	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Activities That Do Not Meet the IRB Definition of Human Subjects Research (NHSR)	#1.1

The purpose of this SOP is to provide guidance on various campus activities that do not meet the IRB definition of human subjects research and may not require IRB review.

I. General Requirements

Certain activities conducted by UNCW faculty, staff and students do not meet the IRB definition of research with human subjects, and thus do not require IRB review. However, those conducting these activities must conduct them in an ethical and professional manner that is consistent with the code of ethics for the applicable professional discipline. If the activity is conducted by a student, it should be conducted under the close supervision of a faculty advisor.

Individuals conducting these activities are strongly encouraged to submit a brief application in the UNCW IRBIS system to notify the IRB of the activity and to obtain confirmation through the IRB that further review is not required. This allows the IRB to be aware of the activity if IRB staff receive any calls or concerns, and provides the individual(s) conducting the research with documentation that confirmation from the IRB was obtained.

II. Scope

This SOP pertains to a variety of campus activities that may involve collecting data from individuals or obtaining data that identifies individuals, but does not meet the definition of human subjects research.

III. Applicable Definitions

A. Human subject (45 CFR § 46.102(e))

A living individual, about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

1. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2. Interaction includes communication or interpersonal contact between investigator and subject.

3. 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

4. Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

5. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

B. Minimal risk

The probability and magnitude of harm or discomfort anticipated in an activity are not greater in and of themselves than those ordinarily encountered in daily life.

C. Research (45 CFR § 46.102(l))

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of HHS policy, whether or not they are supported under a program that is considered research for other purposes.

D. Systematic Investigation

A cohesive approach involving data collection (quantitative or qualitative) from one or more individuals and analysis to address a question or test a hypothesis.

E. Generalizable Knowledge

The results or outcomes gained from systematic investigation are expected to contribute to a theoretical framework of an established body of knowledge, be viewed in some way as relevant to a larger population beyond the data collection or population studied, and intended to be replicated in other settings.

IV. Activities That Do Not Involve Human Subjects

A. Research on Existing Data

Certain activities involving the analysis of de-identified data, either publicly available or collected from a previously approved human subjects study, do not constitute human subjects research, in that there is no interaction or intervention with an individual to obtain the data, and there is no use of private identifiable data. Researchers are advised to submit a brief application in the IRBIS system to describe the activity so that IRB staff may confirm that human subjects are not used.

B. Minors Participating in UNCW Research Activities for Educational Purposes Only

1. Generally

When minors are enrolled in UNCW courses, either through the Isaac Bear Early College or because regularly enrolled UNCW students have not yet reached age 18, researchers may allow them to participate in research activities for educational purposes only, provided that:

a. The study was reviewed by the IRB through the expedited review process or determined to be exempt;
b. The researcher does not use any data obtained from the minor for research purposes (thus not constituting research using a human subject); and
c. The study involves content that a reasonable person would consider appropriate for a minor to be exposed to.

2. Waivers of Parental Permission
Researchers who wish to collect data from regularly enrolled UNCW college students who have not yet reached the age of 18 may do so provided that they request approval from the IRB to waive the parental permission requirement. Researchers interested in this option should refer to the instructions provided in SOP 6.8, section IV.D.2. This option is not allowable for Isaac Bear Early College students.

C. Surveying or Interviewing Key Informants

Members of the UNCW community can plan to conduct research that asks individuals to complete surveys or interviews asking for information on certain topics. Those individuals are considered "key informants" or experts on those topics, rather than human subjects, when the survey or interview questions focus on the topic of interest as opposed to attempting to collect personal information about the individual. While conducting these surveys or interviews meets the IRB definition of research, the key informants/experts are not considered human subjects, and thus the activity may not require IRB review and approval. Researchers are advised to submit a brief application in the IRBIS system to describe the activity, and upload a copy of the survey or interview questions so that IRB staff may confirm that human subjects are not used.

V. Activities that Do Not Meet the IRB Definition of Research

D. Classroom Projects

1. General Requirements

Learning how to conduct ethical human subject research is an important part of a student's educational experience. Research activities that are designed as part of a course requirement for purposes of learning experience only might not meet the IRB definition of "research" in that they are not designed to develop or contribute to generalizable knowledge, and thus may not require IRB review and approval if all of the following conditions are true:

a. Results of the research are either
   i. viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes, or
   ii. viewed by other, limited members of the campus community through a poster presentation or other event that is a required aspect of a course (such as a capstone presentation event);

b. The research procedures pose no more than minimal risk to participants;

c. Vulnerable populations are not targeted (e.g., children under age 18, prisoners, persons who are cognitively impaired, etc.); and

d. When appropriate, some process is in place to inform participants of the voluntary aspect of the activity.

2. Responsibility of the Course Instructor

The course instructor is responsible for communicating to the students information related to the ethical conduct of human subject research, ensuring the protection of participants, and for monitoring the students' progress. Instructors are encouraged to contact IRB staff who will be happy to make a presentation to students on research ethics, even if the activity does not require IRB review. Instructors are also encouraged to instruct students to complete the online human subject protections training offered by the CITI program, although this is not required for activities that do not meet the IRB definition of human subjects research. Instructors are encouraged to direct their students to submit a brief application in the IRBIS system to describe the activity so that IRB staff may confirm that the activity does not meet the IRB definition of human subjects research.

E. Quality Assurance/Quality Improvement Studies

1. General Requirements

It is important for medical practitioners to have the ability in their organizations to determine if certain clinical or administrative practices are effective in their particular settings. When quality assurance/quality improvement (QA/QI) activities (such as reviewing in-house medical records, collecting new patient or provider data, or testing an established intervention for the purpose of improving patient care and informing internal clinical practices) are undertaken to fulfill a course requirement, the activities might not require IRB review and approval if all of the following conditions are true:

a. The activity is not a *systematic investigation* that intends to collect *scientific evidence* on an *untested clinical intervention* to determine how well the intervention achieves intended results;

b. The student conducting the QA/QI activity is an employee of or placed in the organization/facility in which the data is going to be collected *(note: If the student is not an employee or placed in the facility, the project may still be considered a program evaluation rather than QI/QA, if the student is acting as an external evaluator);*

c. The QA/QI activity procedures pose no more than minimal risk to participants;

d. The student conducting the activity will not remove identifiable data from the facility in which they work as part of the project *(note: All of the data needs to be de-identified before it leaves the premises. Students should work with their faculty advisors and the facility in which the project is conducted to ensure any applicable privacy and confidentiality requirements are maintained);* and

e. The facility in which the activity is conducted, or any affiliated institution, does not require IRB review and approval *(note: some QA/QI activities meet the definition of human subjects research. Even if an activity does not meet the UNCW IRB definition of human subjects research, some IRBs interpret the regulations differently or have internal policies that consider all QA/QI activities to be human subjects research. If a QA/QI activity is conducted at a medical center or other institution with its own IRB, the UNCW IRB will likely not have jurisdiction over this determination, and will defer to any determination made by the presiding IRB.)*

2. Responsibility of the Faculty Advisor

The faculty advisor of a student who will conduct a QA/QI activity to fulfill a course requirement is responsible for ensuring that the student has a comprehensive understanding of how to conduct QA/QI activities in an ethical manner, ensuring the protection of participants, particularly in protecting the confidentiality of their data, and for monitoring the student's progress. Faculty advisors are encouraged to contact IRB staff who will be happy to make a presentation to students on research

ethics, even if the activity does not require IRB review. Faculty advisors are encouraged to instruct students to submit a brief application in the IRBIS system to describe the activity so that IRB staff may make a determination that the activity does not constitute human subjects research. Faculty advisors and students are also encouraged to refer to additional guidance documents posted on the UNCW Human Subjects Research website related to QA/QI projects.

F. Program Evaluations

Members of the UNCW community can be presented with the opportunity to conduct evaluations of specific internal or external programs to determine if the programs are effective. When the results of those evaluations will be shared within the organization to be used solely for organizational decision making, and are not intended to be generalized to other institutions or populations, the activities might not meet the IRB definition of "research" in that they are not designed to develop or contribute to generalizable knowledge, and thus may not require IRB review and approval. If evaluators will conduct an evaluation on behalf of an external organization, evaluators should be mindful of the type of data they will receive and comply with any other regulations that may apply, such as HIPAA, SAMHSA, FERPA, etc. Researchers are advised to submit a brief application in the IRBIS system to describe the activity so that IRB staff may make a determination that the activity does not constitute human subjects research.

V. References to Other Applicable SOPs

Name	SOP #

VI. Responsibilities

Title	Responsibility
IRB Staff	Responsible for reviewing applications to determine if an activity constitutes human subjects research.
Instructors/Faculty Advisors	Responsible for properly informing students about activities that require IRB review, providing oversight on activities that do not require IRB review, ensuring research activities that are conducted to fulfill course requirements are done so in an ethical and professional way.
Principal Investigators	Responsible for conducting program evaluations or research activities involving key informants or experts in an ethical manner that is consistent with the ethical norms of the applicable profession.

VII. Resources

A. UNCW IRB Website: http://uncw.edu/sparc/integrity/irb.html
B. U.S. Department of Health & Human Services, Office of Human Research Protections website: https://www.hhs.gov/ohrp/
C. 45 CFR 46 ("Common Rule"): https://www.ecfr.gov/cgi-bin/text-idx?SID=35bc99be4c5c00f1d8df15f265d4c2ef&pitd=20180719&node=pt45.1.46&rgn=div5
D. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
E. U.S. Department of Health & Human Services, Health Information Privacy website: https://www.hhs.gov/hipaa/index.html
F. U.S. Department of Health & Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) website: https://www.samhsa.gov/laws-regulations-guidelines
G. UNCW Policy 04.150, Student Records & Family Educational Rights and Privacy Act (FERPA): https://www.uncw.edu/policies/documents/04150FERPA.pdf