be documented on the consent form signed by the parent or guardian unless the IRB determines that the project qualifies for a waiver of documentation of consent according to Section 6.6.6.2; and

- Permission from parents or guardians:
  - The permission from a child subject's parent or guardian must be obtained:
    - From one parent if the research is no greater than minimal risk (Category 1) or greater than minimal risk with the prospect of direct benefit (Category 2) (see Section 6.5.7.2);
    - From both parent if the research is greater than minimal risk with no prospect of direct benefit (Categories 3 and 4) (see Section 6.5.7.2), unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; and
  - The permission must satisfy the requirements for consent in Section 6.6 unless the project qualifies for a waiver or alteration of consent according to Section 6.6.7 or if the research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children) and an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and if the substituted process is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
  - The permission must be documented according to Section 6.6.6.1 unless the IRB determines that the project qualifies for a waiver of documentation of consent according to Section 6.6.6.2.

Reference:

§46.408(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of subpart A.

§46.408(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

§46.408(c) In addition to the provisions for waiver contained in §46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities

described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

§46.408(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of subpart A.

§46.408(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

6.6.11.2. Assent from Adults with Diminished Capacity and Consent from Legally Authorized Representatives Requirements

(Dated 04/28/22)

The adult assent and legally authorized representative consent requirements for projects that involve adults with diminished capacity to consent as subjects are:

- Assent from adults:
  - The project must describe an adequate process for determining whether a potential subject is capable of providing consent or assent;
  - Assent must be obtained from subjects who are capable of providing assent;
  - Assent is the affirmative agreement to participate in the research, not the absence of objection; and
  - The assent of the subject must be documented on the consent form signed by the legally authorized representative; and
- Consent from legally authorized representatives:
  - The consent must satisfy the requirements for consent in Section 6.6 unless the project qualifies for a waiver or alteration of consent according to Section 6.6.7; and
  - The consent must be documented according to Section 6.6.6.1 unless the IRB determines that the project qualifies for a waiver of documentation of consent according to Section 6.6.6.2.

6.6.11.3. Agreement and Consent from Students, Employees, or Patients of Study Personnel Requirements

(Dated 04/28/22)

The agreement or consent process for studies including subjects who are students, employees, or patients of any study personnel must be free of coercion or undue influence and must satisfy the requirements for agreement in Section 6.3 or must satisfy the requirements for consent in Section 6.6 unless the project qualifies for a waiver or alteration of consent in Section 6.6.7. The written agreement or consent materials must disclose the additional protections (see Section 6.5.7.4) unless the project qualifies for a waiver or alteration of consent according to Section 6.6.7.

6.6.11.4. Consent from Pregnant Women Requirements

(Dated 04/28/22)

The consent process for non-exempt research including pregnant women as subjects must satisfy the requirements for consent in Section 6.6 unless the project qualifies for a waiver or alteration of consent in Section 6.6.7. If the project includes children who are pregnant, the requirements of Section 6.6.11.1 also must be satisfied. For research that is no greater than minimal risk, f the pregnancy status of the subject is not known or not relevant to the research, the consent form is not required to include any information specifically for pregnant women.

The consent of the pregnant women must be obtained for projects in categories 1, 2, or 4 and in addition the consent of the father of the fetus must be obtained for projects in category 3 (see Section 6.5.7.5) unless the father is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

The information in Sections 6.6.3.2 and 6.6.3.10 must include the reasonably foreseeable impact of the research on the fetus or neonate of the pregnant woman.

Reference:

§46.204(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

§46.204(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

§46.204(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

§46.204(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

6.6.11.5. Consent from Prisoners Requirements

(Dated 04/28/22)

The consent process for research including prisoners as subjects must satisfy the requirements for consent in Section 6.6 unless the project qualifies for a waiver or alteration of consent in Section 6.6.7, and in addition, the consent form must include:

- Information that is presented in language which is understandable to the subject population;
- Clear statements that participation in the research will have no effect on the subject's parole; and
- Provisions for follow-up examination or care, if any.

Reference:

§46.305(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

§46.305(a)(5) The information is presented in language which is understandable to the subject population;

§46.305(a)(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

§46.305(a)(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

6.7. Expiration Dates, Check-In Due Dates, and Study Closure

(Dated 04/28/22)

At the time of initial approval of studies that are greater than minimal risk, of studies that do not meet the criteria for expedited review, and of studies that involve interventions or interactions with prisoners,

the IRB establishes an expiration date for approved studies that is no later than one year after initial approval. If the IRB review specified conditions required to secure approval (see Section 6.8.4), the approval date is when the expedited reviewer determined that the conditions have been met. The IRB may also establish an expiration date for studies in other categories based on the need for closer IRB oversight, and documents the reason for establishing an expiration date in the electronic system. The approval period may be less than one year for studies that have substantial or unusual risks or that otherwise require closer IRB oversight. The expiration date included in the outcome letter provided through the electronic system.

Studies approved with expiration dates must complete continuing review prior to the expiration date. Failure to submit a renewal form in sufficient time for the IRB to complete continuing review is considered a deviation, which is considered a major deviation if any human subject research activities take place after the expiration date, and a minor deviation otherwise.

If the research has progressed to the point where it only involves data analysis or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care, a check-in date rather than a new expiration date is established. Otherwise, if the study meets the criteria for approval in Section 6.5, the IRB issues approval no earlier than 30 days prior to the previous expiration date with a new expiration date that is no later than one year after the previous expiration date.

Studies that are approved without an expiration date, studies that are given an exempt determination, class projects, and studies that rely on external IRBs are given a check-in due date that is no later than three years after the initial IRB action date.

The IRB notifies the Principal Investigator of the expiration date or the check-in due date on all outcome letters and by providing reminders at 60, 45, 30, 10, and 1 day prior to the expiration or due date. Principal Investigators are responsible for submitting a study renewal or check-in form even if they do not receive the reminders. Repeated failure to submit required renewal or check-in forms may be determined to be continuing noncompliance (see Section 6.9.7).

A study should be closed when human subjects research activities have ceased, to allow the IRB to determine the starting date for the requirement to retain study records for three years. Principal Investigators must submit a closure form and not merely fail to submit a study renewal form prior to the expiration date or to submit a check-in form prior to the check-in due date.

Reference:

§46.101(l)(3) Research subject to pre-2018 requirements. The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

§46.101(l)(3)(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

§46.101(l)(3)(iii) Research for which a determination was made that the research was exempt under §46.101(b) of the pre-2018 Requirements before January 21, 2019.

§46.101(l)(4) Transitioning research. If, on or after July 19, 2018, an institution planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

§46.101(l)(4)(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

§46.109(e) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in §46.109(f).

§46.109(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

§46.109(f)(1)(i) Research eligible for expedited review in accordance with §46.110;

§46.109(f)(1)(ii) Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7), or (8).

§46.109(f)(1)(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

§46.109(f)(1)(iii)(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

§46.109(f)(1)(iii)(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

6.8. IRB Review Actions

6.8.1. Administrative Review Outcome

(Dated 04/28/22)

When the outcome of administrative review (see Section 6.2) is that the submission qualifies for the requested category, the outcome letter provided through the electronic system includes the submission title, the name of the Principal Investigator, the funding source, the date of the action, and:

- For "Not Human Subjects Research"/"Not Engaged" determinations: a statement that the project qualifies as not human subjects research or not engaged and a reminder that the Principal Investigator must submit a modification if the project changes in a way that might affect the determination;
- For Class Projects: a statement that the faculty review process is acceptable and a reminder that the faculty member is responsible for submitting study modification forms before making any changes to the privacy and confidentiality sections or any other aspect of the review process that could alter the determination, and for submitting check-in/closure reports;
- For "118 determinations": a statement that the project qualifies as a proposal lacking definite plans for involvement of human subjects and a reminder that the Principal Investigator must submit an initial application before involving any subjects in research;
- For study modifications involving only changes to study personnel other than the Principal Investigator, Faculty Advisor, or undergraduate researcher: the study expiration or check-in date, a statement that the study personnel have been added or removed, and a reminder that the Principal Investigator is responsible for ensuring that all study personnel have current training and for submitting study modification forms and check-in/closure forms;
- Initial and revised requests to rely on an external IRB: the designation of the IRB of record, the check-in date, and a reminder that the Principal Investigator is responsible for complying with all requirements of the IRB of record, and in addition, for notifying the Pace IRB about Unanticipated Problems that occur during the study, for submitting study personnel changes for approval prior to submitting them to the IRB of record, and for submitting check-in/closure reports;
- Events that were submitted on a Reportable Event form but are determined by the chairs not to constitute reportable events: an acknowledgement of the submission and an explanation that the event did not constitute a reportable event; and
- Study closures: a statement that the IRB no longer has oversight of the project and a reminder that the Principal Investigator is responsible for submitting an application to the IRB if any human subjects research activities will occur and for complying with record-keeping requirements.

6.8.2. Exempt Determination Outcome
(Dated 04/28/22)

When the outcome of exempt review (see Section 6.3) is that the submission qualifies for one or more exempt category, the outcome letter provided through the electronic system includes the submission title; the name of the Principal Investigator; the funding source; the date of the action; and

- The check-in date (the initial check-in date for an initial submission or modification, and the new check-in date for a check-in form);
- The applicable exempt category or categories;
- Any inclusion of investigators who are not at Pace;
- Reminders that the Principal Investigator is responsible for ensuring that all study personnel have current training, for submitting study modification forms and receive a new exempt determination before making any changes to the study other than minor wording changes to the information sheet or study materials, and for submitting check-in/closure forms; and
- For modifications, a summary of the changes to the study.

6.8.3. IRB Approval Outcome
(Dated 04/28/22)

The IRB approves initial submissions, revised submissions, and study renewals through the expedited or full board process when the IRB determines that the study meets all criteria for approval in Section 6.5.

The outcome letter for approval provided through the electronic system within seven days of the IRB meeting includes the submission title; the name of the Principal Investigator; the funding source; the date of the action; and

- The expiration date or check-in date (the initial date for an initial submission, the current date for a modification, and the new date for a study renewal or check-in form);
- The risk level (greater or no greater than minimal risk);
- Any determinations regarding waivers or alterations of consent or waivers of documentation of consent;
- Any determinations regarding inclusion of children, pregnant women, or prisoners;
- Any inclusion of investigators who are not at Pace;
- For expedited review, the applicable expedited review category;
- Reminders that the Principal Investigator is responsible for ensuring that all study personnel have current training, for submitting study modification forms prior to making any changes in the study, and for submitting study renewal or check-in/closure forms; and
- For modifications, a summary of the changes to the study and any reconsenting determinations.

Reference:

§46.109(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

6.8.4. Conditions Required to Secure Approval
(Dated 04/28/22)

The IRB specifies conditions required to secure approval of an initial submission, revised submission, or study renewal when the full board is able, based upon the assumption that its specified conditions are satisfied, to make all of the determinations required for approval under Section 6.5. The IRB designates one or more expedited reviewer to determine whether the specified conditions are satisfied.

The conditions specified by the full board are recorded in the electronic system, referenced in the minutes, and communicated as required changes to the Principal Investigator through the electronic system within seven days of the IRB meeting. The Principal Investigator must submit a revised submission that responds to each condition specified by the IRB. The expedited reviewer(s) either subsequently determine that the revised submission satisfies all of the conditions, and that the submission is approved (see Section 6.8.3), or return the submission to the full board.

Specification of conditions required to secure approval is not approval of a submission, and no human subject research activities described in the submission (including changes described in study modification forms and continuation of research in renewal forms) may occur until the Principal Investigator has been notified that the conditions are satisfied and the submission is approved.

Reference:

§46.109(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

6.8.5. IRB Tabling

(Dated 04/28/22)

The IRB tables a submission when the full board is unable to make all of the determinations required for approval under Section 6.5 and concludes that the criteria for approval may be satisfied if the Principal Investigator provides additional information or revisions to the study plan.

The reasons for the tabling are recorded in the electronic system, referenced in the minutes, and communicated to the Principal Investigator through the electronic system within seven days of the IRB meeting. The Principal Investigator is notified that they may submit a revised submission that responds to the reasons for the tabling, which is considered at a subsequent full board meeting.

6.8.6. Acknowledgement

(Dated 04/28/22)

The IRB acknowledges a submission or agenda item when no IRB determinations are required, such as for an interim report on a compliance matter or for items provided for the board's information.

6.8.7. IRB Disapproval

(Dated 04/28/22)

The IRB disapproves a submission when the full board is unable to make all of the determinations required for approval under Section 6.5 and concludes that approval criteria are unlikely to be satisfied.

The reasons for the disapproval are recorded in the electronic system, referenced in the minutes, and communicated to the Principal Investigator through the electronic system within seven days of the IRB

meeting. The Principal Investigator is notified that they may respond to the disapproval in person or in writing, including by submitting a revised submission that responds to the reasons for the disapproval, which is considered at a subsequent full board meeting.

Reference:

§46.109(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

6.9. Reportable Events and Compliance Concerns

6.9.1. Unanticipated Problems

(Dated 04/28/22)

An Unanticipated Problem is an event, experience or outcome that meets all three of the following criteria:

- The event is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents (such as the IRB-approved research protocol and informed consent document); and (b) the characteristics of the subject population being studied;
- The event is related or possibly related to participation in the research (meaning that there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- The event suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Examples of Unanticipated Problems are:

- An unexpected adverse reaction to study procedures (but not an adverse reaction that was expected);
- Loss of a laptop containing unencrypted study data; and
- Accidental permanent deletion of study data.

Principal Investigators must submit a Reportable Events form (see Section 3.3.2) within seven days of becoming aware of an event that might constitute an Unanticipated Problem. Any required changes to the study that are discussed in the Reportable Events form must also be submitted as modifications.

6.9.2. Safety Monitors' Reports

(Dated 04/28/22)

If the study has a safety monitor, the Principal Investigator must submit reports from the safety monitor to the IRB:

- If the report recommends any changes to the study, within seven days of receiving the report using a Reportable Events form (see Section 3.3.2); or
- Otherwise, at the time of study renewal or closure (see Section 3.3.1).

6.9.3. Unresolved Subject Complaints

(Dated 04/28/22)

The Principal Investigator must submit a Reportable Events form (see Section 3.3.2) within seven days of becoming aware that a subject's complaint has not been resolved. Principal Investigators must keep records of resolved subject complaints and report them on the renewal/closure form or check-in/closure form.

6.9.4. Changes Immediately Necessary for Subject Safety
(Dated 04/28/22)

The Principal Investigator must submit a Reportable Events form (see Section 3.3.2) within seven days of making a change to an approved study prior to or without IRB approval because the change was immediately necessary for the safety of subjects. Any required changes to the study that are discussed in the Reportable Events form must also be submitted as modifications.

6.9.5. Deviations
(Dated 04/28/22)

A deviation is an event or action that is inconsistent with the approved project plan, IRB requirements, institutional policies, or applicable laws or regulations.

Deviations are classified as major or minor. A major deviation is a deviation that has the potential to harm one or more subject's rights or welfare, substantially damage the overall reliability of the study information, or represent serious noncompliance.

Examples of major deviations are:

- Failure to obtain informed consent;
- Enrolling more subjects than approved by the IRB or subjects who do not meet the inclusion and exclusion criteria in research that is greater than minimal risk;
- Enrolling children in a study that was given an exempt determination or approved to only include adults;
- Failure to follow the protocol in a way that has the potential to cause physical or mental harm to a subject that would be greater than the risks described in the application and consent form;
- Failure to follow the protocol in a way that has the potential to render a substantial portion of the study data unusable; and
- Continuing to carry out research procedures after the study expiration date.

Minor deviations are deviations that do not meet the criteria for major deviations. Examples of minor deviations are:

- Omission of a study procedure that is not crucial to subject's safety or to data integrity;
- Failure to submit a renewal form but not performing any human subject research activities during the lapse in approval; and
- Enrolling more subjects than approved by the IRB in research that is no greater than minimal risk.

The Principal Investigator must submit a Reportable Events form (see Section 3.3.2) within seven days of becoming aware of an event that might constitute a major deviation. Any required changes to the study that are discussed in the Reportable Events form must also be submitted as modifications.

Investigators must keep records of minor deviations and report them on the renewal/closure form or check-in/closure form.

6.9.6. Compliance Concerns
(Dated 04/28/22)

The IRB may receive information in a variety of ways that indicate potential noncompliance, including self-reporting by the Principal Investigator on Reportable Events, modification forms, study renewal/closure, or check-in/closure forms; complaints from subjects or their family members; findings in targeted or routine audits; information obtained in the course of routine IRB business; and communications from study staff or colleagues or supervisors of investigators.

The IRB follows up on unresolved subject complaints as described in Section 4.6.4.1 and on other compliance concerns as described in Section 6.9.7. If any of the information indicates that material changes may have occurred in an approved study prior to or without IRB approval, the IRB documents in the electronic system whether or not verification is needed from sources other than the investigator that no material changes have occurred since prior IRB review. If the IRB obtains information that unapproved changes may have occurred, the IRB evaluates whether it would be appropriate to carry out an audit of one or more of the Principal Investigator's other studies.

Reference

§46.108(a) In order to fulfill the requirements of this policy each IRB shall:

§46.108(a)(3) Establish and follow written procedures for:

§46.108(a)(3)(ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

6.9.7. IRB Actions in Response to Reportable Events and Compliance Concerns
(Dated 04/28/22)

The IRB administrator receiving information about a reportable event or compliance concern consults with the chairs, who within seven days of receiving the information classifies the event as one of the following:

- The event clearly is not a reportable event or compliance concern, in which case, the determination is communicated to the Principal Investigator and, if appropriate, any other individuals involved in reporting the event, and recorded in the electronic system;
- More information is needed, in which case the Principal Investigator or other individuals are asked to provide additional information so the event can be classified; or
- The event is likely to be a reportable event or compliance concern, in which case, the chairs take any immediate action necessary to protect the rights and welfare of subjects, and ensure that the event is added to the agenda for the next full board meeting, which may be a special meeting if IRB consideration is urgent.

The full board consideration of the event includes voting on the following determinations:

- Whether or not the event represents an Unanticipated Problem (see Section 6.9.1);
- Whether or not the event represents serious or continuing noncompliance:

  - Noncompliance is considered serious when the noncompliance has the potential to substantially increase the risks to participants or to substantially decrease potential benefits (including by substantially impacting the validity of the study data);
  - Noncompliance may be considered continuing when it is not corrected or when the noncompliance or a similar instance takes place after at least one notification to the responsible individuals that noncompliance has occurred; and
- Whether or not the immediate actions and planned changes described by the Principal Investigator in response to the event are sufficient to protect the rights and welfare of the subjects and the integrity of the study data;
- Whether or not to request a for-cause audit;
- Whether or not to suspend enrollment in the study (which is not considered suspension of IRB approval of the study); and
- Whether or not to suspend or terminate IRB approval of the study, and if so, the reasons for the IRB's action and the plans for notification of subjects and orderly termination or transfer of the study.

These determinations are recorded in the minutes and communicated to the Principal Investigator through the electronic system. If the determination is that an Unanticipated Problem or serious or continuing compliance has occurred, or that the IRB has suspended or terminated IRB approval, the HRPP Director reports within 30 days of the IRB determination to:

- The Principal Investigator's Department Chair and Dean;
- The Institutional Official;
- The study sponsor if the study has an external sponsor;
- The Office of Human Research Protections if the study is sponsored by a Federal agency that has adopted the Common Rule; and
- The FDA if the study is a clinical investigation involving one or more products regulated by the FDA.

Reference:
Section **46.113**: Suspension or termination of IRB approval of research.
An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

6.10. IRB Recordkeeping
(Dated 04/28/22)

The IRB records maintained by the IRB include:

- The written plan for the HRPP (see Section 4.4);
- Records in the electronic system of materials used in IRB reviews (see Section 6), including all submissions, IRB determinations, and communications with investigators (including statements of any significant new findings provided to subjects for review of study modification forms); written reviews by primary, secondary, and expedited reviewers; any rationales for approving continuing review of research that otherwise would not require continuing review; any rationales for determining that approved research appearing on an expedited review list is greater than minimal

risk; and any rationales/approvals by the Institutional Official for exceptions to policies and procedures;
- Agendas and minutes of full board meetings (see Section 6.4.2.3);
- IRB membership rosters (see Section 5.2); and
- IRB Authorization Agreements, Individual Investigator Agreements, and Collaborating Institution Investigator Agreements specifying the allocation of responsibilities for ensuring compliance between Pace University and the external IRB or investigators (see Section 4.6.7).

All records are retained for at least three years, and records relating to research that is conducted are be retained for at least three years after completion of the research. All records are accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

Reference:

§46.115(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

§46.115(a)(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

§46.115(a)(2) Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

§46.115(a)(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §46.109(f)(1).

§46.115(a)(4) Copies of all correspondence between the IRB and the investigators.

§46.115(a)(5) A list of IRB members in the same detail as described in §46.108(a)(2).

§46.115(a)(6) Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4).

§46.115(a)(7) Statements of significant new findings provided to subjects, as required by §46.116(c)(5).

§46.115(a)(8) The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.

§46.115(a)(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).

§46.115(b) The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

7 Special Approval Requirements

7.1. Research Under FDA Oversight Requirements

7.1.1. Review of Research under FDA Oversight

(Dated 04/28/22)

The requirements for the Pace IRB review of research under FDA oversight include all of the requirements in these policies with the following alterations:

- The term “clinical investigation” has the same meaning as “research”;

- The term "human subject" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient;
- The consent form for clinical investigations must note the possibility that the FDA may inspect the records;
- Waivers of informed consent and waivers of documentation of informed consent are not allowed for clinical investigations;
- All clinical investigations must be given an expiration date and undergo continuing review at least annually; and
- Reports of Unanticipated Problems, serious or continuing noncompliance, or suspension or termination of IRB approval in clinical investigations must be made to the FDA.

The Pace IRB does not review the emergency or humanitarian use of drugs or devices or emergency research.

Reference:
Comparison of FDA and HHS Human Subject Protection Regulations

7.1.2. Research Involving Food Products and Dietary Supplements
(Dated 04/28/22)

Research that involves food products, dietary supplements or other products is permitted without an IND (see Section 7.1.3) if the research evaluates the effect on the structure or any function of the body, and is not intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of disease. The IRB either consults the FDA or requires the Principal Investigator to provide written documentation from the FDA about the regulatory status of the product being used in the study.

Reference:
21 CFR 101.93

7.1.3. Research Involving Drugs Requirements
(Dated 04/28/22)

Any human subjects research involving a drug or biological agent, whether FDA approved or not, requires IRB approval. Studies that involve any drug, drug combination, or biological agent which has not been approved by the FDA for that use may require an Investigational New Drug application (IND) number from the FDA. The IND number and the name of the IND sponsor (holder of the IND) must be clearly indicated in the electronic system. When the investigator holds the IND, documentation from FDA of the IND is required, and the IRB does not accept a statement from the investigator that the FDA received the IND more than 30 days in the past.

Studies conducted under an IND will be reviewed at a full board meeting with sufficient expertise from members or consultants to evaluate the study.

Studies involving the use of approved drugs or biological agents according to approved labeling are IND exempt if they meet all of the following criteria of 21 CFR 312.2(b)(1):

(i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug; and

(ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product; and

(iii) The investigation is conducted in compliance with the applicable requirements for institutional review and informed consent.

Approved drugs or biological agents being studied for an off label use such as an unapproved indication, for use in a different population, or used in a different dose or route than approved require one of the following:

- An IND number obtained from the FDA under 21 CFR 312; or
- Documentation from the FDA stating that the drug or drug combination is IND Exempt; or
- IRB approval of the research as being IND Exempt under 21 CFR 312.2(b).

Studies involving off label use where the Principal Investigator requests that the IRB recognize an IND Exemption must meet all of the following criteria of 21 CFR 312.2(b)(1):

(i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug; and

(ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product; and

(iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product; and

(iv) The investigation is conducted in compliance with the applicable requirements for institutional review and informed consent; and

(v) The investigation is conducted in compliance with the following requirements:

a) *Promotion of the drug.* A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that the drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug; and

b) *Commercial distribution of the drug.* A sponsor or investigator shall not commercially distribute or test market the drug for the purposes for which it is under investigation.

For studies involving off label use where the Principal Investigator requests that the IRB recognize an IND Exemption, the Principal Investigator must provide to the IRB, as part of the submission in the electronic system, sufficient documentation to support items (i), (ii), (iii), and (v) above. This information may include the results of previous studies, including animal and other human studies, discussion of risks, indications for populations who might be at increased risk, etc.

The IRB will approve an exemption under 21 CFR 312.2(b)(2) if the submission is for a study that uses an in vitro diagnostic biological product that involves one or more of blood grouping serum, reagent red blood cells, or anti-human globulin; the diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure, and the diagnostic test is shipped in compliance with 21 CFR 312.160. The IRB will approve an

exemption under 21 CFR 312.2(b)(5) if the study involves the use of a placebo and otherwise does not require an IND.

If the Principal Investigator requests that the IRB approve an IND Exemption, during a full board meeting the IRB will determine whether the 21 CFR 312.2(b) criteria have been met. After review, the IRB may determine that the data presented do not substantiate an IND Exemption or the IRB may require that the Principal Investigator consult with the FDA and obtain a written determination about whether the study will require an IND.

Although the Principal Investigator makes a provisional determination that a 21 CFR 312.2(b) exemption applies, the IRB has regulatory responsibility to review and approve the conduct of a study under the 21 CFR 312.2(b) exemption. The basis for the IRB's determination will be included in the IRB meeting minutes. The Principal Investigator is informed of the finding in the outcome letter.

Reference:
21 CFR 312.160
21 CFR 312
Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND (PDF)

7.1.4. Research Involving Devices Requirements
(Dated 04/28/22)

Any human subjects research involving a device, whether FDA approved or not, requires IRB approval. Studies that involve any device which has not been approved by the FDA for that use may require an Investigational Device Exemption (IDE) from the FDA. The IDE number and the name of the IDE sponsor (holder of the IDE) must be clearly indicated in the electronic system.

Significant vs. Non-significant Risk Devices: A significant risk (SR) device means an investigational device that presents a potential for serious risk to the health, safety, or welfare of a subject and

1. Is intended as an implant; or
2. Is used in supporting or sustaining life; or
3. Is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or

ii. Otherwise presents a potential for serious risk to the health, safety or welfare of a subject.

Studies using devices which are not approved by the FDA or which are being studied for "off-label use" require one of the following:

- An IDE approved by the FDA under 21 CFR 812.30; or
- Documentation stating that the device is exempt from the requirement to have an IDE under 21 CFR 812.2(c):
  - The FDA has approved/cleared the device for the use described in the study; or
  - The device is not a transitional device, was in commercial distribution immediately before May 28, 1976, and will be used or investigated in accordance with the indications in labeling in effect at that time; or
  - The device is not a transitional device, was introduced into commercial distribution on or after May 28, 1976, and will be used or investigated in accordance with the indications in the

labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence (clearance under FDA 510(k)); or
    - The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk; or
    - The device is a custom device as defined in 21 CFR 812.3(b), and the device is being used to determine safety or effectiveness for commercial distribution; or
- An abbreviated IDE based on IRB approval under 21 CFR 812.2(b)(1); or
- An IDE exemption for an in vitro diagnostic device based on IRB approval under 21 CFR 812.2(c)(3).

If the Principal Investigator is requesting that the IRB make an abbreviated IDE determination under 21 CFR 812.2(b), then as part of the submission, it is the responsibility of the Principal Investigator to provide to the IRB sufficient documentation to support the claim that the device, as being used in a particular study, is a non-significant risk device. This information may include the results of previous studies, including animal and other human studies, discussion of risks, indications for populations who might be at increased risk, any information as to how the device has been altered, etc.

During a full board meeting the IRB will determine whether the 21 CFR 812.2(b) criteria have been met and the study is a non-significant risk device study. If the IRB determines that the 21 CFR 812.2(b) criteria have been met, the device is considered to have an "abbreviated IDE" and the Principal Investigator is considered to be the sponsor with responsibilities as described below unless some other company or individual is the regulatory sponsor.

The Principal Investigator of a study that is requesting an abbreviated IDE for use of a non-significant risk device must attest to the responsibilities of sponsor-investigators with abbreviated IDEs. The IRB provides a document with details about each of the following requirements:

1) The device is not a banned device under 21 CFR 895
2) The device will be labeled in accordance with 21 CFR 812.5 and 21 CFR 801.1
3) The study will be monitored in accordance with 21 CFR 812.46
4) The Principal Investigator will maintain records in accordance with 21 CFR 812.140(b) (4) and (5)
5) The Principal Investigator will report as required by 21 CFR 812.150(b) (1) through (3) and (5) through (10)
6) The Principal Investigator will ensure that participating investigators will obtain and document consent from each of their subjects
7) The Principal Investigator will ensure that participating investigators will maintain the records required by 21 CFR 812.140(a)(3)(i)
8) The Principal Investigator will ensure that participating investigators report as required by 21 CFR 812.150(a) (1), (2), (5), and (7)
9) The study will comply with the prohibitions in 21 CFR 812.7 against promotion and other practices

If the Principal Investigator requests that the IRB make an IDE exemption for an in vitro diagnostic device determination under 812.2(c)(3), the Principal Investigator must confirm that the device and testing comply with the exemption requirements for labeling and use.

In evaluating whether the device or sampling procedure is noninvasive, a noninvasive device or procedure (see 21 CFR 812.3(k)) is considered one that does not, by design or intention penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra or enter the ear

beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os. Blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes is also considered noninvasive.

If the IRB determines that an IDE is required, the IRB will notify the Principal Investigator and the sponsor. The Principal Investigator must then consult the FDA for a determination as to the device's regulatory status.

The IRB's determinations regarding non-significant risk device studies, abbreviated IDE requirements, and IDE exemptions are documented in the IRB minutes. The Principal Investigator is informed of the IRB's findings in the IRB outcome letter. The Principal Investigator should provide the sponsor a copy of the letter.

Reference
21 CFR 812.2
21 CFR 812.30

7.2. Research Using Records Covered by the Family Educational Rights and Privacy Act
(Dated 04/28/22)

The Family Educational Rights and Privacy Act (FERPA) establishes requirements for the protection of student education records. Research involving student education records, regardless of the source of funding, must meet FERPA requirements in addition to meeting the criteria for an exempt determination in Section 6.3 or the criteria for approval in Section 6.5. Education records are records that are directly related to a student and maintained by an educational agency or institution, or by a party acting for the agency or institution.

A researcher may obtain student education records from an educational agency or institution under one of the following four conditions:

1. The information is not personally identifiable (all identifiers have been removed, including students' names and other direct personal identifiers, such as social security number or student number; indirect identifiers, such as the name of parents or other family member; address and personal characteristics or other information that would make the students' identity easily traceable; date and place of birth and mother's maiden name; biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting; and other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.);
2. The information is limited to directory information [name; address; telephone listing; electronic mail address; photograph; date and place of birth; major field of study; grade level; enrollment status (e.g., undergraduate or graduate, full-time or part-time); dates of attendance (the overall period of time in which a student was in attendance, not specific daily records of attendance); participation in officially recognized activities and sports; weight and height of members of athletic teams; degrees, honors and awards received; and the most recent educational agency or institution attended];

3. The parent or eligible student (a student who is 18 or older or is attending a post-secondary institution) has provided signed and dated (including via electronic signature) written consent for the release of the education records that includes:
   - The records that may be disclosed;
   - The purpose of the disclosure;
   - The party or class of parties to whom the records may be disclosed; and
   - That the parent or eligible student may request a copy of the records that are disclosed; or
4. The researcher is conducting the study for or on behalf of the educational agency or institution in order to develop, validate, or administer predictive tests, administer student aid programs, or improve instruction and the educational agency or institution enters into a written agreement with the researcher's organization that:
   - Specifies the purpose, scope, and duration of the study or studies and the information to be disclosed;
   - Requires the organization to use personally identifiable information from education records only to meet the purpose or purposes of the study as stated in the written agreement;
   - Requires the organization to conduct the study in a manner that does not permit personal identification of parents and students, as defined in this part, by anyone other than representatives of the organization with legitimate interests; and
   - Requires the organization to destroy all personally identifiable information when the information is no longer needed for the purposes for which the study was conducted and specifies the time period in which the information must be destroyed.

Reference
Family Educational Rights and Privacy Act (FERPA) 34 CFR 99.

7.3. Research Subject to the Protection of Pupil Rights Amendment
(Dated 04/28/22)

When a research project involving surveys, analyses, or evaluations; involving physical examinations or screenings; or involving instructional material used in a research or experimentation program is conducted by a Principal Investigator at Pace University in an educational institution that receives funding from the Department of Education (regardless of the source of funding for the research project itself), the Principal Investigator must confirm that that educational institution is in compliance with the requirements of the Protection of Pupil Rights Amendment (20 U.S.C. section 1232h):

(a) Inspection of instructional materials by parents or guardians: All instructional materials, including teacher's manuals, films, tapes, or other supplementary material which will be used in connection with any survey, analysis, or evaluation as part of any applicable program shall be available for inspection by the parents or guardians of the children.

(b) Limits on survey, analysis, or evaluations: No student shall be required, as part of any applicable program, to submit to a survey, analysis, or evaluation that reveals information concerning—
   (1) political affiliations or beliefs of the student or the student's parent;
   (2) mental or psychological problems of the student or the student's family;
   (3) sex behavior or attitudes;
   (4) illegal, anti-social, self-incriminating, or demeaning behavior;
   (5) critical appraisals of other individuals with whom respondents have close family relationships;
   (6) legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
   (7) religious practices, affiliations, or beliefs of the student or student's parent; or

(8) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program),

without the prior consent of the student (if the student is an adult or emancipated minor), or in the case of an unemancipated minor, without the prior written consent of the parent.

(c) Development of local policies concerning student privacy, parental access to information, and administration of certain physical examinations to minors. Note that these rights transfer from the parents to a student who is 18 years old or an emancipated minor under State law.

(1) Development and adoption of local policies: Except as provided in subsections (a) and (b), a local educational agency that receives funds under any applicable program shall develop and adopt policies, in consultation with parents, regarding the following:

(A) Surveys

(i) The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student; and

(ii) any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received

(B) Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):

(i) Political affiliations or beliefs of the student or the student's parent.

(ii) Mental or psychological problems of the student or the student's family.

(iii) Sex behavior or attitudes.

(iv) Illegal, anti-social, self-incriminating, or demeaning behavior.

(v) Critical appraisals of other individuals with whom respondents have close family relationships.

(vi) Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.

(vii) Religious practices, affiliations, or beliefs of the student or the student's parent.

(viii) Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

(C) Instructional material

(i) The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student; and

(ii) any applicable procedures for granting a request by a parent for reasonable access to instructional material within a reasonable period of time after the request is received.

(D) The administration of physical examinations or screenings that the school or agency may administer to a student.

(E) The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.

(F) Personal information

(i) The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information under subparagraph (E) before the instrument is administered or distributed to a student; and

(ii) any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

(2) Parental notification

(A) Notification of policies: The policies developed by a local educational agency under paragraph (1) shall provide for reasonable notice of the adoption or continued use of such policies directly to the parents of students enrolled in schools served by that agency. At a minimum, the agency shall—

(i) provide such notice at least annually, at the beginning of the school year, and within a reasonable period of time after any substantive change in such policies; and

(ii) offer an opportunity for the parent (and for purposes of an activity described in subparagraph (C)(i), in the case of a student of an appropriate age, the student) to opt the student out of participation in an activity described in subparagraph (C).

(B) Notification of specific events: The local educational agency shall directly notify the parent of a student, at least annually at the beginning of the school year, of the specific or approximate dates during the school year when activities described in subparagraph (C) are scheduled, or expected to be scheduled.

(C) Activities requiring notification: The following activities require notification under this paragraph:

(i) Activities involving the collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose).

(ii) The administration of any survey containing one or more items described in clauses (i) through (viii) of paragraph (1)(B).

(iii) Any nonemergency, invasive physical examination (any medical examination that involves the exposure of private body parts, or any act during such examination that includes incision, insertion, or injection into the body) or screening that is—

(I) required as a condition of attendance;

(II) administered by the school and scheduled by the school in advance; and

(III) not necessary to protect the immediate health and safety of the student, or of other students.

Reference

Protection of Pupil Rights Amendment 20 U.S.C. section 1232h

7.4. Research Subject to Department of Justice Requirements

7.4.1. Research Conducted in the Federal Bureau of Prisons

(Dated 04/28/22)

Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

For research conducted within the Federal Bureau of Prisons, when submitting a research proposal, the applicant shall provide the following information:

- A summary statement, which includes:
  - Names and current affiliations of the researchers.
  - Title of the study.
  - Purpose of the study.

  - Location of the study.
  - Methods to be employed.
  - Anticipated results.
  - Duration of the study.
  - Number of participants (staff or inmates) required and amount of time required from each.
  - Indication of risk or discomfort involved as a result of participation.
- A comprehensive statement, which includes:
- o Review of related literature.
  - Detailed description of the research method.
  - Significance of anticipated results and their contribution to the advancement of knowledge.
  - Specific resources required from the Bureau of Prisons.
  - Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
  - Description of steps taken to minimize any risks.
- Description of physical or administrative procedures to be followed to:
  - Ensure the security of any individually identifiable data that are being collected for the study.
  - Destroy research records or remove individual identifiers from those records when the research has been completed.
- Description of any anticipated effects of the research study on organizational programs and operations.
- Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

Research that is funded by the Department of Justice and conducted in the Federal Bureau of Prisons must meet the following requirements in addition to the criteria for approval under Section 6.5:

- The research is reviewed by the Bureau of Prisons Research Review Board;
- The rights, health, and human dignity of individuals involved are respected;
- The project has an adequate research design and will contribute to the advancement of knowledge about corrections;
- The project does not involve medical experimentation, cosmetic research, or pharmaceutical testing;
- Risks to subjects are minimized;
- Risks to subjects within any one institution are equitable;
- The written informed consent statement to be given to each participant before commencing a research project requiring participation by staff or inmates contains the following information:
  - Identification of the Principal Investigator(s);
  - Objectives of the research project;
  - Procedures to be followed in the conduct of research;
  - Purpose of each procedure;
  - Anticipated uses of the results of the research;
  - A statement of benefits reasonably to be expected;
  - A declaration concerning discomfort and risk, including a description of anticipated discomfort and risk;
  - A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable);

  - A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates an intent to commit future criminal conduct or harm himself/herself or someone else, or, if the subject is an inmate, indicates an intent to leave the facility without authorization;
  - A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility;
  - An offer to answer questions about the research project;
  - Appropriate additional information as needed to describe adequately the nature and risks of the research;
- Written documentation is either:
  - Obtained by having the subject sign the statement of informed consent prior to initiating the research activity; or
  - Waived if the researcher has demonstrated that the only link to the subject's identity is the signed statement of informed consent or that there is significantly more risk to the subject if the statement is signed.
- No incentives are offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both no longer in Bureau of Prisons custody and participating in authorized research being conducted by Bureau employees or contractors.
- The researcher has academic preparation or experience in the area of study of the proposed research.
- The researcher assumes responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the research.
- Except as noted in the informed consent statement to the subject, the researcher will not provide research information which identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertains.
- The researcher will adhere to the applicable provisions of the Privacy Act of 1974 and regulations pursuant to this Act.
- The research design is compatible with both the operation of prison facilities and protection of human subjects.
- The researcher will observe the rules of the institution or office in which the research is conducted.
- Any researcher who is a non-employee of Bureau of Prisons has signed a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
- Except for computerized data records maintained at an official Department of Justice site, records which contain nondisclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
- If a non-employee of Bureau of Prisons will receive records in a form not individually identifiable, advance adequate written assurance that the record will be used solely as a statistical research or reporting record has been provided.
- If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the researcher may be asked to provide

ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

For research conducted within the Federal Bureau of Prisons:

- At least once a year, the researcher shall provide the ORE chief with a report on the progress of the research.
- At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.
- In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
- The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the ORE Chief, Central Office, Bureau of Prisons.

Reference
Judicial Administration – Research 28 CFR 512

7.4.2. Research Supported by the National Institute of Justice
(Dated 04/28/22)

Research funded by the National Institute of Justice must meet the following requirements in addition to the criteria for approval under Section 6.5:

- A privacy certificate approved by the National Institute of Justice specific to this research has been obtained (attain a privacy certificate); and
- The Principal Investigator has provided assurance that the Principal Investigator and all research staff understand the privacy certificate guidelines under 28 CFR 22.23; and
- The consent form confidentiality section includes:
  - The name(s) of the funding agency(ies); and
  - A statement that the subject's private, identifiable information will be kept confidential and will only be used for research and statistical purposes; and
  - A statement that the identifiable data collected is immune from legal process because the researcher submitted a Privacy Certificate; and
  - A statement that the subject will be notified if due to sample size or some unique feature of the data, the confidentiality of the subject's identity cannot be maintained; and
  - A statement that the subject will be asked to provide prior written consent before the investigator discloses any information, including information about child abuse, except that confidentiality will be broken if the participant reports information about immediate risk of harm to subjects or others. The written consent will cover what information would be disclosed, under what circumstances, and to whom, and any potential risks of the disclosure.

For research funded by the National Institute of Justice, a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

Reference
Confidentiality of Identifiable Research and Statistical Information 22CFR22

7.5. Research Subject to Department of Defense Requirements

7.5.1. General Requirements for DoD Supported Research
(Dated 04/28/22)

Research that is supported by any component of the Department of Defense (DoD) must meet all requirements of that component in addition to the criteria for approval under Section 6.5. Support by a DoD component can consist of funding through a contract, grant, or cooperative agreement; use of DoD property, facilities or assets; or inclusion of DoD personnel as subjects (through intervention or interaction or through access to identifiable information).

The Pace HRPP complies with the following laws, regulations, and guidance when conducting, reviewing, approving, overseeing, supporting, or managing DoD-supported research with human subjects:

- Title 32 Code of Federal Regulations Part 219 (32 CFR 219), Department of Defense Regulations, "Protection of Human Subjects" (Note – this is the same as 45 CFR 46, the "Common Rule")
- Title 45 Code of Federal Regulations Part 46, (45 CFR 46) Department of Health and Human Services Regulations, "Protection of Human Subjects," Subparts B, C, and D as made applicable by DoDD 3216.02
- Title 21 Code of Federal Regulations 50, 56, 312, and 812, FDA Regulations
- DoD Directive (DoDD) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research"
- Title 10 United States Code Section 980 (10 USC 980), "Limitation on Use of Humans as Experimental Subjects"
- DoDD 3210.7, "Research Integrity and Misconduct"
- DoD Instruction (DoDI) 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs"
- DoD Instruction (DoDI) 1100.12, "DoD Surveys"
- SECNAVISNT 3900.39D

The Pace IRB does not approve classified research.

Reference
DoD Directive (DoDD) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research" DoDD 3216.02 (PDF)
Title 10 United States Code Section 980, "Limitation on Use of Humans as Experimental Subjects" 10 USC 980 (PDF)
"Research Integrity and Misconduct" DoDD 3210.7 (PDF)
"Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs" DoD Instruction (DoDI) 6200.02 (PDF)
"DoD Surveys" DoD Instruction (DoDI) 1100.13 (PDF),
"HUMAN RESEARCH PROTECTION PROGRAM" SECNAVISNT 3900.39D (PDF)

7.5.2. DoD-Specific Education Requirements
(Dated 04/28/22)

All members of the Pace HRPP complete initial and continuing educational training commensurate with their duties and responsibilities in reviewing, approving, and overseeing human subjects research, as described in Sections 5.3 and 5.5.

All those involved in the conduct of human subjects research fulfill the educational training requirements described in Section 3.2.1.10. It is the responsibility of the Principal Investigator to provide the IRB with a plan to comply with any additional training requirements of the DoD component supporting the research.

7.5.3. DoD-Specific Minimal Risk and Exemption Requirements
(Dated 04/28/22)

For DoD-supported research, the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain.)

The determination that research qualifies as exempt is performed by a member of the IRB staff, not the Principal Investigators, as described in Section 6.3.

7.5.4. DoD-Specific Scientific Review
(Dated 04/28/22)

The IRB will approve research (initial submissions, modifications, and renewals) if the criteria for approval in Section 6.5 are satisfied, including that the research design is scientifically appropriate and the degree of risk to the human subjects is justifiable. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

7.5.5. Additional Protections for Military Research Subjects
(Dated 04/28/22)

Where research subjects include members of the military (both military personnel and DoD civilians), the following additional protections are required to minimize undue influence to agree to participate:

- Service members/civilians shall follow their command/organizational policies regarding the requirement to obtain permission to participate in research involving human subjects.
- Superiors are prohibited from influencing the decisions of their subordinates regarding participation as subjects in research involving human subjects and shall not be present at any human subject recruitment sessions or during the consent process.
- For research involving service members as human subjects that has been determined to be greater than minimal risk and when recruitment occurs in a group setting, the IRB shall appoint an ombudsman. The ombudsman shall not be associated in any way to the research and shall be present during the recruitment in order to monitor that the voluntary involvement or recruitment of the Service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate. For research involving service members as human subjects, that has been determined to be NO greater than minimal risk and when

recruitment occurs in a group setting, and for research involving DoD civilians, the IRB shall determine when it is appropriate to appoint an ombudsman for the purposes described in this paragraph. The decision to require the appointment of an ombudsman should be based in part on the human subject population, the consent process, and the recruitment strategy.

When research involves U.S. military personnel, officers and senior non-commissioned officers must have a separate opportunity to participate.

7.5.6. DoD-Specific Requirements for Research-Related Injury
(Dated 04/28/22)

Consent for DoD-supported research that is greater than minimal risk must include information about available compensation or medical treatments if a research-related injury occurs. For research subject to Department of the Navy (DON) requirements, every project involving greater than minimal risk shall include an arrangement for emergency treatment and necessary follow-up of any research-related injury. The IRB will determine whether research involving minimal risk also might include a similar arrangement for research-related injury.

7.5.7. DoD-Specific Requirements for Reporting
(Dated 04/28/22)

The HRPP Director will report within 30 days of the incident the following to the human research protection officer of the sponsoring DoD component when research involving a DoD-supported research project is involved:

- Notification by any federal department or agency or national organization of a for-cause investigation;
- Unanticipated problems;
- Suspensions or terminations of IRB approval;
- Serious or continuing noncompliance; and
- Change of reviewing IRB.

In addition, for research subject to Department of the Navy (DON) requirements, the HRPP Director will report the following to the DON HRPP Office:

- The initiation and results of investigations into allegations of noncompliance;
- Serious adverse events;
- Audits, investigations, or inspections of research;
- Audits, investigations, or inspections of the Pace HRPP conducted by outside entities;
- Significant communication between institutions conducting research and other federal departments and agencies regarding compliance and oversight; and
- All restrictions, suspensions, or terminations of the Pace University assurances.

7.5.8. DoD-Specific Requirements for International Research
(Dated 04/28/22)

The IRB will work with the sponsoring DoD component as necessary to resolve any conflicts with applicable international laws and requirements and to ensure that the cultural sensitivities in the setting where the research will take place are considered. For international research subject to Department of the Navy requirements with human subjects who are not U.S. citizens or DoD personnel, permission of

the host country and an ethics review by the host country, or local Naval IRB with host country representation, are required.

7.5.9. DoD-Specific Requirements for Protection of Vulnerable Populations
(Dated 04/28/22)

For DoD-supported research, the IRB will apply the protections in Section 6.5.7, with the following additions:

- For Section 6.5.7.2 (Children), all active duty service members and all reserve component members in a Federal duty status as defined by DOD are considered to be adults. When service members, students at service academies, or trainees are under 18 years of age, the IRB shall carefully consider the recruitment process and the necessity to include such members as human subjects.
- For Section 6.5.7.3 (Adults with Diminished Capacity), to be approvable, the research must intend to benefit the individual subject.
- For Section 6.5.7.5 (Pregnant Women), the phrase "biomedical knowledge" is replaced by "generalizable knowledge," and applies to research with pregnant women that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus and to research with fetuses and neonates as human subjects.
- For Section 6.5.7.6. (Prisoners):
  - Review by the expedited procedure is not permitted.
  - The permitted categories of research are those listed in Section 6.5.7.6., except that epidemiologic research is allowable when the research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease, the research presents no more than minimal risk, and the research presents no more than an inconvenience to the participant.
  - If a previously-enrolled subject becomes incarcerated:
    - The Principal Investigator will notify the IRB and include his or her opinion about whether it is in the best interests of the subject to continue to participate.
    - The IRB Chair will either agree to allow the subject to continue to participate or require that all interventions (including obtaining identifiable private information) must cease.
    - The IRB, at a full board meeting that includes input from the prisoner representative, will evaluate whether or not to allow the subject to continue in the research, considering whether the subject can meaningfully consent to continue to participate and whether the conditions of incarceration allow continued participation. The research does not have to be in a category in Section 6.5.7.6..
    - The HRPP Director will report the inclusion of the prisoner-subject to the DoD sponsor within 14 days of the board meeting.
  - Research may not involve detainees (persons captured, detained, held, or otherwise under the control of DoD personnel, but not persons being held primarily for law enforcement purposes). This prohibition does not apply to research involving an investigational drug or device when the same product would be offered to members of the US military in the same location for the same medical condition.
  - Research may not involve Prisoners of War. The IRB is aware of the definition of "prisoner of war" for the DoD component supporting the research.

7.5.10. DoD-Specific Requirements for Waiver of Consent
(Dated 04/28/22)

For research involving a human being as an experimental subject, meaning an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction, the IRB will not waive or alter the requirement for informed consent under Section 6.6.7 unless the Secretary of Defense (or the Secretary of the Navy for research subject to Department of the Navy requirements) has granted a waiver of consent for the research project. If the research involves a human being that does not meet the above definition of an experimental subject, the IRB is allowed to waive or alter the requirement for consent under Section 6.6.7.

The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:

- The research is necessary to advance the development of a medical product for the Military Services;
- The research might directly benefit the individual experimental subject; and
- The research is conducted in compliance with all other applicable laws and regulations.

7.5.11. DoD-Specific Requirements for Subject Payment
(Dated 04/28/22)

Subjects who are on-duty federal personnel and subjects who are off-duty federal personnel in federally-funded research may be compensated up to $50 for each blood draw for scientific or research purposes connected with the care of any person entitled to treatment at Government expense, but not be otherwise compensated for general research participation.

These limitations on payments do not apply to subjects who are off-duty federal personnel or non-federal personnel, except that payment to off-duty federal personnel for general research participation must not be directly from a Federal source (payment from a Federal contractor or other non-Federal source is permissible).

7.5.12. DoD-Specific Requirements for Survey Research
(Dated 04/28/22)

The Principal Investigator for any DoD-supported research involving surveys is responsible for arranging for the review of the survey by the appropriate DoD component. This review is in addition to review by the IRB.

7.5.13. DoD-Specific Requirements for DoD Oversight
(Dated 04/28/22)

The HRPP will support the oversight by the sponsoring DoD component, including communicating to the sponsoring DoD component about:

- information needed to assure that the approval of the initial submission is in compliance with all applicable requirements; and
- IRB-approved substantive changes, including a notification that the Principal Investigator is informed that the changes cannot be implemented prior to acceptance by the sponsoring DoD component; and
- the results of the continuing review

- other information reported as required by Section 7.5.7

The HRPP will also cooperate with any requests by the sponsoring DoD component for a site visit.

7.5.14. DoD-Specific Requirements for Conflict of Interest
(Dated 04/28/22)

For research subject to Department of the Navy requirements, investigators, key research personnel, IRB members, and other personnel must disclose all conflicts of interest, including any financial interests for themselves, spouses, and dependent children. No person shall be involved in any review or approval of a protocol when there may be a conflict of interest.

7.5.15. DoD-Specific Requirements for Multi-Site Research
(Dated 04/28/22)

For DoD-supported multi-site research, there will be a formal agreement between organizations that specifies the roles and responsibilities of each party.

8 Definitions
(Dated 04/28/22)

Adults are defined as persons who have attained the legal age for consent to treatments or procedures involved in the research.

Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research.

Clinical investigation is defined as any experiment that involves a test article and one or more human subjects and that is either subject to requirements for prior submission to the FDA, or the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Clinical trial is defined as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Deviations are events or actions that are inconsistent with the approved project plan, IRB requirements, institutional policies, or applicable laws or regulations. **Major deviations** are deviations that have the potential to harm one or more subject's rights or welfare, substantially damage the overall reliability of the study information, or represent serious noncompliance. **Minor deviations** are deviations that do not qualify as major deviations.

Exempt research is research that meets the definition of human subjects research but is not required to meet all of the criteria for approval because all of the research activities qualify for one or more specified exempt categories (see Section 3.2.2)

Expedited review is review by one or more experienced reviewers rather than at a full board meeting (see Section 6.4.1).

Human subject is defined as a living individual:

1. About whom a researcher obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. About whom a researcher obtains, uses, studies, analyzes, or generates identifiable private information about the individual or identifiable biospecimens; or
3. Who is or becomes a subject (either a healthy human or a patient) in a clinical investigation, either as a recipient of the test article or as a control, or upon whose specimens, either identified or not identified, an investigational device is used.

Intervention includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information). An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by Pace HRPP policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Protected Health Information (PHI) is individually identifiable health information that is held or transmitted by a covered entity (a health plan, health care clearinghouse, or health care provider) or its business associate, in any form or media, whether electronic, paper or oral. Health information is information, including demographic data, that relates to the individual’s past, present or future physical

or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual. Health care encompasses care, services, or supplies related to the health of an individual, including (1) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual that affects the structure or function of the body; and (2) sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription. Individually identifiable means that the information identifies the individual or there is a reasonable basis to believe it can be used to identify the individual. Health information identifiers are any of the following of an individual or of relatives, employers, or household members of the individual:

1. Names;
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
    - The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
    - The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000;
3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Telephone numbers;
5. Fax numbers;
6. Email addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) addresses;
16. Biometric identifiers, including finger and voice prints;
17. Full-face photographs and any comparable images; or
18. Any other unique identifying number, characteristic, or code, including any code that includes or is derived from any of the identifiers on this list.

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. For purposes of this definition, a systematic investigation is the use of a predetermined method to gain information by collecting and analyzing data. Generalizable knowledge is conclusions that can be applied to circumstances outside of the specific instances of the investigation.

Serious Adverse Event (SAE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or

disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research that that:

(1) results in death;
(2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Serious or Continuing Noncompliance is noncompliance that has the potential to substantially increase the risks to participants or to substantially decrease potential benefits (serious) or that is not corrected or takes place after at least one notification to the responsible individuals that the same or similar noncompliance has occurred.

Significant Financial Interest (as defined by the Pace University policy (PDF) on research conflicts of interest) means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration (salary or other payment for services) received from the entity in the 12 months preceding the disclosure and the value of any equity interest (including any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of disclosure, when aggregated, exceeds $5,000.
- With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration (salary or other payment for services) received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (including any stock, stock option, or other ownership interest) in the entity.
- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available).

Notwithstanding the foregoing, the term Significant Financial Interest does not include:

- Salary, royalties or other remuneration from the University if the Investigator is then employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001 (a), an

academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

- Income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001 (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- Travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents (such as the IRB-approved research protocol and informed consent document); and (b) the characteristics of the subject population being studied; AND
- is related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Reference:

§402(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

§46.102(b) *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

§46.102(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

§46.102(e)(1)(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

§46.102(e)(1)(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

§46.102(e)(2) *Intervention* includes both physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

§46.102(e)(3) *Interaction* includes communication or interpersonal contact between investigator and subject.

§46.102(e)(4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

§46.102(e)(5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

§46.102(e)(6) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

§46.102(e)(7) Federal departments or agencies implementing this policy shall:

§46.102(e)(7)(i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of "identifiable private information," as defined in paragraph (e)(5) of this section, and "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This

reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

§46.102(e)(7)(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate "identifiable private information," as defined in paragraph (e)(5) of this section, or an "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the FEDERAL REGISTER after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

§46.102(i) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

§46.102(j) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

§46.102(l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

§46.102(l)(1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

§46.102(l)(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

§46.102(l)(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

§46.102(l)(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

§46.303(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

§46.303(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide

alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

21CFR50.3(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

45CFR160.103 Definitions

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information:

(i) In education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) In records described at 20 U.S.C. 1232g(a)(4)(B)(iv);

(iii) In employment records held by a covered entity in its role as employer; and

(iv) Regarding a person who has been deceased for more than 50 years.

45CFR164.514(b) A covered entity may determine that health information is not individually identifiable health information only if:

(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;
(J) Account numbers;
(K) Certificate/license numbers;
(L) Vehicle identifiers and serial numbers, including license plate numbers;
(M) Device identifiers and serial numbers;
(N) Web Universal Resource Locators (URLs);
(O) Internet Protocol (IP) address numbers;
(P) Biometric identifiers, including finger and voice prints;
(Q) Full face photographic images and any comparable images; and
(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information

9 Abbreviations and Acronyms

(Dated 04/28/22)

AAHRPP – Association for the Accreditation of Human Research Protection Programs
CITI – Collaborative Institutional Training Initiative
DoD – Department of Defense
FWA – Federalwide Assurance
HIPAA – Health Insurance Portability and Accountability Act of 1996
HRPP – Human Research Protection Program
IND – Investigational New Drug
IDE – Investigational Device Exemption
IRB – Institutional Review Board
NIH – U.S. National Institutes of Health
NSF – U.S. National Science Foundation
OHRP – U.S. Office of Human Research Protections
PHI – Protected Health Information