

Memorandum

To: All Faculty and Staff subscribed to the IRB listserv
From: Michael Henderson
Associate Vice President for Research Regulatory Compliance and
Strategic Initiatives
Subject: Update on Human Subjects IRB Guidance Related to COVID-19
Date: March 26, 2020

Dear Colleagues,

The Temple University IRB is in receipt of questions regarding continuity of research in response to COVID-19. Please see below for our immediate answers.

Please note that the IRB will be continuing to review submissions; however, the IRB will be doing 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, funded research, and research that does not involve "in-person" data collections. This practice aims to reduce the administrative burden associated with the increased number of submissions to the IRB. 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.

Follow-up to OVPR 3/16/2020 Memo:

Please be advised that the [March 16, 2020 message to the research community](#) from the Office of the Vice President for Research identified the following categories of potential essential research that may continue with approval of the Associate Dean for Research or equivalent administrator as an exception to the requirement to the ramp-down of on-campus research until further notice:

- Research related to COVID-19 will be considered essential research and may be continued.
- Activities to maintain research capabilities, including maintaining animals, unique reagents, and essential equipment, materials, and core facilities can be supported through designating essential personnel involved in providing continuity for those activities. Please discuss these needs with the Associate Dean for Research or equivalent administrator in your school or college.

- Clinical, social, educational or behavioral research that is of significant value and benefit to the study participants may continue with the approval of your Associate Dean for Research or equivalent administrator.

As a result, in-person research that is not essential should be replaced with remote visits or postponed until such time that the COVID-19 outbreak is under control **For Clinical Research involving in-person visits:**

Temple University Health System, including Temple University Hospital, Temple Faculty Physicians, and Temple Physicians Inc. have implemented procedures to limit in-person appointments. New patient visits will not be scheduled for the next two weeks, unless there is an urgent need. Patients who, in the opinion of their clinician, do not need to come in for an in-person appointment will be seen via tele-medicine methods. Those that are required to be seen in-person will undergo a double screening procedure, at the entry point of the applicable clinic.

For non-clinical research studies, every effort should be made to limit in-person interactions with subjects. Alternative procedures to continue a given study (e.g. remote data collection) should be implemented. The IRB is recommending the same precautions for research visits.

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 research is deemed Essential, below are instructions for communicating changes in research to the IRB:

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 a Reportable New Information (RNI) 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).
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.
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 mean an additional consent form for the remote data collections and

consent for the standard study—once in-person research no longer impacted by COVID-19.

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](#).
