Franklin University Human Research Protection Program (HRPP) and Institutional Review Board (IRB)
COVID-19 Response

March 20, 2020: Effective immediately, all face-to-face human subjects research activities must cease until further notice. This includes activities involving Franklin University researchers (faculty, student, staff) at any site. Principal Investigators are expected to pass this notification on to all human subjects research personnel immediately.

The Franklin University HRPP is communicating this additional precautionary measure in line with CDC recommendations to practice social distancing and Franklin’s requirement to pause face-to-face instruction. A decision chart is included at the end of this message to assist researchers.

Guidance Regarding New Studies

- Franklin’s IRB will continue to review new study submissions through the Cayuse system and communicate with researchers in the same manner. At this time, the Franklin IRB plans to continue to hold virtual full board meetings on the scheduled dates.
- Any new study that proposes to use face-to-face means of data collection will not be issued an approval letter until further notice.

Guidance Regarding Currently Approved Studies

- Researchers must contact affected study participants to cancel any upcoming face-to-face visits.
- If a study cannot be conducted virtually, cease research activities. Examples of virtual means are included below.
- A switch to virtual means does not require an amendment to the IRB at this time.
- Modifications to add face-to-face (in-person) interactions will not be approved or exempted until further notice.

The IRB will allow the following changes without an amendment to the IRB protocol:

- Substitution of telephone, web conferencing, and secure electronic communication to conduct data collection procedures normally done in-person. These methods may be added when possible and practical for mitigating research risks related to COVID-19 to subjects or others. If there are questions about any changes to participant risk, please contact the IRB Office at irb@franklin.edu.

If researchers choose to implement use of these practices, the revised documents must become part of the study file in the Principal Investigator’s records. To allow the IRB to have a record of the implementation of the procedure above, please send an e-mail message noting the study record title(s), PI name, and reference number(s) to the IRB (irb@franklin.edu) within 10 business days of the implementation. The office will include this information in your study file in the Cayuse system.

Please direct questions to the IRB Office at irb@franklin.edu. We thank the research community in advance for their cooperation.
Is the human subjects research already approved/exempted by the Franklin IRB?

No, it is a new study
Submit for review in Cayuse IRB. No face-to-face human subjects research will be approved.

Yes, it is an existing study

Does the existing study currently involve any face-to-face activity with research participants?

Yes
Can the face-to-face activity be switched to virtual means (e.g., Zoom, Skype, telephone)?

Yes
Switch to secure virtual means. An amendment to the IRB protocol is not required at this time.

No
Continue human subjects research activities that do not involve face-to-face interactions.

STOP! Cease all face-to-face human subjects research activity!

No, all activities are virtual or by telephone

Can the face-to-face activity be switched to virtual means (e.g., Zoom, Skype, telephone)?

No

Franklin IRB Decision Chart for Human Subjects Research During COVID-19 Restrictions

Contact Franklin’s IRB at irb@franklin.edu

We would like to thank Purdue University for sharing their IRB COVID-19 Response that we have adapted for Franklin University.