

## Educational Activities Possibly Involving Human Subjects

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### POLICY:

- I. Research and teaching at the UIC must meet the highest ethical and professional standards.
- II. Definitions of research and the strength of the boundary between research and education may vary widely among disciplines. However, normal educational activities, including those designed to train students in research techniques and methods, or to qualify students as researchers, when those activities are conducted as part of courses or in normal classroom settings, often fall outside the federal definition of "research" under 45 CFR 46.102(d) and do not require IRB/OPRS review and approval. For such activities, ethical supervision is provided by the faculty, program directors, department heads/chairs, and college deans.
- III. Researchers must consult the appropriate definitions of "research" and "human subject" to determine when they must submit a proposal for review by the IRB.
- IV. Graduate theses and dissertations are clearly understood as "research" and fall within IRB jurisdiction when "human subjects" (as defined in 45 CFR 46.102(f)) are involved.
- V. If a student and/or the faculty advisor/class instructor is unsure whether or not the student's project involves human subjects research, they should contact an OPRS staff member for advice at (312) 996-1711.

### DEFINITIONS:

- I. "RESEARCH INVOLVING HUMAN SUBJECTS" means any activity that either:
  - A. Meets the DHHS definition of "research" and involves "human subjects" as defined by DHHS; or
  - B. Meets the FDA definition of "research" and involves "human subjects" as defined by FDA.
- II. "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)).

- III. "HUMAN SUBJECT" as defined by 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)).
- A. "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)).
  - B. "Interaction" as defined by DHHS regulations means communication or interpersonal contact between investigator and subject (45 CFR 46.102(f)).
  - C. "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)).
  - D. "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).
- IV. "RESEARCH" as defined by FDA regulations means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations (21 CFR 50.3(c), 21 CFR 56.102(c)).
- A. "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act" means any use of a drug other than the use of an approved drug in the course of medical practice (21 CFR 312.3(b)).
  - B. "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act" means any activity that evaluates the safety or effectiveness of a device (21 CFR 812.2(a)).
  - C. "Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research (21 CFR 50.3(c), 21 CFR 56.102(c))."
- V. "HUMAN SUBJECT" as defined by FDA regulations means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient (21 CFR 50.3(g), 21 CFR

56.102(e)). A human subject includes an individual on whose specimen a medical device is used.

## PROCEDURES:

- I. In general, student research projects or assignments will fall into one of three potential review categories:
  - A. Student projects that are solely classroom directed exercises and that do not meet the definition of research, and therefore, do not require IRB review (i.e., activities associated with research methodology courses, field practicum<sup>1</sup>, and internships).
  - B. Student projects that meet the definition of research under 45 CFR 46.102(d) and that meet the requirements for one or more of the six exemption categories (<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c>) require submission to the IRB/OPRS for review and an exemption determination.
  - C. Student projects that meet the definition of research and that involve human subjects, but do not qualify for an exemption. These projects require review and approval by the IRB. Projects that involve minimal risk and that meet the requirements of one or more of the expedited review categories are eligible for expedited IRB review (<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c8>). Projects that either do not meet the requirements of the expedited categories or that involve greater than minimal risk require full (convened) IRB review.
- II. Student projects that do not require either IRB or OPRS review:
  - A. Student projects that have the objective of providing research experience for the student and that do not have the intent or goal to contribute to generalizable knowledge when the project is begun, do not require either IRB or OPRS review or approval. For example, research practica are student projects completed in a course designed to provide students with an opportunity to practice various research methods such as interviews, observations, survey techniques, and sometimes data analysis. These projects are not undertaken to contribute to generalizable knowledge and will not be shared with individuals outside the classroom. Other examples of classroom activities include patient evaluations for nursing students and student counseling techniques.
  - B. Generally, these projects involve minimal risk to the subjects, and it is highly recommended that the students record data anonymously (i.e., no names, social security numbers, or codes that can be directly linked to the subject's name). Frequently, students engaged in learning research techniques

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<sup>1</sup> Masters of Public Health (MPH) Capstone projects that are only submitted in writing to faculty reviewers and/or presented at a forum open only to the School of Public Health (SPH) community do not require IRB review and approval. However, if MPH students plan to submit their capstone paper for publication or for presentation at meetings open to the public (e.g., a regional conference), they must seek the appropriate level of review through OPRS and the IRB, as they may be conducting "human subjects research."

conduct research that focuses on controversial or compelling topics. Occasionally, focusing on these sensitive areas, such as collecting data about illegal activities (i.e., drug abuse, child abuse, prostitution) can cause emotional distress to subjects or potential risk to the subject if there is a confidentiality breach. Although practica are not under the purview of the IRB, the OPRS staff is available to provide the student and/or the faculty advisor with guidance regarding protections that could be part of the student research protocol. The faculty advisor or instructor should ensure that the research practica are conducted according to current ethical standards for the discipline.

- III. Student projects that meet the definition of research and require an exemption determination by the IRB/OPRS or IRB review via expedited or convened review:
- A. Any research that is conducted by students (graduate, undergraduate) that will contribute to generalizable knowledge and involves human subjects, must be reviewed by the IRB before the research may begin. This includes students conducting research for their thesis, dissertation, classroom or independent study projects.
  - B. Student projects that are exempt from IRB/OPRS review include any project that meets the definition of research, includes human subjects, and that meets the criteria for one or more of the exemption categories in the federal regulations.
    - 1. An exemption determination means that the research is exempt from meeting all the research requirements outlined in Subpart A of 45 CFR 46 and would not require continuing IRB review. However, these projects still require that the IRB or OPRS make the exemption determination prior to initiation. This determination cannot be made by the researcher. Student projects in this category include projects that might involve interview procedures which collect the data anonymously (i.e., without the recording of names, social security numbers, or other codes that can be directly linked to the subject).
    - 2. Examples of research in this category include observations of persons in commonly accepted settings (provided the researcher does not interact with the subject), studies that focus on normal educational practices, curriculum, instructional techniques, or management strategies, or studies involving existing data sets or files in which subjects cannot be identified.
    - 3. Please refer to the UIC OPRS form *Claim of Exemption* application or the Getting Started portion of the OPRS web-site for further information regarding the exemption categories and the exemption review process.
  - C. It is recognized that time constraints accompany projects of this nature, and every effort will be made to review the applications in a timely manner. The student researcher and/or the faculty advisor should plan on submitting a Claim of Exemption application at least two weeks before the research is to begin. Normally, this should allow ample time for the review process to occur. If the project is a requirement for graduation, it is suggested that the

applications be submitted very early in the semester in order to allow time for the review process and conduct of the research.

- D. All non-exempt student research projects must be submitted for IRB review and approval before the research may begin. For further information regarding the expedited and convened review processes, please refer to the OPRS web-site Getting Started page and the Initial Review application forms (either Biomedical/Health Sciences or Social/Behavioral Sciences, which ever is most appropriate to the research protocol).

IV. Guidelines for Instructors and Faculty Advisors.

- A. Even if student projects do not meet the definition of research involving human subjects, it is highly suggested that the research course include basic information about the existence of and the reasons for human subject protection regulations designed to safeguard human research subjects. Students should be familiar with the concepts of ethical conduct of research, risk/benefit analysis, confidentiality, and informed consent, particularly when student research involves the submission of a Claim of Exemption application or an Initial Review application for either expedited or convened review. It is the instructor's or Faculty Advisor's responsibility to ensure that student research is conducted according to current and applicable ethical standards.
- B. Instructors are responsible for screening the individual student research projects and making an initial determination regarding whether or not the project may require IRB review or a determination of exemption. If the student and instructor are uncertain about IRB review and approval or an exemption determination, they should contact an OPRS staff member at (312) 996-1711. When the research requires IRB review and approval or an exemption determination, it is the instructor's/Faculty Advisor's responsibility to assist the student in preparing the materials to be reviewed by the IRB. If the instructor will not fulfill the role of the Faculty Advisor, he/she should assist the student in obtaining an adequate Faculty Advisor. The Faculty Advisor is responsible for supervising the student and ensuring that the conduct of the research meets ethical and academic standards, including the adherence to UIC policies and procedures for human subjects research. The instructor/Faculty Advisor must also maintain the research records for three years after completion of the research, as required by the federal regulations. Depending upon the type of research, longer record retention periods may be required (i.e., research that involves the use of protected health information).
- C. Before the research protocol application is submitted to the IRB, faculty advisors must ensure that both the student (undergraduate and graduate) and the Faculty Advisor have completed the required human subjects protection training. If training has not been completed, OPRS will not be able to accept the student's application for IRB review. Additionally, if the research involves the use of PHI, both the Faculty Advisor and the student must complete HIPAA Research 101 training. For further information regarding the educational requirements for research investigators, please refer to the OPRS web-site:

<http://tiggeruic.edu/depts/ovcr/research/protocolreview/irb/education/index.shtml>.

- D. In instances where a class of students will be conducting group or individual research projects of a very similar nature as part of a classroom instruction, and the instructor believes that the research requires IRB review and approval, the instructor may submit a single protocol (an umbrella protocol) that covers the research conducted by all the students. All research conducted by the students must fall under the parameters described in the umbrella protocol. Each student should be listed as a co-investigator on the umbrella protocol application to the IRB and meet the necessary human subject protection training requirements.

**REFERENCES:**

[21 CFR 50.3\(c\)](#), [21 CFR 56.102\(c\)](#), [21 CFR 312.3\(b\)](#), [21 CFR 812.2\(a\)](#), [21 CFR 50.3\(g\)](#),  
[21 CFR 56.102\(e\)](#)  
[45 CFR 46.102\(d\)](#), [45 CFR 46.102\(f\)](#)

**REVISION LOG:**

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4.0, 10/01/08	3.0, 8/3/06	Introductory material removed.