Human Subject Research and the Institutional Review Board (IRB) process

Question 1: Does your project involve human subjects? (That includes ANY interaction with a living person for data collection, including: interviews, surveys, analysis of previously collected data - see full definition below.)

If no then STOP HERE because your project does not require IRB approval because it does not involve human subject research.

If yes, then proceed to Question 2.

Question 2: Does your project fit the definition of generalizable knowledge?

*According to the UIC Office of the Protection of Research subjects: Research completed as part of a Classroom Project, Capstone or Senior Thesis **does not** meet the definition of generalizable knowledge and you **do not need IRB approval** to present your findings at the Student Research Forum and other research forums and symposia held on campus where the purpose is to share the results of student research.*

However, if your project **does meet** the definition of generalizable knowledge because you or another member of your research team intends to present some or all of your work at a professional meeting or publish them in a journal or other professional venue **outside UIC**, then proceed to question 3.

If no then STOP HERE because your project does not require IRB because it does not fit the definition of generalizable knowledge.

If yes, then proceed to question 3.

Question 3: Will your research be carried out as part of your Capstone supervisor's research program and therefore be covered by their IRB Approval? Ask them if you are unsure.

a. If yes, you will need to provide the Name of the UIC Faculty Advisor/Mentor (Principal Investigator) and Protocol # of the UIC IRB Approved study when you submit your abstract to the UIC SRF or apply for research grants.
b. Also if yes, ask your capstone supervisor if they have added you as Key Research Personnel to their protocol. Your supervisor can contact Charles Hoehne (choehne@uic.edu) or Cynthia Tom-Klebba (cklebba@uic.edu) at OPRS for guidance if they are not sure whether this step is necessary or have other questions.

If you answered yes, then STOP HERE because your project will be covered by your supervisor's IRB approval.

Question 4: Are you the principal investigator for your project and therefore need IRB approval?

If you answered YES, then it means your research project –

a) Involves human subjects,
b) and you plan to present or publish your work outside UIC,
c) and it is not covered by your capstone supervisor's IRB approval,
d) so you are the principal investigator and your capstone supervisor is your faculty sponsor.

Consult with your capstone supervisor and then contact Charles Hoehne (choehne@uic.edu) or Cynthia Tom-Klebba (cklebba@uic.edu) in the Office of the Protection of Research Subjects as quickly as possible to begin the process of applying for IRB approval as the principal investigator.

Your research must be approved by the UIC Institutional Review Board **BEFORE YOU CAN BEGIN YOUR PROJECT.**

Definitions of human subject and generalizable knowledge – for more information, go to the UIC Office of the Vice Chancellor for Research Human Subjects webpage - http://research.uic.edu/compliance/irb

"**Human Subject**" as defined by the U.S. Department of Health and Human Services (DHHS) regulations means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. [45 CFR 46.102(f)]

- "Intervention" as defined by DHHS regulations means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. [45 CFR 46.102(f)]
- "Interaction" as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]
- "Private information" as defined by DHHS regulations means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). [45 CFR 46.102(f)]
- "Identifiable information" as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

"**Research**" as defined by DHHS regulations means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

OPRS has determined that the following activity does not represent human subjects research because it does not contribute to generalizable knowledge and the submission of a Determination of Whether An Activity Represents Human Subjects Research at UIC form has been waived:

- The project is limited to course-related activities designed specifically for educational or teaching purposes; where data is collected from and about human subjects as part of a class exercise or assignment and is not intended for use outside of the classroom.
- OPRS includes capstone and senior theses in the definition of course-related activities designed specifically for educational or teaching purposes.