CSU IRB Guidance for Research Involving Human Participants

Frequently Asked Questions: COVID-19 and Human Research

Is the CSU IRB operating as usual?

The CSU IRB is fully functional and operating at our standard capacity. We expect this to continue even if the University suspends operations for contagion control purposes. https://www.csuohio.edu/coronavirus-update/coronavirus-update All CSU IRB staff are able to work from home, should it become necessary. All email addresses will continue to be monitored with the same or greater frequency as typically provided.

The current differences to standard operations:

• Priority of IRB review is being given to all inquiries, requests, new protocols, and modifications related to COVID-19.

• Priority of IRB review is also being given to changes in research that are directly related to COVID-19 to enhance participant safety. To ensure timely processing of new or modification submissions related to Covid19, we ask that the researcher identify them by including **Covid19** in the CAYUSE application title.

• All IRB phone messages/emails will continue to be monitored with the same or greater frequency as typically provided.

Are there suggestions for in-person monitoring of participant safety?

Some studies require in-person study visits in order to conduct safety monitoring of the participants. Researchers should plan for alternatives to in-person monitoring visits, if possible. For example, interviews could be conducted by phone or email. Visits to participants' homes might be an alternative location for examinations or specimen collection. Or, perhaps the schedule of monitoring could be safely modified or delayed. These modifications to safety monitoring procedures should be approved in advance by the IRB, except when necessary to eliminate apparent hazards to a participant and there is not sufficient time to obtain IRB approval. Consult with your IRB team (216) 687-3624 or email John J. Jeziorowski, CSU IRB chair @ j.jeziorowski@csuohio.edu if you have questions. If you do need to change an approved monitoring procedure to eliminate immediate possible danger, please report it to the IRB within five days, following the CAYUSE modification request reporting format. Refer to the FDA (21 CFR 56.108 (a)(4)) and OHRP (45 CFR 46.108 (3)(iii)) for information regarding implementing changes in

research prior to IRB approval in order to eliminate apparent hazards to participants. Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19, or to continue to provide medically necessary study care to participants who have been placed in isolation or quarantine because of suspected or known exposures. The CSU IRB encourages investigators to take such steps as necessary to eliminate apparent immediate additional risks to participants and investigators alike.

Can I still interact with my research participants?

The IRB understands that, per clinical care guidelines, you may need to ask research participants to complete a short screening for exposure to the novel coronavirus or symptoms of illness before they are scheduled for any study-related visits and in-person interactions. Research participants with possible exposure or symptoms of illness should be re-scheduled for a date in the future. The CSU IRB recognizes that the novel coronavirus situation and public health authority recommendations are rapidly evolving. This type of specific screening procedure does not require IRB approval. In addition, University researchers should abide by all recommendations/regulations currently being enacted by Cleveland State University. Finally, the CSU IRB recommends the development of possible alternatives to in-person study visits that are important for participant safety and monitoring.

Do I need to register modifications with ClinicalTrials.gov?

Some studies registered at the federal site ClinicalTrials.gov are modifying their research procedures to include testing for assessment of COVID-19 symptoms. The ClinicalTrials.gov information for the study should be updated to include these new procedures, if they are done for research purposes. If they are being added as public health surveillance activities in coordination with public health authorities, the registration information does not need to be modified. The federal requirement about modifications is that any research-related changes that are communicated to the participants (past, ongoing, future) must be added to the study's ClinicalTrials.gov registration with 30 days after IRB approval of the modification.

I need to modify my study procedures to occur remotely. How do I do that?

Many studies are modifying their procedures to replace in-person study visits with "remote" options for questionnaires, surveys, check-ins, screening, and consenting. Remember that these changes must be approved in advance by the IRB as a CAYUSE Modification to the study, unless they are necessary to eliminate immediate apparent hazards to participants. If you have any questions about whether a remote option is possible or approvable (especially for consent), contact the CSU IRB at (216) 687-3624 or j.jeziorowski@csuohio.edu as your CSU IRB is prioritizing these modifications.

I'd like to temporarily suspend my study enrollment. What do I do?

No action is required on your part should you choose to voluntarily halt or suspend or delay participant enrollment in a previously approved study. Please keep in mind that if you are relying on an external IRB for oversight, you will also need to contact that reviewing IRB for submission instructions.

Is study visit cancellation recommended?

The CSU IRB does not have specific recommendations or requirements about postponing or cancelling study visits, but we believe it would be prudent for investigators to follow recommendations of Cleveland State University and the State of Ohio https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/Novel-Coronavirus/Resources-for-the-Public/ to minimize risks to participants. You may choose to hold study visits remotely if feasible for the study. You may also consider changing the schedule of study visits. You will need to submit a modification to your protocol before implementing any changes (unless they are necessary to eliminate apparent hazards to the participant and there is not time to obtain IRB approval) if the study is not exempt and the protocol specifies in person visits. You do not need to modify your protocol in order to hold visits remotely or to change the schedule if the study is exempt or if the IRB protocol does not specifically describe whether the visit would be in person or remote, or give specifics about visit schedule. Other organizations, as an institutional policy, have implemented screening procedures for COVID-19 exposure or symptoms prior to in person clinical or study visits. You should follow any requirements or recommendations of the facility with which you are collaborating. If you implement screening procedures in order to identify participants whose visits should be postponed or delayed, you do not need to modify your protocol to include the screening procedure because it is not a research procedure. You might also consider whether you will need other flexibility in order to continue implementing the research. For example, many low risk procedures qualify for a waiver of written documentation (signed) consent. If the protocol describes written consent, you may wish to modify it to remove that requirement to allow for easier remote implementation. Exempt research can implement these changes without submitting a modification. You do not need to modify the risks section of consent materials. Potential exposure to COVID-19 should not be considered a risk of study procedures. Additional information pertaining to COVID-19 can be found at: https://www.cdc.gov/coronavirus/2019-ncov/faq.html

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Cleveland State University thanks the University of Minnesota, the University of Washington, the University of California, Davis and the Veterans Health Administration for their public sharing of materials about COVID-19 preparation plans related to human research.