State University of New York, Canton College of Technology
Institutional Review Board

Guidelines for Submission of IRB Registration Form

Projects require review by the IRB only when they involve research on human subjects as defined by the Federal regulations for the protection of human subjects (45CFR 46). A project may meet the definition of research, but not that of human subjects. A project may involve interaction/intervention with or collection of data about individuals, but does not involve research or human subjects as defined by the regulations.

If your project does not involve research on human subjects, as defined below, but does involve either interaction/intervention with or collection of data about individuals, please complete and submit the IRB Registration. If you are unsure, please contact the IRB.

The responsibility for determining whether an activity constitutes human subjects research rests with the investigator. Since the University will hold them responsible if the determination is not correct, investigators are urged to submit the registration form to request confirmation from the IRB that an activity does not constitute human subjects research.

Definitions in 45CFR 46:
Research is defined as a systematic investigation designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge in a particular field of study. Generalizable knowledge is knowledge that has implications for a broader group of people or that will be used to influence policy or practice. It is usually described in a formal protocol utilizing scientific methods that sets forth an objective and a set of procedures to reach that objective.

Human Subject means a living individual about whom and investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) individually identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, drawing blood, dispensing drugs, administering other treatments) and manipulations of the subject or the subject's environment (controlling environmental light or sound, presenting sensory stimuli, making voice, digital or image recordings) that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject through surveys, interviews, focus group meetings, etc.

Individually Identifiable data includes, but is not limited to, names, social security numbers, medical record numbers, addresses, phone and fax numbers, email addresses, account numbers, license or certificate numbers, vehicle identifiers, codes which the researcher could reasonably use to identify a living individual, or combinations of information from which a persons identity could easily be determined. Data could be from previously conducted surveys or interviews, from medical, educational or financial records, or from a publicly available database.

Private data includes biological specimens and information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information or specimens provided for specific purposes which the individual can reasonably expect will not be made public (e.g., a medical or student record). Private data must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information, either directly or through a coded link) in order for obtaining the data to constitute involvement of human subjects.

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Registration Form

Please complete this form if you propose to conduct a project that involves interaction/ intervention with or collection of information about human individuals that meets one or more of the criteria below.

IRB review is not required because:

- The project does not meet the Common Rule definition of research.
- All data/specimens are about/from deceased individuals.
- Results will be shared only with the client or stakeholder(s) for private use for evaluation of an established program or for other non-research purposes.
- The project utilizes only data from secondary sources that are not individually identifiable.
- The project is an internal evaluation intended for quality control of ongoing program only.
- The project involves only oral history activities, such as open ended interviews, that ONLY document a specific event or the experiences of individuals without intent to draw conclusions, generalize findings, or influence policy or practice.

Project Title:
Principal Investigator (PI):
PI Department:
PI Phone & email:
Co-Investigators (list all co-investigators):
Faculty Advisor (if PI is a student):

Provide below a brief description of the purpose of this study and the type and source of the information on individuals that you will use.

Investigator's Assurance

I certify that the information provided in this Registration Form is complete and accurate. I understand that as Principal Investigator, I have ultimate responsibility for the ethical conduct of this project.

Principal Investigator: _____ Date: _____

Faculty Advisor's Assurance

I certify that the student is knowledgeable about the regulations and policies governing the research and has sufficient training and experience to conduct this particular study.

Faculty Advisor: _____ Date: _____

Please submit this form to the IRB

Excluded from IRB review: _____ Date: _____
IRB Chair/Designee