

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

POLICY UPDATE

August 16, 2021: Effective immediately, face-to-face human subjects research activities in the United States may resume on a limited basis. Any international face-to-face human subjects research activities will be evaluated on a case-by-case basis. This notice applies to activities involving Franklin University researchers (faculty, student, and staff) with new and existing IRB protocols.

On March 20, 2020, in response to the World Health Organization's (WHO) declaration of COVID-19 as a global pandemic, Franklin University issued a moratorium on all face-to-face human subjects research activities until further notice. The decision was based on the Centers for Disease Control (CDC) and the Ohio Department of Health (ODH) guidance, Ohio Governor Mike DeWine's order to stay at home, and Franklin University's campus closure.

COVID-19 vaccines are now widely available to any adult in the United States who wishes to receive one. As such, and in keeping with guidance provided by the CDC and ODH, the Franklin University IRB is lifting the ban on face-to-face research on a limited basis. Please review details provided below for more information and contact the IRB Office with any questions. We encourage all investigators to discuss their face-to-face projects with the IRB prior to finalizing research designs and proposals.

We recognize the continued volatility of COVID-19 and strongly encourage all researchers to design face-to-face research projects only when virtual data collection methods seriously threaten the feasibility or integrity of a study. If in-person interactions are necessary, please implement COVID-19 protocols when possible:

- Practice safe distancing, when necessary and appropriate.
- Wear masks or face coverings indoors, when necessary and appropriate.
- Wash or sanitize your hands often and continue respiratory etiquette.
- Get tested and stay home if you have been in contact with persons who have COVID-19 or if you show symptoms of COVID-19.

The IRB recommends that research teams refer to the following table when designing studies that include face-to-face data collection procedures:

INDIVIDUAL VACCINATION STATUS <i>This includes the study participant and research team member who will have in-person interactions</i>	MASK OR FACE COVERING	SOCIAL DISTANCING (6 FEET OR MORE)
VACCINATED	Not required (but consider current guidance) <i>Except in settings where masks or face coverings are required for all people regardless of vaccination status (e.g., healthcare, childcare, K-12, select businesses)</i>	Not required (but consider current guidance)
NOT VACCINATED/ UNKNOWN	Recommended <ul style="list-style-type: none"> • <i>indoors.</i> • <i>outdoors when within a 6-foot distance from others.</i> 	Recommended <i>Individuals are encouraged to distance if in a crowded setting or in areas that are not well-ventilated.</i>

GUIDANCE REGARDING NEW STUDIES

Any investigator proposing face-to-face data collection for a new study must include in their submission to the IRB a justification for the need to conduct in-person research and a discussion of safety protocols that will be used to protect the research team and study participants. You should also consider any industry, local, state, regional, and/or federal recommendations in place and include that information with your submission, as applicable. You will be prompted to provide this information in Cayuse IRB.

The following list provides some examples of projects that the IRB will consider approving for face-to-face data collection:

- An EdD candidate may design a study that assesses the effectiveness of a new teaching method in the classroom. This project cannot be conducted in a virtual format.
- A DHA candidate will interview colleagues who work in the same hospital.
- A DBA candidate is conducting an observation of store managers and their interactions with employees.

**** NEW STUDIES ****

ADDITIONAL IRB REQUIREMENTS FOR STUDIES PROPOSING FACE-TO-FACE RESEARCH ACTIVITIES

1. A justification for the need to conduct in-person research
2. A discussion of safety protocols that will be used to protect the research team and study participants
3. Any industry, local, state, regional, and/or federal recommendations in place, as applicable

GUIDANCE REGARDING CURRENTLY APPROVED STUDIES

If your study was designed and approved for virtual data collection and you plan to switch to or add face-to-face data collection methods, you must submit a modification to the IRB for review and approval. You cannot implement changes to your protocol without prior IRB approval. Doctoral candidates should discuss any changes with their dissertation chair and work with their committee to design modifications that minimize risk to investigators and participants.

Any research team submitting a modification to switch to or add face-to-face data collection must include in their submission to the IRB a justification for the need to conduct in-person research and a discussion of safety protocols that will be used to protect the research team and study participants. You should also consider any industry, local, state, regional, and/or federal recommendations in place and provide that information with your submission, as applicable. You will be prompted to include this information in Cayuse IRB. Moreover, investigators should consider and be prepared to discuss the following:

- Where will you collect data? Provide complete details about the location(s) where you will collect data.
- What are the in-person procedures?
- Does face-to-face data collection affect participation requirements or eligibility criteria?
- Can subjects participate virtually if they do not wish to have face-to-face interactions?
- Does in-person data collection change the initial risk assessment?
- How does this change modify participant access and recruitment procedures?
- What new considerations should be made for privacy and confidentiality?
- Does your data security plan require modifications?
- Do your informed consent or recruitment materials need updated?
- Do you need to compensate subjects who travel to participate in your research?

**** MODIFICATIONS TO CURRENTLY APPROVED STUDIES ****

ADDITIONAL IRB REQUIREMENTS FOR STUDIES PROPOSING FACE-TO-FACE RESEARCH ACTIVITIES

1. A justification for the need to conduct in-person research
2. A discussion of safety protocols that will be used to protect the research team and study participants
3. Any industry, local, state, regional, and/or federal recommendations in place, as applicable
4. A complete, thorough discussion of the questions listed in the guidance above. All amended documents must be included with the modification submission.

GUIDANCE REGARDING INTERNATIONAL RESEARCH

Many international borders remain closed to visitors. Franklin University recognizes the rapidly evolving nature of COVID-19 and the fluidity of policies and mandates as situations change; however, the IRB expects that many borders will not reopen to non-essential travelers for at least several months, as countries face new COVID-19 outbreaks and lack vaccine supplies to inoculate their populace.

Investigators who live in the United States and wish to conduct face-to-face international research should carefully explore and consider current situations in the countries of interest and determine if travel is permitted and research is possible at this time. Investigators should not plan for international travel unless the research cannot be conducted virtually.

Franklin University has several international students who live in foreign countries and do not need to travel to conduct their research. In these cases, students must adhere to the current guidelines in the countries and local governments where they are living. For example, if masking is required of everyone, regardless of vaccination status and indoor/outdoor setting, face-to-face research must be conducted with all parties wearing masks.

If you live outside of the United States or intend to travel internationally to conduct research, please contact the IRB early to ensure adequate preparations are in place. The IRB will determine whether the international research is appropriate considering current situations, whatever they may be. Again, we encourage investigators to conduct virtual research and avoid travel for face-to-face research when possible; please carefully consider the necessity of travel at this time.

Any investigator submitting a protocol for international face-to-face data collection must include in their submission to the IRB a justification for the need to conduct in-person research and a discussion of safety protocols that will be used to protect the research team and study

participants. Investigators planning international research should also submit with their application materials a summary of the current COVID-19 situation in the country or countries where data collection will take place, identifying restrictions or any protocols that must be followed to conduct research. You will be prompted to include this information in Cayuse IRB.

** <u>INTERNATIONAL RESEARCH</u> **
ADDITIONAL IRB REQUIREMENTS FOR STUDIES PROPOSING FACE-TO-FACE RESEARCH ACTIVITIES
1. A justification for the need to conduct in-person research
2. A discussion of safety protocols that will be used to protect the research team and study participants
3. A summary of the current COVID-19 situation in the country or countries where you propose traveling to collect data, identifying restrictions or any protocols that must be followed to conduct research

Please direct questions to the IRB Office at irb@franklin.edu. We thank the research community in advance for their cooperation.