Fullerton College Institutional Review Board

POLICY FOR CLASSROOM RESEARCH INVOLVING FACULTY AND STUDENTS



I. Introduction

The Fullerton College Institutional Review Board (IRB) is guided by the government's health and human services 45 CFR 46 (Common Rule) in its definition of classroom research that is low risk and non-generalizable. In accordance with the Common Rule, the IRB distinguishes between low-risk research conducted in a classroom as part of the learning experience from more than minimal risk research that may or may not be conducted to add to generalizable knowledge or a professional body of knowledge. The primary purpose of this policy is to clarify what types of research projects must be reviewed by the IRB versus classroom research that is exempt.

II. Definitions

- 1. Exempt classroom research projects are part of the student's coursework; is supervised by a faculty member; has as its primary purpose the development of the student's research skills; does not present more than minimal risk to participants or to the student investigator; does not include any persons as research subjects under the age of 18; does not include any persons as research subjects who are classified as part of a vulnerable populations according to Code of Federal Regulations; is not going to be disseminated in a public form during the semester or in the future. See information on studies that quality for exempt status under the Office for Human Research Protections Section 46.104 on the hhs.gov Webpage.
- 2. Dissemination means the distribution of findings and includes, but is not limited to, masters and doctoral theses/dissertations, presentation at a scientific meeting or conference, submissionto or publication (paper or electronic) in a scientific journal, and posting on the Internet.
- 3. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (a.) data through intervention or interaction with the individual, or (b.) identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes 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 whichhas 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). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

4. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life (i.e., when environmental conditions are non-stressful and ideal), unobtrusive activities occurring in public settings, or in a classroom setting. For additional information, see §46.104 Exempt research.

III. Policy for IRB Approval of Classroom Research Projects

1. <u>Projects that Need IRB Approval</u>: Projects that do not meet all of the exempt classroom research conditions, which are stated below, must be submitted to the IRB for review prior to starting data collection. https://ie.fullcoll.edu/irb/

Application to the IRB for these student research projects must include a faculty member who will be named as the *Principal Investigator* of the project and who will assume responsibility for the project.

Note: Faculty members who collect student data for classroom activities must adhere to the requirements stated below or they will need to submit proposals for IRB approval.

- 2. <u>Exempt Classroom Research Projects</u>: projects that meet all of the conditions stated below may be conducted under the supervision of the faculty member without submitting a protocol to the IRB.
 - a. the student research projects do not exceed minimal risk and are conducted by students as a part of non-disseminatable classroom assignments. The activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures, including research methods (interviewing, observation and survey techniques, as well as data analysis). In such cases, the classroom projectdoes not require Fullerton College IRB submission and approval.
 - b. the projects must meet the definition of classroom research/student research. This isdefined as a project which:

is a normal part of the student's coursework; is supervised by a faculty member; has as its primary purpose the development of the student's research skills; does not present more than minimal risk to participants or to the student investigator; does not include any persons as research subjects under the age of 18; does not include any persons as research subjects who are classified as part of a vulnerable populations according to Federal regulations (see below); is not going to be disseminated in a public form during the semester or in the future.

c. the projects must meet all the criteria for an Expedited Review as defined in the Federal Regulations: HHS Government Expedited Review. If the faculty member has concerns or doubts,

he/she should consult with the Office of Human Subjects Research.

d. the projects do not involve a special population or sensitive topic area is part of the project. If the activity involves special populations or sensitive topics, they need to be submitted for Fullerton College IRB approval.

Categories of sensitive information include information:

1) Relating to sexual attitudes, preferences or practices; 2) Relating to use of alcohol, drugs or other addictive products; 3) Pertaining to illegal conduct; 4) Pertaining to an individual's psychological well-being or mental health; 5) Relating to childhood trauma; 6) Personal Genetic Information; 7) Information that if released could reasonable damage an individual's financial standing, employability, or reputation within the community; 8) Data that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination.

Categories of special subject population:

- 1) Minors (under eighteen years of age). 2) Fetuses or products of labor and delivery; 3) Pregnant women (in studies that may influence maternal health); 4) Prisoners; e) Individuals with a diminished capacity to give informed consent.
- e. faculty teaching research methods and overseeing student research projects are expected to understand the philosophy, ethics and practice of protecting human subjects in research; to adhere to these principles during the conduct and supervision of classroom research projects; andto teach these practices and principles to students. Faculty will be responsible for ensuring thatall student research projects are conducted in accordance with federal regulations and principles regarding protection of human subjects in research.
- f. Faculty who will be Principal Investigators on classroom research projects must complete the *Social & Behavioral Research* program through the Collaborative Institutional Training Initiative (https://citiprogram.org/).

IV. Tips for Faculty and Additional things to Consider

Please note that, consistent with Fullerton College policy, all teaching assignments involving human subjects must respect the rights and welfare of all individuals involved. The following suggestions for the faculty members provide guidance concerning student classroom projects:

1. Consider the nature and intent of the activity. If the course assignment involves systematic data collection and if any intent of the activity is to develop or contribute to generalizable knowledge -- an indication of which is intent to publish the data -- then the student classroom project is probably research and needs to be individually reviewed and approved by the IRB.

- 2. IRB approval cannot be made retroactive. If there is any likelihood that the results of the project might later be used for research that does lend to generalizable knowledge (for example,a presentation to a group other than the class), IRB approval must be sought prior to conducting the research. IRB approval cannot be granted retroactively.
- 3. Minimize risks whenever possible. Faculty members should help students understand that they are obligated to minimize risks for human subjects with whom they interact during the completion of their assignments. Depending on the circumstances, faculty members may find some of the following suggestions for students helpful:

Have students take the *Social & Behavioral Research* program through the Collaborative Institutional Training Initiative (https://citiprogram.org/) which covers human subject protection before collecting information from others.

Encourage the use of anonymous data collection so that data are not linked to specific individuals.

Have information identifying individuals kept separately from the information collected from those individuals. This includes ensuring that consent forms are not linked to the data and that IP addresses are not linked to the data.

Collect project data at the end of the course, or within a short time afterward, and request all copies in the student's possession be destroyed.

Ask for help! Ask the Office of Institutional Effectiveness for guidance when you are unsure of what review process is needed for a student classroom project (ie@fullcoll.edu)

V. Thesis/Dissertation Research

Thesis and dissertation projects involving human subjects are considered research as defined by 45 CFR 46 and require review by the Fullerton College IRB.

NOTE: This policy of student research that does not need IRB approval applies to student class assignments only. Those independent research projects conducted by students, such as honors projects, and independent study projects, that collect data through interactions with living people or access to private information fall under the jurisdiction of the IRB. Application to the IRB for these student research projects must include a faculty member who will be named as the *Principal Investigator* of the project and who will assume responsibility for the project