

April 28, 2020

Re: Human Subject Research and COVID-19 Situation

Dear Colleagues:

The continued health and safety of our University of Toledo and regional communities continues to be top priority during the COVID-19 pandemic. This is an update on my prior letter, dated March 17, 2020, regarding temporary restrictions on human subject research. At this time, we cannot ease restrictions on face-to-face interactions with human research participants; therefore, the current restrictions will continue through May 30, 2020. We will continue to reevaluate this timeframe.

As a reminder, **essential studies** are defined as essential to the immediate health and well-being of the participant (meaning that the interactions provide immediate and necessary therapeutic benefit for a participant's medical condition, or the interactions cannot be safely discontinued). This also includes research on COVID-19. The Principal Investigator of essential studies should have already notified the IRB, via the FYI xform in IRB Manager, if they are continuing face-to-face interactions. If you have not done this AND are conducting face-to-face interactions, you must notify the IRB immediately.

For **non-essential studies**, please note the following:

1. Decisions to ramp up research with human subjects will be based on direct benefit to participants versus increased risk due to COVID-19.
2. When face-to-face interactions are determined to be permissible by the Institution, and then (re)approved by the IRB, researchers must have appropriate personal protective equipment such as masks. Please prepare accordingly. Note that specific procedures for requesting IRB approval of face-to-face interactions will be provided at a later time.
3. The majority of Social, Behavioral & Educational (SBE) research with human subjects has little to no direct benefit to participants. ***We are encouraging all PIs, to whom this applies, to submit an amendment request to the IRB to modify data collection methods from face-to-face to remote methods at this time.*** All requests to modify a study must be submitted via the regular amendment process in IRB Manager.
 - a. The Human Research Protection Program (HRPP) is providing training and assistance with amendment requests via regularly scheduled small group WebEx trainings. You can find more information on the HRPP webpage: <https://www.utoledo.edu/research/rsp/irb/IRB-Training.html>
 - b. For more information on remote data collection tools, refer to the HRPP guidance document page: <https://www.utoledo.edu/research/rsp/irb/guidance.html>



**Office of Research
and Sponsored Programs**

- c. You can find helpful documents and videos on using IRB Manager at:
<https://www.utoledo.edu/research/rsp/irbmanager.html>

I encourage you to visit the [COVID-19 website \(Research Guidance\)](#). This webpage continues to be updated regularly and will be the source of ongoing guidance in this evolving situation. Also, you can contact the [Human Research Protection Program \(HRPP\)](#) for guidance.

Sincerely,

Frank J. Calzonetti
Vice President for Research