

Memorandum

To: All Faculty and Staff subscribed to the IRB listserv
From: David Comalli, PH.D.
IRB Assistant Director
Subject: Update on Human Subjects IRB Guidance Related to COVID-19
Date: July 13, 2020

Dear Colleagues,

The Temple University IRB is in receipt of questions regarding restart of in-person research. Please see below for our immediate answers and suggestions.

Summation of recent information regarding the return to research:

As per the [March 16, 2020 message to the research community](#) from the Office of the Vice President for Research, the majority of in-person research was halted due to the COVID-19 pandemic. The most recent announcement from the Office of the Vice President: [May 23, 2020 – Update on COVID-19 Return to Research Planning Process and Guidelines](#) described the Phased approach to returning to non-remote research at the university. We are currently in Phase 3 and are approaching Phase 4 (targeted for August 31, 2020). The additional requirements for human subjects research are listed below.

1. Any study occurring outside a hospital setting that requires removal of Personal Protective Equipment (PPE) from the participant must receive approval from the IRB (via an RNI) and research dean prior to initiating. See below for additional information.
2. Participants need to be screened prior to participating. These screening questions are not designed to contribute to the data collected for the research. They should not be kept as data for analysis, unless approved by the IRB. The screening should involve (at a minimum):
 - a. Temperature screening (no participation for temperatures greater than 99.8 degrees Fahrenheit).
 - b. No one in the participant's household has been diagnosed with COVID-19 within the last 14 days.
 - c. No participant can have been in close contact (within 6 feet for 10+ minutes) with anyone (including outside the home) with a confirmed COVID-19 diagnosis within the past 14 days.
 - d. The participant must not report having lost the sense of taste or smell within the past 14 days.
3. Participants and research staff must apply hand sanitizer or wash hands immediately prior to entering the designated research space.

4. Investigators should encourage participants to contact the research team if they are diagnosed with COVID-19 within 2 weeks of visiting the designated research space. However, researchers are not to initiate this contact.
5. If social distancing cannot be maintained in accordance with EHRS guidelines, participants and investigators are required to use augmented personal protection equipment, including face shields. More information about requirements can be directed to Greg Lupinski, Director of EHRS (greg.lupinski@temple.edu). Note, these EHRS guidelines are for research outside of the hospital; for research occurring in the hospital, hospital policy should be followed.
6. Social distancing requirements for waiting areas must be specified (if applicable).

When to contact/submit to the IRB regarding removal of PPE for research:

Of the 6 requirements listed above, requirements 2-6 are set forth by the university, and therefore do not require notice to the IRB of their implementation.

The IRB is particularly interested in instances that requires the removal of PPE for the purposes of research. In some cases, the removal of PPE increases the risk of a research study by potentially exposing participants to the virus that causes COVID-19. As such, the IRB has a requirement to evaluate the risks in relation to the benefits of the study and ensure that participants are properly informed of the risks of participation (45 CFR §46.111).

If a research participant is removing PPE for a standard of care procedure (one that would occur, at that time, regardless of the research), then the IRB does not need to be informed. This is because it does not increase the risk associated with the research. Similarly, the hospital has policies in place that prohibit removal of PPE in situations that would increase the risk of spreading COVID-19.

For clinical trials designed to determine the efficacy or safety of a COVID-19 treatment or vaccine: Temple IRB or the IRB of record have already considered the risks associated with the study, and therefore requirement 1 does not apply.

For studies that already have IRB approval: IRB approval is required before any research procedures that require the removal of PPE are restarted.

- This approval is granted after IRB review of a submitted Reportable New Information (RNI) submission.
- The selected category should be category 14.
- Include proof of approval from the PI's research dean or equivalent.
- Include a consent addendum designed to communicate to the subject what PPE will be removed, why, and that this will increase the risk of exposure to COVID-19.

For studies that have not received IRB approval: Of course, IRB approval is always required before any research procedures are started. If the research requires the removal of PPE, the points requested above should be considered and reflected in the Initial submission or a response submission to Modifications Required to Secure Approval. As the study is not yet approved, submission of an RNI is unnecessary.

When to contact/submit to the IRB regarding changes in methods due to COVID-19

Despite approval for a return to certain in-person research, efforts should be made to limit in-person interactions with subjects. Alternative procedures (e.g. remote data collection) to continue or begin a given study should be implemented if they do not impact study validity.

Regarding New Subject Enrollment:

The decision to enroll new subjects, to continue clinical research visits, or to replace in-person visits with telemedicine visits, should be made by the applicable clinician/investigator. For research that is sponsored, the study sponsor or FDA may provide additional guidance regarding required visits/procedures. It is recommended that they be consulted before making any changes. Additionally, consultation with your Research Associate Dean or administrative equivalent or designee is advised.

If your in-person research activities are permitted based on Temple's Phased approach, below are instructions for communicating changes in research to the IRB:

Note: *The below recommendation #3 has changed since the last memo from the IRB.*

All changes must be approved by the IRB prior to their implementation.

1. If your study has active participants (i.e., already enrolled in a longitudinal study), and changes need to be made to protect subjects from the immediate hazard posed by COVID-19, submit an RNI (Category 13) submission that includes: what the changes are; why they are being implemented; why this does not negatively impact the risk/benefit ratio of the study; and when these temporary changes will be ended (this should be event-based, not date-based).
If the change substantially impacts the study design, consult with the IRB (IRB@temple.edu) to determine if a Modification submission is more appropriate.
2. If your study is approved, but does not have active participants, and you wish to change your methods and/or methodology to include remote data collection for the period that COVID-19 is of concern, submit a RNI that contains: what the changes are; why they are being implemented; why this does not negatively impact the risk/benefit ratio of the study; when these temporary changes will be ended (this should be event-based, not date-based), **and an addendum to the consent form.** This addendum should be in lay language, be labeled as a COVID-19 Consent Addendum (or other equivalent language); contain what is being changed to the study methods; and explain why the changes are being made.
If the change substantially impacts the study design, consult with the IRB (IRB@temple.edu) to determine if a Modification submission is more appropriate.
3. If your study is not yet approved, the study documents will need to be changed to include how the study will be handled while COVID-19 is of concern. This will likely require language in the protocol and consent that address these concerns, but allow for the COVID-19-specific changes to be removed once the concerns have dissipated.

Please note that the IRB will be continuing to review submissions; however, the IRB will continue to do so remotely for the time being. Due to this modified review process and the influx of changes and questions related to how COVID-19 is being handled, the Temple IRB appreciates your patience given the likely increase in turnaround times for

some reviews. Additionally, the IRB will be prioritizing COVID-19 research. Please note that instructions from the Vice President for Research and Institutional Official, as well as federal, commonwealth or local authorities may issue a guidance or instruction with respect to in-person research that supersedes the IRB-issued approval letter you receive.

Thank you for your continued cooperation and patience during this time of extraordinary events and fluidity.

Current updates from Temple's Novel Coronavirus (COVID-19) website can be found [here](#) and continued research operations updates can be found [here](#).
