

IRB Guidance on Resuming In-Person Research Activities & Consent Modification

As of August 5, 2021, approval from the Office of the Provost is no longer required for research that involves in-person conduct. COVID language for in-person research is still required; specific language provided below.

1. The PI should amend their informed consent document consistent with the language outlined below. If needed, the initial application or modification request will be returned to the PI to verify this part of the process. For research projects that are covered by reliance agreements, where Ferris IRB is relying on an external IRB, the PI should contact the IRB of Record to confirm any changes to COVID procedures and informed consent and comply with those changes. Where those procedures are silent on COVID-related procedures and consent, an inquiry should be made by the PI as to the feasibility of implementing the following Ferris consent changes.
2. For face-to-face research that is currently paused, any other research protocol changes that are occurring since the pause (COVID-related, changes to data collection dates, or others), should be included in the modification request.

Research Informed Consent Changes: The PI should add the following to their informed consent document with adaptations where specified in red. If there are additional changes to the informed consent language that are protocol-specific, those will be considered as part of the modification request. All study participants included in any component of the face-to-face research protocol going forward from the approval to resume must be consented, or re-consented (if previously consented and their participation is ongoing) with the updated informed consent document.

Consent Document Language Change:

“This research study has some parts that must be conducted in-person. As a result, your participation can put you at risk of contracting the SARS-CoV-2 virus, which can result in the COVID-19 disease (commonly known as "COVID-19"). COVID-19 can be spread person-to-person. COVID-19 can range from mild to severe and may result in the need to quarantine or self-isolate if you show symptoms or test positive. It may also result in loss of work time. In its most severe form, it can cause death. Symptoms to watch for include fever, cough, headaches, fatigue, muscle or body aches, loss of taste or smell, sore throat, nausea or diarrhea. Costs associated with COVID-19 related illness are not covered or reimbursed as part of this study [INVESTIGATORS: The paragraph above may be edited if there are specific aspects of risk that you feel should be expressed or are unique to this study].”

Due to the ongoing COVID-19 pandemic, Ferris State University is using many health and safety precautions and restrictions as recommended by our facility, public health, and governmental authorities. These are intended to reduce the risk of spread of the virus. Measures being taken to reduce the risk of spread of the COVID-19 virus as part of this study include: [INVESTIGATORS: please insert an overview of the prevention measures being used in this study. Summarize the strategies outlined in the form you submitted to request re-opening of face-to-face research.]

By participating in this study, you agree to participate in the protection strategies being used to reduce COVID-19 risks. Failure to comply with these procedures may necessitate your removal from the study. Even with these strategies in place, the risks of becoming ill from COVID-19 cannot be eliminated. If you have any questions regarding COVID-19 or the protection measures being used, please discuss this with a member of the study team.”

[Optional Section] Additional information regarding COVID-19 can be found at:

1. [Ferris COVID-19 information hub.](https://www.ferris.edu/coronavirus) (https://www.ferris.edu/coronavirus)
2. [State of Michigan Coronavirus information site.](https://www.michigan.gov/coronavirus) (https://www.michigan.gov/coronavirus)
3. [Center for Disease Control and Prevention Coronavirus site.](https://www.cdc.gov/coronavirus) (https://www.cdc.gov/coronavirus)