PACE UNIVERSITY
Office of Research

Frequently Asked Questions: Impact of Coronavirus (COVID-19) on Human Subjects Research

Please review these 'Frequently Asked Questions' and then if you have further questions, we encourage you to reach out to us by emailing paceirb@pace.edu.

1. **What does the 'pause' mean for research studies involving in-person, face-to-face interactions with research participants?**
   In March of 2020, Pace University issued a policy to pause most human subjects research activities involving in-person, face-to-face interactions.

   As the majority of the University's campuses are now at 'Alert Level Green,' ***this 'pause' is being lifted with an effective date of May 1, 2022*****.**

2. **Why is there a delay in lifting the 'pause' until May 1st if Pace has moved to 'Alert Level Green'?**
   When investigators carry out research involving human subjects, they are treating 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.

   Between now and May 1, 2022, the resumption of research involving interactions with human subjects must consider the risk to the study participants and the participants' community, as well as that to research staff and to the Pace community.

3. **Are any exceptions to the 'pause' allowed before May 1st for human subjects research?**
   Yes, however most research activities involving in-person, face-to-face interactions are paused until May 1, 2022 -- ***unless*** canceling or postponing the interaction would increase the risk to the research participant's safety or well-being by:

   A. Depriving them of a potential direct benefit and the interaction is required to deliver that potential direct benefit (such as an investigational drug, device or surgical intervention that is not available via standard of care); or by

   B. Preventing the collection of safety data (such as a follow-up visit that the Principal Investigator deems is necessary to detect or monitor potential adverse events).

   Examples of studies that would meet the criteria listed above at 3. A. or 3. B include:

- Studies in which research participants are receiving interventions or clinical care that is related to their research participation (e.g., test results coming back that might have clinical implications for their care);
- Some studies evaluating treatments for chronic conditions, such as Type 2 Diabetes Mellitus; depression, etc.;
- Studies assessing the safety or efficacy of an intervention which, if stopped, would significantly and adversely impact its potential scientific or societal benefit. For example, a research assessment involving blood collection that is only valuable if collected at a very specific time. This must be measured against the risk to participants, including the risk of exposure of COVID-19.

4. **How do I re-start in-person, face-to-face interactions for an ongoing study?**
   Before resuming in-person, face-to-face interactions, submit a request to the IRB by logging into IRBNet, completing a 'Study Revision Form,' and then uploading it as a subsequent package.

   The IRB will then review the submitted request, make a determination, and send an outcome letter to the Principal Investigator.

5. **What is the effect of the 'pause' on studies with a 'pending review' status?**
   The IRB will continue to review and approve submissions. For studies that are approvable, but do not meet the exception (noted above at 3.A) allowing in-person interactions, the IRB will approve the study and explicitly note that it may not start until the 'pause' in research activities is lifted on May 1, 2022.

6. **What does this 'pause' mean for research activities that do not involve in-person, face-to-face interactions?**
   There are no restrictions at this time for ongoing research involving on-line in-person, face-to-face visits or interactions and/or remote (e.g., telephone) data collection. Research-related activities, including pre-screening, recruitment and enrollment activities that do not involve in-person, face-to-face interactions with research participants may continue.

7. **Does Pace have a HIPAA-compliant platform available that will facilitate on-line visits and allow encrypted streaming video sessions?**
   Yes. In May of 2020, the Office of Research completed the beta-testing phase for PaceHealth (https://pacehealth.zoom.us). This is a new type of Zoom account that provides a HIPAA-compliant platform for expanding your research capabilities and telehealth offerings while utilizing the resources and hardware that you already have.

   PaceHealth is available to our Pace community of researchers and clinicians. If you would like more information or are interested in migrating your current Zoom account to PaceHealth, please send an e-mail to paceirb@pace.edu.

8. **How and when does the IRB need to be notified of study changes?**
   The appropriate process for making changes to research studies in *force majeure* circumstances, such the current COVID-19 pandemic, follows below:

   For non-exempt research studies:

   - The regulations (at §46.108(a)(3(iii)) require "*prompt reporting to the IRB of proposed changes in a research activity…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." [emphasis added];***
     - For a change made to the research in order to eliminate apparent immediate hazards to research participants, submit a report promptly via the electronic submission system, IRBNet, within five (5) business days of the event – or, if this is not possible, as soon as it is feasible to report it;
     - The written report to the IRB of the changes made to eliminate any apparent immediate hazards to a research participant should include:
       - The exact change made;
       - The reasons for the change and its potential impact on the study's data interpretation;
       - Whether the Principal Investigator is proposing an amendment to the protocol, informed consent form, or other research-related document as a result of the change.

   - For all other changes to human subjects research, an amendment or modification would be submitted, reviewed and approved by the IRB prior to its implementation.

   For exempt research studies: Modifications or changes to research granted an Exempt Determination by the IRB do not need to be reported to the IRB *unless* they alter the Exempt Determination status.

9. **How do research participants need to be notified of visit cancellations and changes if the University's 'Alert Level' changes from Green to Yellow, Orange or Red?**
   When a study visit needs to be changed to a phone call or some other type of on-line or remote encounter, or a study visit is cancelled or re-scheduled, the research participant should be told the reasons for these cancellations and changes. They should also be told that they will be contacted again when the visit can be rescheduled. These types of messages to research participants do not require IRB approval.

10. **What types of additional disruptions to research may occur in the future?**
    The Principal Investigators of studies that are not 'paused' should anticipate staffing shortages due to research and ancillary support staff being unable to work in-person for any number of reasons -- care of children due to school closings, travel restrictions, illness, etc. Additional disruptions that

could involve being unable to obtain access to protective equipment or other research-related materials should also be anticipated.

11. **What is the most important consideration in responding to research disruptions?**
    The most important consideration for Principal Investigators of ongoing research would be to identify any research procedures that would be essential for the safety and well-being of their research participants. A Principal Investigator can then develop a contingency plan which would allow them to continue to deliver these procedures and to monitor for safety in the face of research disruptions.

12. **What else should I plan for?**
    Principal Investigators need to identify procedures that are not essential to participants' safety, but that are important to the integrity of the study data, and then determine whether alternative methods, such as remote contact via phone, e-mail, videoconference, telemedicine, or electronic survey, would mitigate its loss.

    This 'FAQ' is a living document. It will be updated based on changes in our understanding of the virus, and governmental and public health guidance.