UToledo IRB Guidelines: Resuming Non-Essential Face-to-Face Human Subjects Research Activities

August 27, 2020

The IRB's primary focus is to protect research participants in research during the COVID-19 pandemic. UToledo has additional guidelines and policies aimed at protecting the general population (e.g., restriction of visitors to campus, lab workers, students). Please see the following website for more information: https://www.utoledo.edu/coronavirus.

Face-to-face interactions with human subjects on non-essential research studies must at least adhere to the following UToledo IRB guidelines below to resume. The two scenarios not yet addressed in prior communications and guidance are: (*i.*) **non-essential** research taking place in a typical medical setting where there is additional researcher/participant scheduled visit(s) required to participate in the study and (*ii.*) non-essential studies that do not take place in a typical medical setting.

This guidance applies only to research taking place in UToledo facilities. If research is taking place at an **external** location, researchers must submit the FYI Xform to the IRB for review of proposed face-to-face interactions with human subjects. This includes research taking place at ProMedica.

GENERAL CONSIDERATIONS

- The IRB expects researchers to continue to use **remote technologies** to conduct research whenever possible.
- Participants must be asked the COVID screening questions and informed of personal protective equipment (PPE) requirements, such as wearing a mask, BEFORE they travel to campus. This must be documented.
- All in-person research MUST incorporate appropriate risk reduction strategies (distancing, disinfection, PPE, symptom screening) described below.
- When face-to-face interactions occur for research purposes, groups cannot exceed 10 people.
- Participants are NOT allowed to bring others with them to the study appointment. This includes a prohibition from minors accompanying research participants. If your participant requires an exception, please submit the FYI Xform for IRB review.

SCREENING REQUIREMENTS BEFORE STUDY VISITS

Participants:

- Being seen in a typical medical setting:
  - Appropriate PPE per UTMC procedures are required.
  - If the researcher anticipates that the group of subjects targeted for enrollment cannot wear protective face coverings/mask, then this must be stated in the study protocol (or submit the

FYI Xform, See Appendix 1).

- Not being seen in a typical medical setting:
  - Before the participant arrives at the study location, have the participant complete a **screening questionnaire** and/or other materials to evaluate their individual risk. See Appendix 2.
  - Check the participants' **temperature** with a non-contact infrared thermometer as they enter the building or area where the research will be conducted.
  - If the subject's temperature is higher than 100 F (37.8 C), and this could be explained by an external factor (for example, walking a long-distance), wait five minutes and retake.
  - If you (study team) are conducting the screening survey and temperature readings, the results should be saved in the research record. This documentation MUST be per subject and properly secured.
  - See PPE and distancing requirements in the table below.

Researchers:

- Researchers must complete *and document* a symptom screen for themselves, including temperature, on each day that in-person contact is planned with one or more research participants. The symptom screen only needs to be completed once per day but must be completed prior to in-person contact with a research participant. See the sample screening questions in Appendix 2.

RESEARCH ACTIVITIES AND REQUIRED SAFETY MEASURES

Research Activity	Guidelines
Verbal interaction with no physical contact • Interviews • Focus groups (10 or fewer people) • Behavioral tasks and observation • Education	• Covid-19 pre-screening questionnaire and temperature recordings for the researcher and participant prior to the visit • Schedule participants to avoid overlap and waiting time • Disinfect research area between participants • Researchers and participants wear masks at all times. • Minor participants must be mature enough to follow safety guidelines. • Adhere to the most protective guidelines re: density, face covering, and physical distancing • If offering snacks, they should be individually wrapped servings. • If the participants can not wear masks due to the nature of the research, then you must submit the FYI Xform for IRB approval before initiating activities. PPE options can include a plastic room divider OR eye protection, surgical mask, and face shield for the researchers.
Physical contact with participant or other procedures that require proximity	• In addition to following the guidelines above, researchers must use eye protection and surgical masks. • If the participants can not wear masks due to the nature of the research and saliva, throat and/or nasal specimens are being collected, then you must submit the FYI Xform for IRB approval before initiating activities. Required PPE must include gloves, protective gown, eye protection, surgical masks and face shields for the researchers.

MODIFICATIONS TO IRB PROTOCOLS:

- SOPs for personal protective equipment (PPE) and COVID-19 screening questionnaires do NOT require approval by the IRB, as long as the screening data are not used for research.
- However, if existing IRB-approved procedures must be revised (e.g. to adjust the number of study visits, or to make some data collection remote), please submit an amendment to the IRB for review.
- Exception Requests: If a research study cannot adhere to the applicable safety guidelines for scientific or other reasons, the PI must request an exception by submitting the FYI Xform to the IRB (Appendix 1).
  - Not being able to procure PPE is not an acceptable reason to grant an exception.
  - For **external IRB** studies, you must still submit an FYI Xform to the IRB to ask for an exception for your study. Please contact the HRPP staff for any questions.

FREQUENTLY ASKED QUESTIONS:

Q. What if a participant refuses to wear a mask or comply with other safety precautions?

A. The study visit should either be rescheduled for a time when the participant agrees to comply or terminated if the participant states that they will not comply (in which case the subject should also be withdrawn from the study).

Q. What if I cannot follow all the guidelines while conducting my in-person research activities?

A. Submit the FYI Xform to the IRB to request an exception. Do not initiate research activities before the request has been reviewed and approved. See Appendix 1.

Q. What if I'm not sure how to apply the above guidelines to my unique research activities?

A. Please email or call your Human Research Protection Program staff member. A modification may be required to document the specific precautions needed for your study.
https://www.utoledo.edu/research/rsp/irb/StaffIRB.html

Q. What if my participant tested negative for COVID yesterday?

A. You MUST still follow the procedures in this document, including the COVID screening questionnaire.

APPENDIX 1: What to include in your FYI Xform when requesting an exception

1. Which specific safety precautions are impossible to perform while maintaining scientific integrity?
2. Why is it not possible to comply with those precautions?
3. What steps will be taken to mitigate risk in lieu of those precautions?

APPENDIX 2: Example COVID-19 SCREENING QUESTIONNAIRE/SCRIPT

Screening questions can include those listed in the sample COVID-19 Screening Tool below, which can be modified to fit the participant population and the location of in-person interactions.

Any YES answer should be considered sufficient reason to postpone in-person visits if it cannot be explained by an underlying medical condition.

Note: Using these screening questions does NOT require an IRB modification if the data will not be used for research.

COVID-19 Screening Tool	
Participant Name or ID Number: _____	
Assess Exposure:	
Y N	1. Had contact in the last 14 days with someone with confirmed COVID-19?
Y N	2. Lives in a facility that has COVID-19 confirmed cases in the last 14 days?
Y N	3. Tested positive for COVID-19 in the last 14 day?
Assess for Symptoms:	
In the last 14 days have you had any TWO of the following:	
Y N	1. Fever (100 F [37.8 C])?
Y N	2. Chills or rigors?
Y N	3. Muscle aches and pain?
Y N	4. Headache?
Y N	5. Sore throat?
Y N	6. New loss of taste or smell?
In the last 14 days have you had ONE of the following:	
Y N	7. Cough?
Y N	8. Shortness of breath?
Y N	9. Difficulty breathing?
Y N	10. Vomiting or diarrhea?
If yes to the above questions:	
Reschedule the visit for at least 3 weeks later.	
If no to the above questions:	
Notify them of the required PPE per the guidance document.	