Research with Humans during COVID-19

Hello NC State University Researchers!

The IRB hopes that you are taking care of yourself while being cognizant of your social responsibilities, including social distancing. In light of COVID-19, our office is providing guidance regarding your research practices with human subjects. This guidance is being implemented to protect research participants, researchers, and the larger NC State community from risk of infection from COVID-19. It is our expectation that you minimize in person contact with research participants and follow all precautions as recommended by NC State University, the CDC, and the WHO. Please do not increase risk of infection to participants by implementing non-critical health related research procedures.

- Please remain up to date with NC State University’s Guidance
- Please follow guidance from the CDC and the WHO
- If your study is sponsored by NSF or NIH, please follow their guidance

Is the IRB still running?
Yes! Submit proposed protocols as normal, all of our operations are shifting to remote work. We are happy to meet with you via phone, video conferencing, or chat. The best way to reach all of the staff is via email. The only thing that has changed is in person training sessions through the libraries and in person meetings. Our office is able to meet virtually as requested.

Recommendations on Changing Aspects of Your Research Procedures
The IRB recommends that you make changes to your research procedures involving in person interactions in order to minimize exposure to COVID-19.

- Interactions with participants should be performed remotely (e.g., by phone, Zoom, or other means) whenever possible. Remember, however, that any deviation from an approved IRB protocol must be approved by the IRB unless such change is necessary to eliminate an apparent immediate hazard.
  - For example, if you planned to hold a focus group meeting in a conference room, and you have decided to move this meeting to Zoom or another platform, you will submit an amendment request for your protocol to the IRB office.
- Interactions with participants for research purposes that cannot be performed remotely AND do not provide an immediate benefit to a participant’s health or well-being should be postponed until further notice.
- If you are completing research with human subjects in partnership with UNC-Chapel Hill researchers and doctors and UNC-Chapel Hill is your IRB of record, you must follow guidance from the UNC-Chapel Hill IRB on completing research with humans in hospitals and the UNC-Chapel Hill IRB’s temporary policy.
- If you are completing research with human subjects in partnership with Duke researchers and doctors and the Duke IRB is your IRB of record, you must follow the guidance from the Duke IRB on completing research with human subjects.

I want to amend my approved protocol to continue research during COVID-19
If you need to alter your research processes from currently IRB approved processes or forms due to COVID-19 (e.g., virtual consent, virtual interviews) please submit these as amendments

- In the title of your study, make it say “COVID-19 Amendment: <title>” - This will alert the IRB staff to rush your review/approval for this activity.
In the amendment request on the “title” tab, make sure to describe the changes and why you are making them. This includes any changes to the consent processes including alterations/waivers of signature or other elements as required.

On each tab of the IRB application, make appropriate changes to the text boxes. Instead of writing over what is already there, scroll to the bottom of the text box and write “Amendment March 2020: _____” and then fill in the blank with what the changes are. You can also change the month based on when you submit the amendment.

Make sure to upload any new documents or any altered documents with their changes tracked.

If your research requires samples to be drawn as part of their research participation, you can have the samples collected at another organization, such as participants’ local provider clinic, provided that this group routinely provides sample collections as a service. This will need to be reflected as an amendment and it should be clear that these samples are taken for research purposes and it should be clear that the samples are not taken for medical purposes.

As a reminder, initiating research or amendments to research without IRB review and approval is not permitted.

Please keep in mind, it is expected that you maintain your current data management plan or update the management plan via an IRB amendment based on any changes in your procedures.

I want to submit a new protocol and implement study interventions during the COVID-19 outbreak

If you want to submit a new protocol during this time, please do so. If you want to collect data during this time, all data collection should be done virtually, and the documentation reflected as such.
  - To avoid constant amendments, you can also include procedures that take place in person after NC State University gives the all clear for normal practices.
  - If including 2 types of procedures, make sure the documentation provided matches both sets, and that you provide two different documents for the 2 different procedures.

If you want to submit and get approval for research that will take place later on, make sure to note that no data collection will take place during the COVID-19 outbreak.

We realize that this is a challenging time for you and for all of us in our community, including for our research subjects. Please work with the IRB staff both to move your research forward while protecting the health and safety of subjects and researchers. Please feel free to contact the IRB office at any time if you have any questions or concerns.