Human Subjects Research COVID-19 Update – October 29, 2020

The Fordham IRB understands the continuation of human subjects research at the University is vitally important. For the safety of the University community and research participants, researchers must make all efforts to continue to conduct their procedures remotely and limit in-person interactions to the extent possible. If goals of the study can be met without in-person contact with participants, such procedures must continue to be used during the COVID-19 pandemic.

If the goals of the study cannot be met remotely, the Fordham IRB will take serious consideration to determine if in-person data collection is permissible on a case-by-case basis. It should be noted that research participants who will come on-campus for study participation are considered visitors. Currently, Fordham is earnestly limiting visitors on campus.

Some examples of research that may be approved for in-person research are:

1. Research that minimizes in-person contact and can safely be conducted;
2. Research being conducted on campus in a classroom where students are already participating in in-person learning;
3. COVID-19 related research and clinical trials;
4. Research that offers the prospect of direct benefit to participants;
5. Clinical trials and research funded by federal or foundation sponsors;

If a request for in-person research will be submitted for review, please read through the following guidance and instructions on how to submit such request to the IRB.

KEY POINTS:

- All University requirements for on-campus activities must be followed. Please refer to the Fordham University re-opening pages on the website for the most up-to-date information.
- It is important to note that the IRB cannot monitor the state of COVID-19 across all locations and time periods, so for studies conducted outside of New York, it is the responsibility of investigators to stay informed and follow all orders, regulations and laws set forth by the state and local government where the research study is being conducted.
- If in-person research procedures are being conducted not on a campus of Fordham (e.g., in community clinics, at other domestic or international sites, etc.),
compliance with local requirements is required. All requirements and safety measures must still be followed.

- If the University’s IRB is **not** the reviewing IRB for a study, compliance with any more stringent restrictions or requirements established by the reviewing IRB is required.

**Before you restart your study, make sure that you have:**

- Your study visit space can accommodate the recommended physical distancing.
- The ability to screen study subjects for COVID-19 symptoms by phone prior to the study visit and at the time of the on-site study visit. Please see below questions for screening. The IRB recommends keeping a log of screening information.
- Adequate personal protective equipment (PPE; masks and/or gloves) and hand washing supplies for both study subjects and staff.
- Cleaning supplies on hand to clean furniture and study equipment that come in contact with the study subjects. PIs and/or research personnel are responsible for cleaning surfaces and study equipment.
- Examined the study protocol and contacted the study sponsor and the IRB, where appropriate, about any modifications, including changes in protocol, remote/virtual/tele-research visits, new risks to study subjects, or any other study protocol issues.
- It is strongly advised to conduct several mock study-visit practice sessions so that study personnel can practice the new workflow.
- All study personnel who will have direct contact with study participants may be required to be screened with VitalCheck before returning to campus. More information can be found [HERE](#). Please reach out to HR to inquire if VitalCheck screening is required.
- The University has instituted mandatory universal COVID-19 testing for all faculty, students and staff. All students and employees who will be on campus will be required to get tested prior to arrival or when they arrive, and again at an interval to be determined after they have been on campus. On-campus testing for students and employees with results within 24 hours, or as quickly as possible thereafter. Please find more information [HERE](#).

**General Requirements for In-Person Data Collection:**

- All research subjects and study personnel must wear masks. Any subject who arrives without a mask will need to be provided one by campus security or the researcher upon entering campus or building.
- Research subject interviews or contact with research staff must adhere to physical distancing guidelines. Subjects should be seen in areas that allow 6 feet of separation at all times, except when contact is necessary to complete study procedures, for example physical examinations or other study procedures that require contact.
• If there is not an available sink for participants to wash their hands, areas where study subject visits will take place should have hand sanitizer available. When wall-mounted dispensers on campus are available, please use these to sanitize hands.
• All surfaces and/or study equipment should be sanitized between participants. Please include details with your request on how sanitization/cleaning will be conducted.
• A log should be kept of dates and times of visits by research participants for contact tracing purposes.

Screening Questions

1. In the past two weeks, have you tested positive for COVID-19 or are you currently being monitored for COVID-19?
2. In the past two weeks, have you had contact with someone who tested positive for COVID-19?
3. Do you currently or have you in the past 14 days, experienced the new onset of symptoms of COVID-19 (fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat)?

Below is a SAMPLE script for use when talking with research participants. This script can also be given as a “hand-out” to participants. Please revise the script as you see fit according to your protocol.

SAMPLE Script for Discussing Safety Information with Study Subjects

I’d like to share what we are doing to make sure you stay as safe as possible while participating in research studies here.

• All study personnel and staff will be wearing masks, and we’ll also provide a mask to you and anyone who comes with when you arrive, if you don’t have one.
• We also require all of our employees to screen themselves for symptoms daily before they come into work, and we’ll screen you for symptoms the day of your visit.
• We are following meticulous infection control practices, including disinfection, wearing gloves, and hand washing.
• We are limiting the number of visitors accompanying people for their study visits, and are enforcing strict social distancing practices.
• We’re also being careful about who we ask to come for in-person study visits, and when possible are using telephone or video conferencing to reduce the number of study subjects coming to our research areas at the same time.
• We know that COVID-19 will be in our community for many months. We appreciate your continued participation in our study. Please ask if there is anything you are concerned about.
The following SAMPLE consent form language should be included in your consent form(s). Please revise accordingly to be specific to your study.

Potential risks of COVID-19. Since some of the assessments will be conducted in-person, there may be some risks for contracting COVID-19. However, the researcher will follow safety procedures to minimize the risks of contracting COVID-19. The safety procedures include:

1) The PI/researchers will be wearing a mask and gloves at all times during the meeting,
2) you will be asked to wear a mask (a mask will be provided if you do not have one) during all parts of the meeting (include any exceptions here),
3) The PI/researchers will sanitize the study area/testing device, etc. in between each participant,
4) the researcher will maintain 6 feet distance from you.

Although the researcher cannot guarantee that there are no risks of COVID, when all the safety procedures are followed, the risk of contracting/transmitting COVID-19 should be minimal.

*When possible, researchers should consider obtaining consent through remote means prior to face-to-face contact to reduce time in close proximity.*

Steps to submitting your request to begin/resume in-person research:

1. All requests for in-person research will be reviewed by the convened IRB at their monthly meetings. Therefore, researchers should submit materials for review by the applicable submission deadline which can be found on the IRB website.
2. The form titled “Request to Begin or Resume In-Person Data Collection” should be submitted on Mentor either with your new protocol submission or as an Amendment for already approved research studies.
3. Submit all applicable revised documents and new materials for review with your amendment. (Recruitment materials, Consent Forms, etc.)
4. Once your study is approved to conduct in-person research, please contact Public Safety on the campus where you will be collecting data.

These guidelines are subject to change at any time. Please check the Fordham IRB website and the Mentor system for the most updated information.