CENTRAL MICHIGAN UNIVERSITY
COLLEGE OF MEDICINE
OFFICE OF RESEARCH AND GRADUATE STUDIES

Instructions for Resuming In-person Human Subject Research at CMU

In compliance with the State of Michigan regulations for COVID-19 and to keep our CMU community safe from spread of the virus, CMU's office of Research and Grants issued these policies:

- *Investigators are encouraged to exclude from participation any person at high risk for complications of COVID-19 according to the CDC guidelines: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/*
- *Investigators may request approval of protocols that include persons at higher risk only if this is justified by clear direct benefits to participants.*
- Studies that require in-person contact between investigators and participants are subject to review and approval by the VP of Health Affairs (Dr. Kikano) and the VP of Research and Innovation (Dr. Weindorf) on a case by case basis. In the case of approval, separate documentation on resuming the HSR requiring in-person contact will be provided.
- All surveys and interviews (including focus groups) should continue to be conducted virtually, unless the investigator can justify why in-person interaction is needed. Such investigators should include this rationale in their IRB application (for new protocols), or in an Amendment request (for IRB-approved studies); they must also submit a HUMAN SUBJECTS RESEARCH COVID-19 checklist.
- All in-person interactions shall follow CDC and CMU policies for proper PPE and social distancing.

For investigators who paused their IRB-approved research:

First, be sure to consider whether changes are needed to the description of the study procedures in the application, and/or to the recruitment and consent document(s). If so, submit an amendment request for review and approval by the IRB.

For example, if currently-approved inclusion criterion is adults age 18 and older, an amendment is needed to exclude high risk individuals from participation. This change to exclusion criteria would require modification of the study protocol, the consent form, and any recruitment materials. Another example: If some of the study procedures will now take place on-line (e.g., reviewing consent form and obtaining participants' consent), an amendment is needed to make this change.

Submission of an Amendment request is NOT required if the only changes to the study are requirement that participants and investigators wear face-coverings, and electronic distribution of the "Participating in Human Subjects Research" flyer to participants prior to the first meeting.

Once IRB approval is obtained for the amendment request, before resuming in-person research activities, you must submit and receive approval of a HUMAN SUBJECTS RESEARCH COVID-19 checklist from Drs. Weindorf and Kikano.

For investigators who intend to initiate new research:

Submit an application and supporting materials to the IRB for review and approval. Do not discuss plans for mitigation of risks associated with COVID-19.

Once IRB approval is obtained, a HUMAN SUBJECTS RESEARCH COVID-19 checklist must be reviewed and approved by Drs. Weindorf and Kikano prior to initiation of in-person research activities.

Human Subjects Research COVID-19 Checklist for submission to Drs. Weindorf and Kikano

All investigators who intend to engage in in-person human subjects research must submit and receive approval of a COVID-19 plan. The checklist can be found at https://www.cmich.edu/office_provost/ORGS/ComplianceandResearchIntegrity/InstitutionalReviewBoard/Pages/Restarting-Human-Subjects-Research-.aspx . Please contact Susan Klumpp, klump1se@cmich.edu to schedule an appointment to discuss with Drs. Weidorf and Kikano.

Investigators are encouraged to monitor the ORC/IRB website to stay informed on changes to this guidance.