

COVID-19 Human Subjects Research Guidelines

Request to Resume Face to Face Data Collection

The IRB's mission is to protect Human Research Subjects from any harm that could befall them by participating in research. The CORONAVIRUS pandemic provides additional risks to research subjects beyond those they usually encounter.

Since the Spring of 2020, researchers at St. John's University have been prohibited from collected data face-to-face and have been restricted to collecting all data virtually. As the COVID-19 virus infection rate has reduced, and New York State has opened up, some researchers have sought permission to collect data face-to-face. The IRB has agreed to allow this under certain conditions.

The IRB encourages all researchers to collect data virtually when possible. All researchers who wish to collect data face-to-face must explain to the IRB why the data for their project cannot be collected virtually.

I. IRB COVID-19 Application Requirements

- a. Consistent with the University's global mission, researchers at St. John's University collect data across many jurisdictions. The rates of COVID-19 infections vary widely by location. Therefore, the IRB requests that researchers specify the geographic area where they plan to collect data. Researchers must indicate the country, state, county, and city or town where they intend to collect data and describe the extent of the COVID-19 pandemic disease in that area. One possible source of this information is the Johns Hopkins University CORONAVIRUS Resource Center (<https://coronavirus.jhu.edu/>). However, researchers are free to use other sources of information.
- b. Researchers must also describe any statistics indicating the degree of infection or any regulations concerning quarantine or health guidelines provided by the state or local government where they intend to collect data. For example, New York State hosts a website that gives information on the rates of infections, positive test results, and reopening guidelines for ten regions throughout the state (<https://forward.ny.gov/>). If researchers are collecting data in other jurisdictions, they should consult the local government's websites. If researchers are collecting data in more than one area, their IRB application should provide this information for each location to collect data.
- c. We recognize that the rate of CORONAVIRUS infections varies widely by the type of building or facility where researchers might encounter subjects. All applications should describe the type of facility where the researchers will recruit subjects and whether that type of facility is known to have a higher infection rate or houses people who are at higher risk of infection or mortality.

- d. Researchers must comply with all St. John's University COVID-19 policies based on federal and state public health regulations (e.g., physical distancing, face coverings, cleaning/disinfection, etc.). In addition to these policies, researchers must obey all the facility regulations where they conduct their study. These policies and how researchers will comply with them must be stated in the application for approval.
- e. All researchers must specify how they will comply with any Federal, State, or local government safety guidelines. The researchers are responsible for discovering what regulations exist in any location where they will collect data. The US Government's Center For Disease Control and Prevention (CDC) provides an extensive website with information on preventing CORONAVIRUS infection (<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html>). The local jurisdiction where researchers wish to collect data might have additional guidelines or requirements about behaviors that could control the disease's spread. For example, New York State provides a web site that describes the State's re-opening guidelines and regulations to prevent infections (<https://forward.ny.gov/>). Researchers must describe in detail what procedures they will take to comply with the CDC, State, and any local governmental requirements. Such statements will include the use of Personal Protective Equipment (PPE), social distancing, partitions that separate the researchers and subjects from each other, and any other any federal, state, or local restrictions.
- f. All researchers will provide a comprehensive COVID-19 safety plan in the methods section of their Cayuse application.
- g. Our website on informed consent statements includes some elements related to the risks of infections when participating in research at this time. (<https://www.stjohns.edu/academics/research/grants-and-sponsored-research/human-participants-irb-animal-use-research> a description of any reasonably foreseeable risks or discomforts to the subject). All consent forms in studies with face-to-face data collections must specify that "participating in this study puts me at risk for exposure and contracting COVID-19." Also, informed consent statements should include a section indicating that the study could be terminated if a serious rise in COVID-19 infection rates occurs. Such termination will affect any treatment that the study provides to the subject.

II. IRB COVID-19 Guidelines Following IRB Approval

The CORONAVIRUS is an exceptionally infectious disease, and the rates of infection can change quickly in any location. Because of this potential rapid change in infection rates, we ask all researchers to take the following actions.

- a. The infection rate could change between the time a researcher receives IRB approval to start their project and the time they begin data collection. All researchers must file an **Update Report** to the IRB on the day they start data collection. This report should specify that the COVID-19 infection rate has not significantly increased where they are

collecting data and that there has been no change in the State or local government regulations since the protocol for their study was approved. (This report will be uploaded to your IRB application in Cayuse.)

- b. Researchers are responsible for informing the IRB if the infection rate changes significantly where they are collecting data and stopping data collection if such a change occurs or if the State or local government imposes restrictions on social contact. The researcher can file an **Incident Report** if such an event occurs.
- c. All researchers should make contingency plans to stop collecting data and switch to virtual data collection if a series of infections arise.
- d. All researchers must submit notification to the IRB when the F2F aspect of their research is completed. (This notification will be uploaded to your IRB application in Cayuse.)

We recognize that the COVID-19 places more responsibility on researchers and that preparing an IRB application involving face to face contact will be more difficult. Each study will be reviewed on a case by case basis.