Office of Research Compliance
Information and Guidance for Research Submissions

Ideate Access and Instructions

Ideate is the IRB protocol submission, review, and management system.

Getting Started with Ideate: https://www.qc.cuny.edu/about/administration/Provost/ORC/Documents/GETTING%20STARTED%20-%20NEW%20USERS.pdf

Ideate Tips and Tricks: https://www.qc.cuny.edu/about/administration/Provost/ORC/Documents/IDEATE%20TIPS_FAQS.pdf

Required Research Training

- Required for all CUNY investigators
- Complete the required CITI trainings at www.citiprogram.org.
- Complete BOTH of the following trainings and add them to your IRB application:
    - HSR for Social & Behavioral Faculty, Graduate Students & Postdoctoral Scholars>>Basic (when conducting Human Subjects Research)
    - Responsible Conduct of Research Training>>Basic (when conducting ANY research)
- More info and instructions at http://www.cuny.edu/research/research-compliance/training-education/citi-training/

Definition of Human Subjects Research

A project must (1) constitute research; and (2) involve human subjects.

Research

You must be conducting a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge for an activity to be considered research.

- A systematic investigation must include a plan for data collection and analysis.
- Generalizable knowledge *generally* includes plans to publish or disseminate research rules outside of the CUNY system.

Human Subjects

A human subject is a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention nor interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

In summary, in order to warrant IRB review, your project must satisfy the following three criteria:

1. Be a systematic investigation
2. Be designed to contribute to generalizable knowledge
3. a.) Obtain data (or biospecimens) through intervention or interaction with and individual; OR b.) Obtain, use, study, analyze or generate identifiable private information

If you do not think your project satisfies ALL THREE of these criteria, you can contact the Queens College Office of Research Compliance stating why you don't think your project satisfies these 4 criteria and we may issue a Not Human Subjects Research Determination outside of the Ideate system vial email.

See Office for Human Research Protections Decision Tree here as an additional resource: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

Information, Definitions and Guidance on private identifiable information can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html

Exempt Categories

The IRB application asks "Are you applying for exemption." Your answer to this question is important and will generate different questions in the IRB application so please review the exemption categories before answer this question.

A list of exemption categories can be found here: http://www.irb.emory.edu/policies/review-types/exempt.html

If you are applying for and receive an exemption determination, no consent form is required.

Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures (including email or internet surveys), interview procedures or observation of public behavior must include an explicit statement and explanation regarding one of the following in the Research Design and Methodology section of the IRB application:

1. The data obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

3. The data obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

Expedited Categories

A list of expedited categories can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

Greater than Minimal Risk Studies

Greater than Minimal Risk studies are generally those studies where the probability and magnitude of harm or discomfort anticipated as a result of an individual's participation in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations.

Recruitment

- All recruitment materials need to be submitted as an attachment. This included website text, emails, social media posts, posters, flyers, oral recruitment scripts, text to be advertised on social media, etc.
- Recruitment materials should include:
    - PI name
    - Statement about whether or not compensation will be provided
    - Clear statement that the study is research
    - Contact info
    - Study title
    - Brief mention of eligibility criteria
- Clearly state whether or not you will have access to email addresses or any other contact information as part of the recruitment process.
- State whether or not you will be using SONA or another subject pool.
- If the study involves online surveys or questionnaires, state how the survey links will be distributed.

Research Involving Vulnerable Populations

Pregnant Women

See CUNY policy for research involving pregnant women: https://www.cuny.edu/wp-content/uploads/sites/4/page-assets/research/research-compliance/human-research-protection-program-hrpp/hrpp-policies-procedures/Pregnant_Women_8_1_13.pdf

Children

See CUNY policy for research involving children: https://www.cuny.edu/wp-content/uploads/sites/4/page-assets/research/research-compliance/human-research-protection-program-hrpp/hrpp-policies-procedures/Children.pdf

Prisoners

See CUNY policy for research involving prisoners: https://www.cuny.edu/wp-content/uploads/sites/4/page-assets/research/research-compliance/human-research-protection-program-hrpp/hrpp-policies-procedures/45-Prisoners-1.1-12-27-18-1.pdf

Prisoner research funded by the Department of Health and Human Services (HHS) requires Queens College Administration to make a special notification to the Office of Human Research Protections. See list of HHS agencies below and make special note whether or not your projects is funded by HHS in your IRB application.

https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html

Research Involving Cognitively Impaired Individuals

- State who will assess the potential participant's capacity to consent and how this will be done. Whenever possible, this should be done by independent evaluators (i.e., those not involved in research) should assess capacity to ensure that only appropriately screened individuals may be enrolled.
- Detail procedures for providing notice to the participant and, if necessary, the Legally Authorized Representative (LAR), regarding the capacity assessment. Opportunities for objection and review are integral to the protection of all research participants. Researchers should provide notice to the participant and/or LAR that an assessment will be conducted, as well as the results of the assessment, and any consequences of a determination of incapacity. Potential participants and/or surrogate decision-makers should be notified of a planned capacity assessment, as well as the results of the assessment and any consequences of a determination of incapacity.
- Attest that the LAR will be identified according to the surrogate hierarchy of the Family Health Care Decisions Act.
- Obtain assent, if possible, from the cognitively impaired individual. If assent cannot be obtained, this individual must not dissent. Signs of dissent may not be obvious. If signs of dissent are present or – where assent is possible – assent is not provided, researchers may not enroll or allow continued participation of the individual.
- Provide scientific rationale for including cognitively impaired individuals in research that does not explicitly study medical conditions that impair capacity.

Risks

Risks must *always* be included in the informed consent form and in the IRB application

- Breach of confidentiality is always a risk of human subjects research. Also include this in the consent form.
- There may often be emotional discomfort or stress associated with surveys
- Include all other risks of the research

Certificate of Confidentiality (CoCs)

- Protect researchers from being required to disclose information collected as part of a research study in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings.
- CoCs should be considered when researchers are collecting identifiable information related to illegal activities, drug, alcohol use, stigmatizing behavior, HIV/AIDS and other STDS, mental well-being, genetics, and sexual experiences and preferences.
- CoCs do not remove the need for mandated reporting or reporting otherwise required by federal, state, local laws. Data protected under CoCs may still also be disclosed when it is necessary for medical treatment or other uses consented by the individual and other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.
- Language must be added to informed consent notifying the participants that you have obtained a CoC.
- CoCs are issued automatically for all NIH-funded projects.
- CoCs only apply to research in the U.S.

See more information and how to apply for a CoC here https://grants.nih.gov/policy/humansubjects/coc.htm

Privacy and Confidentiality

- State whether or not you will have access to subject emails or any other identifiable information during recruitment or at any point throughout the study. If you will, then all references to anonymity need to be removed throughout the protocol.
- List any and all identifiable information that will be collected as part of data collection.
- Signed consent forms and any other physical materials with identifiable information should be kept in a locked cabinet in a locked office or laboratory at Queens College or CUNY institution.
- Consent forms and other identifiable information should be kept separate from any study data.
- A list of research personnel that also has access to the consents or the physical materials must be included.

- Storage of Identifiable data on computers, hard drives, USBs, and mobile devices should include info on encryption, password protected files, computers issued by Queens College or CUNY. State how, where will the data will be secured (e.g. password protected file on password protected computer at Queens College).
- Identifiable data in clouds should use one of the CUNY approved cloud services (OneDrive, Dropbox, Sharepoint) and include info on encryption and password protection.
- State who on the study team will have access to the data.
- State if data will be stored without any identifiers or with codes, etc. If the data is coded, and there is a linked list of codes and identifiers, this list should be stored separately from all coded data. Identifiable information should not be stored on student researchers' computers after the study has ended.

Consent

- Consent templates and guidance is located at http://www.cuny.edu/research/research-compliance/human-research-protection-program-hrpp/hrpp-policies-procedures/
- Documented consent (signed form) is not needed for studies that qualify for exemption.
- When names and signatures are on a consent form, it becomes identifiable information and increases the risk of breach of confidentiality.
- Use internet or oral consent (waiver of documentation of informed consent) when appropriate and applicable. Projects where waiver of documented informed consent (no signed consent form) would be applicable are:
    - The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.Each subject(or legally authorized representative)will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR
    - The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;

Audio/Video Recording

- State how audio recordings will be secured in the Privacy and Confidentiality section
    - when/if they will be transcribed and destroyed?
    - what type of device they will be recorded on?
    - what security/password/encryption protections does the device/application provide?

Compensation

- Include the method (cash, check, gift card, etc.), timing (at what point will they receive the compensation) and amount of compensation.
- Clearly state whether or no payments will be pro-rated in the IRB application and in the consent form. E.g. if a subject partially completes a study procedure or completes some of the procedures but not all, will they receive partial payment?

Research in NYC Public Schools

- Research being conducted in NYC Public Schools requires approval from the NYC DOE IRB. Include the name of the school(s) where you are conducting the research in the Research Design section of the application.
- State that you are seeking NYC DOE IRB approval in this section and that you will add it as an amendment to your IRB application once you receive it. If you have already received approval from the NYC DOE IRB, upload it as an attachment.
- Provide approval letters from school administrators allowing you to conduct research.

International Research

If conducting human subjects research in another country, you must consider differing regulations, laws, and guidelines that govern such research in these nations.

The International Compilation of Human Research Standards (https://www.hhs.gov/ohrp/sites/default/files/2020-international-compilation-of-human-research-standards.pdf) is an amazing resource that outlines over 1,000 of these standards in 133 countries, as well as standards from a number of international and regional organizations. The document covers:

1. General human subjects research
2. Drugs, Biologics,and Devices
3. Clinical Trial Registries
4. Research Injury
5. Social-Behavioral Research (also see Description and Analysis of Social-Behavioral Research Standards: https://www.hhs.gov/ohrp/international/social-behavioral-research-standards/index.html)
6. Privacy/Data Protection(also see Privacy International reports: https://www.privacyinternational.org/reports)
7. Human Biological Materials
8. Genetic (also see the HumGen International database: http://www.humgen.umontreal.ca/int)
9. Embryos, Stem Cells, and Cloning

Additional Resources

CUNY HRPP Polices, Procedures, Guidance, and Templates: https://www.cuny.edu/research/research-compliance/human-research-protection-program-hrpp/

Queens College Office of Research Compliance: https://www.qc.cuny.edu/about/administration/Provost/ORC/Pages/default.aspx?/

Human Research Protections Program (HRPP) and Institutional Review Board (IRB) Overview: https://www.qc.cuny.edu/about/administration/Provost/ORC/Pages/IRBOverview.aspx

45 CFR 46, the Common Rule regulations for Research Involving Human Subjects: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML