

## Face-to-Face Human Subjects Research Activities Restricted Effective March 20, 2020

**NOTE:** *This guidance is directed at researchers conducting studies under the oversight of the UNM IRB (irbmaincampus@unm.edu).*

Given the rapidly evolving circumstances regarding COVID-19 and UNM's focus on the health and safety of faculty, staff, students, and the community, the Office of the Vice President for Research and the Office for of the UNM IRB have issued revised standards related to research involving human participants.

Effective immediately and until further notice, **research interactions with human research participants must be performed remotely** (e.g., phone or other university-supported online tools such as Zoom, Opinio, etc.), unless the research procedure(s) is essential to ensure participant health, safety, or well-being (see the *Exception for Essential Research Visits* described below). Remote methods of data collection may be conducted if part of the originally approved protocol or an approved modification. **Research procedures involving face-to-face interaction with research participants must be postponed**, unless the research procedure(s) is essential to ensure participant health, safety, or well-being.

**Exception for Essential Research Visits:** Research visit(s) that are *essential* to ensure participant health, safety, or well-being may continue using face-to-face interactions if no remote options are available. The decision about whether a research visit is essential to the health, safety, or well-being of a participant is determined by the principal investigator, the participant, and/or the participant's care provider. Decisions must be informed by current public health guidance regarding the COVID-19 outbreak. Decisions about visits should be especially conservative for participants at [heightened risk](#).

**Please note that the need for face-to-face research visits is extremely unlikely given UNM's research portfolio. External partners who utilize UNM IRB may contact the OIRB for consultation. PIs of federally funded projects are encouraged to frequently consult their agencies websites for updated guidance.**

Face-to-face essential research visits must adhere to current guidelines to reduce exposure for study participants and research staff. For example:

1. Remotely screen all participants just prior to an in-person visit for possible exposure to the novel coronavirus or symptoms of respiratory illness such as fever, cough, and shortness of breath or difficulty breathing. Consult current public health guidance to determine appropriate screening questions. Research participants with possible exposure or symptoms may not participate in face-to-face interactions until after the time recommended by current public health guidance. ***This screening does not require prior UNM IRB approval.***
2. ***Ensure every day that all research staff who interact with participants are symptom-free and have not been exposed to the novel coronavirus.***

3. **Ensure appropriate infection control measures** are taken at the site of the face-to-face visit. For example, ensure availability of hand sanitizer, hand washing facilities, disinfectant wipes, etc. Train staff on appropriate cleaning and infection control procedures necessary to mitigate COVID-19 spread. Use appropriate personal protective equipment when handling human specimens.
4. Stay **aware of and abide by all applicable recommendations, policies, and actions** of federal and state public health authorities, University of New Mexico, non-UNM facilities where research is conducted, etc.

## Effect of the restriction on pending IRB applications

IRB review of submitted applications will continue as usual. Studies that involve face-to-face interaction may be approved with the condition that face-to-face interactions cannot begin until after the restrictions are lifted.

## Notifying participants of visit cancellations

If a study visit needs to be cancelled, participants should be informed of the reason and that they will be contacted again when the visit can be rescheduled. ***These messages to participants do not require prior UNM IRB approval.***

## Notifying the UNM IRB

Visit cancellations related to COVID-19 do not need to be reported to the IRB. If you need to adjust data collection procedures during this time (such as conducting phone interviews instead of in person interviews), that adjustment can be made without prior IRB approval. We ask that you record these interactions on the Protocol Deviation form and submit that at the time of your next IRB submission. Federally funded studies must report the deviation to the IRB within 30 days. If you have specific questions, please contact the OIRB at [irbmaincampus@unm.edu](mailto:irbmaincampus@unm.edu) or (505) 277-2644.

## For research approved by an external IRB

Consult the Reviewing IRB for guidance on:

- Whether COVID-19 screening requires prior IRB approval
- Whether/how to report the restrictions on face-to-face study procedures
- Whether/how to modify an approved study to allow remote procedures

*Created on 3/20/2020 based on COVID-19-HSR-Restrictions guidance published by Iowa State University.*