

September 2021

Considerations for Human Subjects Research at SMCM During COVID-19 Pandemic (Sept 2021 Update)

As we begin the 2021-2022 academic year, St. Mary's College's Institutional Review Board (IRB) has updated its protocols related to COVID-19 safety. Please review the following information carefully.

IN-PERSON RESEARCH: As of August 2021, in-person research may resume at SMCM provided the researcher follows protocols consistent with campus, local health department, and CDC guidance. However, researchers who can conduct their research through virtual means are strongly encouraged to do so.

If you must conduct research in person, please make clear the steps you will use to prevent the spread of COVID-19 within your IRB proposal in the risks assessment section of the eIRB document. This should include a rationale in which you explain why data cannot reasonably be collected online. If the research is to be conducted in person indoors, masking is required. Social distancing and sanitation practices are highly encouraged. If you have participants (adult or children) coming to campus from the community, they are required to abide by all campus policies for visitors when on campus including masking. Researchers may choose to implement a symptom tracker requirement of their own (it should be included in the IRB proposal) since the College no longer requires this step for visitors.

In addition, consent forms for in person studies must include the following statement of COVID risk:

To participate in this study, you must appear in person. The evidence to date suggests that COVID-19 and its variants are most easily spread through person-to-person contact. Although the researchers have safeguards in place to reduce the likelihood of transmission, it may still be possible to become infected. In signing this consent form, you acknowledge that you understand this risk and wish to participate.

Even if you plan to conduct the research in person, you may want to include a "back-up" virtual plan in your IRB proposal, if possible, that involves a transition online so that you can switch to virtual data collection without interruption should the College make changes to its policies during the time of the research. If a switch in format is not in the approved proposal, you will have to submit an amended proposal for review before changing the format of the study design.

ONLINE RESEARCH: Investigators may conduct online research studies without changes to procedures.

Regardless of the type of research you are engaging in, this is also a time to be particularly sensitive to the needs of participants who may want to avoid interactions or not participate in research studies that they had previously agreed to. Remind them when following up about participation or during the consent process that their decision to postpone or not to participate will not jeopardize their future relations with St. Mary's College of Maryland.

Questions can be directed to the IRB co-chairs, Dr. Jennifer Tickle (jttickle@smcm.edu) and Dr. David Morris (dbmorris@smcm.edu).

Thank you,
St. Mary's College of Maryland IRB