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.

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, Vaccination Status, and Campus Access

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

1. Complete CITI COVID “Back to Campus” training modules and include the certificate of completion as part of your submission outlined in the Administrative Approval section below. Also, please email this training certificate to Bill Graffeo at william.graffeo@qc.cuny.edu.

2. Queens College faculty, student, and staff researchers will upload their vaccination documentation into CUNYfirst.

3. Queens College faculty, student, and staff researchers will use their QCards to access campus via a swipe process at entrance gates. Your QCard will contain information regarding your vaccination status and your campus access.

3. Requests for visitors (research subjects, non-QC collaborating researchers, non-QC research assistants etc.) will be submitted 5 business days prior to the requested visit so that the visitor can be input into the Cleared4 system, where they will upload their CDC vaccination card or a negative PCR test dated within 7 days of their visit.

4. Approved visitors (research subjects, non-QC collaborating researchers, non-QC research assistants etc.) will be registered in QCA20 (Proxyclick) for specific dates, times and locations once their vaccination/test documentation has been verified. They will answer the questions in the visit prep email and receive a QR code if approved. They must show the QR code to the Public Safety Officer at the Main Gate on Kissena Blvd.

Administrative Approval

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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/](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 “Back to Campus” 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):

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SAFETY PROTOCOL

a. All in-person participants will comply with Cleared4 and QCA protocols in order to access campus. All appointments will be scheduled at least five (5) 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 (at all times when on campus) 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.