HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

COVID-19 - IRB-HSBS Guidance on the Research Pause (Updated 4/30/2020)

President Schlissel and Vice President for Research Cunningham have issued a pause in all research with human participants that involves face-to-face interaction under IRB-HSBS oversight, with some exceptions. This policy, which will remain in effect until further notice, is being implemented to protect research participants, researchers, and the larger U-M and other impacted communities from risk of infection from COVID-19.

Immediate pause for all research involving face-to-face interactions with participants

All face-to-face research interactions or interventions with participants, including exempt and not regulated projects must pause, with limited exceptions. This includes studies conducted outside the University, at both domestic and international sites.

Examples of research activities that must be paused:

- Studies that require participants to enter a U-M laboratory space
- Face-to-face interviews/focus groups
- Home visits with participants, or face-to-face meetings at other locations, even if data are collected via computer, recording, or observation of public behavior

Exceptions to the pause:

- Projects actively studying influenza and COVID-19 and working directly with the CDC or NIH
- Some international research projects may continue depending on the COVID-19 virus situation in the country where the research is taking place:
    - Where the interaction/intervention with participants is conducted by international partners or U-M researchers are conducting the research in-country with international partners, investigators should consult with the local IRB/ethics board regarding the continuation of the research. If the local IRB determines that it is safe for the work to continue, then the project may proceed. ***PIs must provide documentation of this determination to the IRB.*** Modified procedures to eliminate or minimize the need for person-to-person contact are recommended and the investigator must continue to monitor the changing COVID-19 situation.
    - Where U-M researchers are already in-country and are actively conducting face-to-face subject interactions independently, the research must be paused and procedures modified to eliminate direct interaction, unless the investigator can demonstrate that the research is being conducted in an area of low risk for COVID-19. Investigators must monitor the changing COVID-19 situation.

Research activities that may continue during the pause

- Studies or research procedures that do not involve any direct interaction with participants
    - Web surveys
    - Telephone or audio-video conferencing
    - Mail surveys
    - Self-collection of biospecimens (e.g., a cheek swab or spit kit) mailed to the lab
- Data analysis, either secondary use projects or data analysis activities on other projects

Strategies for continuing research during the pause

- Amend your study to convert face-to-face data collection or other procedure to a remote method described above. For projects that collect sensitive, identifiable data, consider whether the revised procedures introduce any additional risk to participants
- Continue research procedures in an IRB-approved study that do not involve face-to-face interaction during the pause

IRB REVIEW of COVID-19-RELATED SUBMISSIONS

The IRB staff will prioritize submissions related to COVID-19. Please help us by labeling your submissions following the instructions below.

Amendments to eliminate face-to-face subject interactions in response to the pause

Full board or expedited review studies

- Include **COVID** in the amendment title to alert the IRB staff to the need for priority review.
- In the Amendment cover sheet, describe the need for the change in terms of minimizing risk under the COVID-19 emergency.
- Edit the IRB application to reflect the proposed changes, including any changes to the informed consent process or documents. Consider whether the proposed change may impact potential risks to the participants, particularly for projects that collect sensitive and identifiable information, such as the introduction of additional informational risks from video recording an interview, or privacy risks of interviewing a teenager at home rather than at a clinic. Remember that you must use data collection and management tools that are approved by the institution and appropriate for the level of sensitivity of your data, such as U-M Qualtrics, BlueJeans, and M+Box. See the ITS Safe Computing Sensitive Data Guide.

Exempt or not regulated studies

- **Amendments are not required** to change the mode of data collection from face-to-face to remote on exempt studies
- **Exception** - exempt studies that collect identifiable and sensitive data (exempt with limited IRB review) may require an amendment if the new mode of data collection impacts data security or subject privacy which must be reviewed by the IRB. These studies may be covered by an NIH Certificate of Confidentiality.

Amendments to add the study of COVID-19 to the protocol

Before creating an amendment to an existing study, evaluate whether the new work would more appropriately be submitted as a new application. If new survey questions are being added to an on-going study or adding an additional COVID-19-specific biospecimen collection to a flu study for projects qualifying for the CDC/NIH COVID-19 exception described above, an amendment would appropriate.

Full board or expedited review studies

- Include **COVID** in the amendment title to alert the IRB staff to the need for priority review.

- In the Amendment cover sheet, describe the proposed addition to the study. Be sure to include a statement of relevance to the COVID-19 emergency.
- Edit the IRB application to reflect the proposed changes, including any changes to the informed consent process or documents. Consider whether the proposed change may impact potential risks to the participants. Remember that you must use data collection and management tools that are approved by the institution and appropriate for the level of sensitivity of your data, such as U-M Qualtrics, BlueJeans, and M+Box. See the ITS Safe Computing Sensitive Data Guide.

Exempt studies

- **Amendments are not required** to change the mode of data collection from face-to-face to remote on exempt studies
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New Studies of COVID-19 or the COVID-19 Crisis

- Include **COVID** in the title
- Remember, new research proposals cannot be approved if they include face-to-face interactions, unless they involve working directly with the CDC/NIH as described in the exception above or if the intent is that only non-face-to-face study procedures will be implemented before the pause is lifted.

During this time, IRB review of other submissions not related to the COVID-19 emergency may be delayed.

Information about IRB Operations

The IRB-HSBS is open and fully operational with most staff members working remotely. IRB meetings, when necessary, will be held by videoconference. As always, your IRB staff liaison is available to answer questions via email (best) or phone. In the short term, IRB-on-the-Road and educational sessions have been cancelled but we will resume when it is safe to do so. You can also contact us at irbhsbs@umich.edu or 734-936-0933. These are monitored throughout the day and on the weekend.

For the most up to date information during this time, please check the IRB-HSBS website, the UMOR COVID-19: Research Operations site, and the University's Coronavirus site.