CLASSROOM EXEMPTED RESEARCH

OBJECTIVE

The purpose of this standard operating procedure is to describe the procedure for the UNC Asheville faculty to process certain classroom and student research protocols.

DESCRIPTION

Activities involving human subjects for which the primary purpose of the engagement is to provide a learning experience in research methods or procedures do not meet the federal definition of research and are excluded from IRB oversight. It is recognized that such activities may be of benefit to students and/or the community and not meeting the formal designation of research is not an assessment of the potential value of the activity.

DEFINING CLASSROOM RESEARCH/ACTIVITIES

If an activity is found to meet the research definition it may be considered for exemption of IRB oversight based on criteria defined by the Protection of Human Subjects (45 CFR 46) and provided in the exemption form. Some otherwise exempt projects may not be granted an exemption based on factors such as those involving greater than minimal risk, targets vulnerable populations, or involving methods or questions with sensitive, personal, or incriminating topics.

All of the following must be true in order for human subject activities in a classroom setting to be considered outside the purview of the IRB:

- It is a normal part of the student’s coursework;
- It is supervised by a faculty member;
- Its primary purpose is the development of student skills;
- It does not involve more than minimal risk;
- It does not include any research subjects under the age of 18;
- It does not involve any persons who could be considered as coming from protected or vulnerable populations;
- It does not involve personal, incriminating, or sensitive topics; and
- It is not pursued in order to publish the results or share at professional and academic conferences and gatherings.
Research projects involving human subjects for which the primary purpose of the research is to be a learning experience in the methods or procedures of research do not meet the federal definition of “research” and are eligible for a classroom exempted protocol unless the research involves greater than minimal risk, targets vulnerable populations, or involves methods or questions with sensitive, personal or incriminating topics.

A full definition of research and minimal risk are provided within this operating procedure’s definitions.

**PROCEDURE**

The faculty advisor must request an exempt status determination from the IRB by submitting a completed Exemption Form via the IRB software management system. Before applying for exempt status, the faculty advisor should confirm that their study is, in fact, considered research with human subjects.

The Exemption Form should be completed. This should include a copy of the syllabus for the course, along with any other relevant documents (e.g., informed consent / parent permission / assent / information sheet, surveys, interview questions, data collection sheets, recruitment materials, facility authorization, etc.)

A. **Training Requirements**

Faculty who serve as advisors or supervisors of student research, both undergraduate and graduate, must complete Collaborative Institutional Training Initiative (CITI Program) education requirements. Assistance with CITI Program certification is available on the IRB website or through the Office of Research and Sponsored Programs.

Student researchers are strongly encouraged to take and complete the CITI Program for human subjects’ protections. In most circumstances, course completion certificates are transferable to graduate schools.

B. **Continuation of Classroom Research**

No classroom research declaration will be granted a continuation beyond one year.

C. **Modification of Classroom Research**

Minimal changes to exempt studies may not need to be reviewed. Modification requests would not typically be required for the following types of modifications to the approved study:

- Personnel changes (e.g., change in members of the research team; however, change in the lead investigator requires a modification request)
- Change in the number of subjects to be enrolled
- Change of status (e.g., continuing to enroll additional subjects)
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- Non-substantive editing of associated documents (e.g., recruiting announcements, consent/assent documents)
- Change in tool used in the protocol that is unrelated to human subject risk (e.g., substitution or minor revision of instrument used in the study)

It is the responsibility of the faculty advisor to document minor changes to the approved classroom study. In the event of an audit, these documented changes must be provided to the IRB.

Any substantive change to the classroom research may invalidate its exempt determination. The faculty advisor is responsible for consulting with the IRB when changes are planned, to ascertain whether a new exempt determination, IRB review, or no action is required. Faculty advisors may contact the IRB via email detailing the changes. The IRB Chair will acknowledge the changes and notify the faculty advisor if any further action needs to be taken.

APPLICABLE REGULATIONS AND GUIDELINES

- 46 CFR 46.115 Protection of Human Subjects (Department of Health and Human Services)

DEFINITIONS

Classroom – Singular research project distributed workload over the entire class or smaller projects conducted by teams of student researchers. Individual student projects within a classroom setting does not qualify for the classroom/team exemption.

Exempt – Research that is found to be “exempt” is still considered to be human subjects’ research. However, it is exempt from meeting the requirements of the federal human subjects’ regulations, including the requirement for initial and annual IRB review.

Minimal risk – UNC Asheville applies the definition of minimal risk provided in the federal regulation (45 CFR 46.102): The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Student research projects that fit the categories below are generally considered minimal risk:

- Research involving the use of educational tests, survey procedures, and interview procedures;
- Observation of public behavior if anonymity is maintained;
- Research with subjects who are elected or appointed public officials or candidates for public office, regardless of whether the subjects may be identified or the information is sensitive;
- Research on individual or group characteristics or behavior in such areas as perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, provided that anonymity and confidentiality are maintained;
- Research employing oral history, focus group, program evaluation, or quality assurance methodologies;
- Collection of data through voice recordings for research purposes;
• Research involving the collection or study of existing data, documents, or records if the sources are publicly available or the information is recorded so subjects cannot be directly or indirectly identified.

Research - “Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” 45 CFR 46.102(d)

To be considered a “systematic investigation”, the concept of a research project must meet all of the following:
• Attempt to answer research questions (in some research, this would be a hypothesis).
• Is methodologically driven, that is, it collects data or information in an organized and consistent way.
• The data or information is analyzed in some way, be it quantitative or qualitative data.
• Conclusions are drawn from the results.

“Generalizable Knowledge” would include one or more of the following concepts:
• The knowledge contributes to a theoretical framework of an established body of knowledge.
• The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study.
• Publication, presentation or other distribution of the results is intended to inform the field of study.
• The results are expected to be generalized to a larger population beyond the site of data collection.
• The results are intended to be replicated in other settings.
• Web based publication for professional purposes.

Sensitive Topics - Research involving topics that may cause greater than minimal distress among participants or confidential information that could place a participant at risk if disclosed are considered sensitive topics. Any interview, survey, or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but no limited to, any of the following sensitive topics require IRB review and approval:

• Sexual orientation, sexual harassment, sexual assault, sexual molestation or abuse, incest, practices of contraception, abortion, and/or pregnancy;
• Substance use and/or abuse including but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics, any prescription medication legally or illegally obtained;
• Questions regarding mental health (e.g., suicide, depression, obsessive-compulsive disorders, drug use, underage drinking, gambling, and/or eating disorders);
• Traumatic experiences (e.g., being a victim of violence, child abuse, senior abuse, war or combat experiences).

Vulnerable populations – Children, persons seeking emergency treatment, persons geographically located outside the United States, and prisoners are considered to be a vulnerable population.
Classroom Research Project Checklist

This document is intended to assist UNCA instructors in assessing whether classroom research projects may be excluded from expedited or full Institutional Review Board (IRB). All items below must be satisfied for classroom projects to proceed outside of IRB review. For questions relating to such projects, we encourage instructors to contact the IRB at irb@unca.edu.

☐ The research project is to be performed by students enrolled in a graduate or undergraduate course at UNCA as a requirement for completion of the course.

☐ The overriding and primary purpose the project is as a learning experience in the methods and procedures of research.

☐ The instructor is fully aware of all aspects of the research project and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of those activities.

☐ There is no intent on the part of the instructor or student to produce generalizable knowledge or to disseminate the findings beyond presentation to instructors or peers in a UNCA classroom setting.

☐ The project involves minimal risk to subjects (i.e., when "the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests").

☐ The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed.

☐ The project does not involve persons from vulnerable populations as participants.

☐ The project involves the voluntary participation of individuals without any coercion or pressure being placed upon them. The instructor/students have considered whether a consent document should be provided to participants.