



Return to In-person Human Subjects Research Activity Plan for Queens College

A. Background

This plan is a proposed revision to the Queens College Research Reopening Plan approved by Jose Luis Cruz, Executive Vice Chancellor of Academic Affairs, on July 4, 2020. Currently, the strategy states that research involving human participants will not occur until Queens College enters Stage 3 of the plan. Specifically, the plan states that “only approved human subject research deemed essential should be conducted face-to-face, until there is availability of a vaccine, herd immunity, or other effective and readily available prophylactic or therapeutic health advances.” In short, the proposed revision would allow human subjects research that involves face-to-face interactions with participants to be conducted during Stage 2 of the plan.

B. Purpose

The purpose of this document is to outline permitted face-to-face human subjects research interactions, the process for receiving approval to conduct research that includes face-to-face interactions with human subjects, and information to be included in the investigator’s IRB application. Queens College recognizes the importance of research for faculty and students; however, careful steps must be taken as we prepare a return to in-person human subjects research in the wake of the COVID-19 pandemic. As a result, human subjects research activity that involves face-to-face interactions will be considered on a case-by-case basis in order of priority set forth in section C. and in accordance with the requirements set forth in sections D below and in accordance with New York State and Queens College guidelines in effect at the time of review.

Human subjects research protocols involving face-to-face interactions will be reviewed in accordance with adherence to the Queens College Research Reopening Plan, which allows for 50% capacity of Queens College laboratory space during Stage 2.

C. Permitted Face-to-Face Activity for Human Subjects Research Projects and Consideration for Approval

Research that involves face-to-face informed consent procedures, in-person data collection, and offsite face-to-face recruitment will be considered on a case-by-case in the following order of priority:

1. Externally funded, deadline-driven work requiring stipulated deliverables (grant/contract deadlines) that must be conducted on site or in the field (with documentation of deadlines) (regardless of researcher rank or tenure status; includes any required research staff)
2. Externally funded research that must be conducted on site or in the field (with award documentation) (regardless of researcher rank or tenure status; includes any required research staff)
3. Research by graduate or undergraduate students who are near degree completion (with advisor or area head support/presence per college requirements)
4. Untenured faculty research (with department chair/program head support), graduate students, and postdoctoral research associates.
5. Research requiring season-specific sample collections
6. Tenured Associate Professors and Professors (with department chair/program head support).

Face-to-face recruitment on the Queens College campus for human subjects research projects is **not** currently permitted.

D. Process for Receiving Approval to Conduct Human Subjects Research Involving Face-to-Face Interactions

COVID-19 Training and Health Screening

All investigators planning to engage in human subjects that involve face-to-face interactions must complete the following:

1. Queens College New York State COVID-19 Response: Return to Work Training on Blackboard. Step-by-step instructions are available at <https://support.qc.cuny.edu/support/solutions/articles/15000035044>. This training only needs to be completed once.
2. CUNY Health Screening available by downloading the Everbridge app and logging in with your CUNYFirst credentials. See instructions for “How to Download and Use the Everbridge Mobile App.” **NOTE: The CUNY Everbridge Health Screening must also be completed by study participants who the research team will be interacting with face-to-face.**
3. Complete the Proxyclick Queens College Access 2020 (QCA20) questionnaire which will be emailed to you once you have requested campus access via <https://provost.qc.cuny.edu/departments/access>.

Administrative Approval

All research involving direct, in-person human subjects research activity must be submitted to and receive 1) department chair approval; and 2) approval from the school’s dean. Once the dean has approved the project, 3) they will present it to the Queens College Ad Hoc Working Group on Reopening (AHWGR) for approval.

Submissions must include 1) a copy of the investigator's human subjects research protocol; 2) the COVID-19 Protocol Safety Submission Review Form for Human Subjects Research Projects Involving Face-to-Face Interactions; and 3) a proposed list of spaces for in-person interactions.

IRB Approval

Additionally, human subjects studies must receive a Human Research Protection Program (HRPP) determination or Institutional Review Board (IRB) approval before any research activity is initiated. Please note that any modifications to prior-approved protocols will also require IRB review and approval. Principal Investigators must submit new applications and amendments to existing protocol via the Ideate system at <https://ideate.cuny.edu/home/>.

Research involving direct, in-person interaction with vulnerable populations (e.g., minors, elderly persons, pregnant women, prisoners, immunocompromised individuals) will be considered on a case-to-case basis and reviewed with greater scrutiny with regards to risk determination.

Research Conducted Off-Site (at institutions other than Queens College)

Queens College researchers traveling to other institutions (including other CUNY campuses) to conduct off-site research must follow the health safety protocols for Queens College outlined in sections D and E of this document as well as the health safety protocols as set forth by the institutions where the investigators are engaging in research activity. This administrative approval is separate from IRB approval or any IRB Authorization Agreements that may be required. Documentation of the administrative approval of the research and safety plan must be included in the investigator's submission to AHWGR and the Ideate IRB application submission to the Queens College HRPP Office.

E. IRB Ideate Application Requirements

The following items must be incorporated into the project proposal and the Ideate IRB application to comply with NYS law and the Queens College Approved Research Reopening Plan:

1. Upload COVID-19 CITI training certification to the Attachments tab.
2. Add the following statements to the Research Design>>Overview section of the IRB application:
 - a. Time on campus will be limited to tasks requiring essential face-to-face contact; all other tasks will be conducted remotely.
 - b. In-person appointments to obtain consent and/or collect data will be scheduled to avoid potential overlap between participants.
3. Please add the following information to the Research Design>>Overview section of the application (in addition to any other safety precautions specific to the research that may need to be implemented by the research team):

SAFETY PROTOCOL

- a. All in-person participants will comply with Everbridge and QCA20 wellness check protocols in order to access campus. All appointments will be scheduled at least three (3) business days prior to the appointment.
 - b. All research personnel will wear a nose and mouth covering mask while traveling, on-campus, and/or interacting with human subjects and/or other research personnel, and wash hands/use sanitizer (including hand washing with soap, water, and paper towels, or an alcohol-based hand sanitizer containing 60% or more ethanol and 70% or more isopropanol for areas where hand washing is not feasible) upon arrival on campus.
 - c. Research personnel will limit the sharing of objects and discourage touching of shared surfaces; or, when in contact with shared objects or frequently touched areas, wear gloves (trade-appropriate or medical); or, sanitize or wash hands before and after contact.
 - d. Research personnel will instruct human subjects to wear a face covering during face-to-face interactions and will not engage in any in-person interaction unless all parties involved are wearing face coverings.
 - e. Research personnel will instruct human subjects that a distance of six feet must be maintained between all individuals and ensure that this is adhered to.
 - f. Research personnel traveling to campus via public transportation travel will make an effort to travel at off-peak times.
 - g. Research personnel will maintain their personal health log in accordance with the Queens College Approved Research Reopening Plan.
 - h. Researchers personnel will follow all other requirements outlined in the Queens College Approved Research Reopening Plan, Queens College safety guidelines, and New York State Guidance.
4. Include documentation of approval from the Queens College Ad Hoc Working Group on Reopening.
 5. Include the following language in your consent form: "This is research conducted in-person and will entail face-to-face interaction with research staff. All in-person research conducted at a CUNY campus follows national, state, local and CUNY COVID-19 safety guidelines. Additionally, this research has been approved by a CUNY Campus in-person research resumption committee and uses all required safety guidelines."
 6. Include documentation of the administrative approval of the research and safety plan at other institutions (if applicable).
 7. Amendments to previously approved research where the investigator seeks to restart activity that involves face-to-face interactions should include numbers 1-4 above.