

IRBMED Guidance: Initiating New COVID-19 Related Research

Initiating New Human Participant Research Related to COVID-19

All human research must comply with University of Michigan Office of Research (UMOR) [procedures for Activation](#) of new studies, including studies that related to the study of COVID-19.

Human research projects related to COVID-19 may include interaction/intervention with COVID-19 positive patients or may be limited to secondary use of existing data or samples. If you are planning to initiate or amend a research protocol to study COVID-19, consider the following topics as applicable:

- **Informed Consent Process and/or Document** - If your proposal includes interaction or intervention with COVID-19 patients, describe a thorough informed consent process in your IRB application as the standard methods of informed consent may not be feasible. The FDA guidance ([Conduct of Clinical Trials Clinical Trials during COVID-19](#)) discusses various options for obtaining informed consent from COVID-19 patients who are in isolation. In addition, IRBMED has also published [guidance for electronic informed consent procedures](#). The study team should review these guidance materials while preparing the plans for informed consent.
- Contact the **U-M COVID-19 Biorepository** if you need to obtain existing samples (blood, etc.) of COVID-19 patients.
- If your proposal includes **developing or validating COVID-19 tests** (diagnostic or antibody), review FDA guidance and the corresponding FAQs (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2>). In your IRB application, state specifically whether or not the results of these investigational tests will be shared with the participants.

For any specific questions or guidance about IRB procedures, contact IRBMED at your earliest opportunity (irbmed@umich.edu) When submitting an email with COVID-19 related questions, note this in the subject line of your email so that we can prioritize these requests appropriately. If your question is about the UMOR Activation process, contact them at human-research-activation@umich.edu.

Emergency Use of a Test Article

Procedures to request emergency use of an investigational test article will remain the same. For additional information, refer to <https://az.research.umich.edu/medschool/guidance/emergency-use-test-article-life-threatening-circumstances>