UNIVERSITY OF NORTH CAROLINA CHARLOTTE | DIVISION OF RESEARCH

Guidance: Examples of Activities that Do and Do Not Require UNC Charlotte IRB Review and Approval

The Investigator has the responsibility for initial determination as to whether an activity is human subjects research. The University will hold Investigators responsible if an IRB application was not submitted when required. As such, it is strongly recommended that Investigators contact the Office of Research Protections and Integrity for guidance and confirmation regarding the applicability of the federal human subjects research regulation and UNC Charlotte policy.

This guidance document provides descriptions of activities and associated determinations regarding the requirements to submit to the IRB.

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Innovative Procedures, Treatment, or Instructional Methods	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method using human participants. The investigation is designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge.	YES
	The use of innovative interventions that are designed solely to enhance the well-being of an individual patient or client and have a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to the particular individual. There is no plan to generalize results or publish finding.	NO *(unless FDA regulations requiring IRB approval apply such as use of: articles (e.g., drugs, devices, biologics) that have not been approved for use in humans; articles requiring exemption from FDA oversight; articles under an IND/IDE)*
Behavioral and Social Sciences Research	Focuses on individual and group behavior, mental processes, or social constructs and usually generates data by means of surveys, interviews, observations, studies of existing records, and experimental designs involving exposure to some type of stimulus or environmental intervention.	YES
Class Projects/ Assignments Research Methods Classes	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge or contribute to generalizable knowledge. Activities may be presented in the course (oral or written) with no dissemination outside of the class (e.g. published or disseminated as a capstone or at a conference). Activities may not be used/presented at a student researcher symposium (undergraduate or graduate). Activities are not intended to be used as foundational to an honor's or master's thesis or doctoral dissertation and will not be used as part of/in the thesis or dissertation. Activities are not associated with sponsored research (e.g. grant, contracts, etc.).	NO *(but instructors have an obligation to ensure students meet professional and ethical standards)*

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Capstone Projects Senior Design Projects	Capstone projects are often similar to class projects. These projects generally occur as part of fulling class or culminating program requirements (final product, presentation, performance indicator). These projects generally are not designed to or intended to contribute to generalizable knowledge. Including no publication or external presentation. The requirements and limitations listed above for class projects apply to capstone projects as well. Senior design projects are often similar to capstone projects and intended to be culminating projects. These projects are often applied practical projects. As with capstone projects, the project is generally not designed to develop or contribute to generalizable knowledge. The focus may be on applying skills or considering feasibility and practicality rather than pilot testing or a larger study that is intended to develop or contribute to generalizable knowledge. The requirements and limitations listed above for class projects apply to senior design projects.	NO *(but instructors have an obligation to ensure students meet professional and ethical standards)*
Honor's thesis Master's thesis Doctoral dissertation	Graduate studies which involve human subjects or a clinical investigation which results in a thesis, a dissertation research, or capstone.	YES *(unless the project fits another category where IRB submission is not required.)*
Internet Research	Research involving online interactions with human subjects where identifiers are known or can be ascertained such as email addresses, certain websites and bulletin boards. Also includes data collected where an individual cannot be directly identified and data are collected through online intervention or interaction with research subjects. E.g. completion of an online survey.	YES
	Research involving online interactions with/data collection from human subject internet community members that may expect a level of privacy and confidentiality such as vulnerable populations (HIV patients, alcoholics anonymous, sexual abuse survivors etc.). Also includes data collected where an individual cannot be directly identified and data are collected through online intervention or interaction with research subjects.	YES
Clinical Investigations	Involves research to increase scientific understanding about normal or abnormal physiology, disease states or development and to evaluate the safety and effectiveness or usefulness of a medical product, procedure, or intervention. Experiments using a test article (e.g., investigational drug, device, or biological) on one or more human subjects that are regulated by the Food and Drug Administration (FDA) or support applications for research or marketing permits for products regulated by the FDA. Products regulated include foods, including dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products that aid in diagnosis or treatment of injury or illness.	YES

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Standard Diagnostic or Therapeutic Procedures	The collection of data about a series of established and accepted diagnostic or therapeutic procedures, or instructional methods for dissemination or contribution to generalizable knowledge.	YES
	An alteration in patient care or assignment for research purposes.	YES
	A diagnostic procedure added to a standard treatment for the purpose of research.	YES
	An established and accepted diagnostic, therapeutic procedure or instructional method, performed only for the benefit of a patient or student but not for the purposes of research.	NO
Quality Assurance Quality Improvement Program Evaluation**	Practice of evidence-based medicine; quality assurance or quality improvement projects designed to improve clinical care, patient safety, health care operations, etc. The activity is designed to bring about immediate positive changes in the delivery of health care, programs, or business practices in the local setting. The design does not include comparison or control groups but may include measuring outcomes of the initiative. There is no intent or plan to use the data collected for a secondary research purpose and/or to generalize the findings to the larger community.	NO *(see below for additional information)* *Note: when working in/for a healthcare organization, the organization may require IRB review of some kind, even if UNC Charlotte does not. It is the researcher's responsibility to confirm requirements with the organization.*
	Practice of program evaluation, self-assessment of programs or business practices, and other quality improvement projects where methods rather than humans are the subject of the study. There is no intent or plan to use the data collected for a secondary research purpose and/or to generalize the findings to the larger community.	NO *(see below for additional information)*
	Quality assurance, quality improvement, or program evaluation projects conducted, at least in part, for research purposes. Design may feature comparison or control groups. The original intent and/or secondary intent is to collect data for research purposes to generalize the findings.	YES *(see below for additional information)*
Repositories (e.g., data, specimen, etc.)	A storage site or mechanism by which identifiable human tissue, blood, genetic material or data (could include audio and/or video recordings) are stored or archived for research by multiple Investigators or multiple research projects.	YES
Research involving coded biological specimens/coded private information	Analysis of coded human specimens or coded private human data where: ● The data/specimens were not collected for the currently proposed research, (I.e., current use is for secondary research) ● The investigators cannot link the coded data/specimens back to individual subjects. ● The investigators and the holder of the key (data provider) enter into an agreement (e.g., data use agreement) prohibiting the release of the key to the investigators under any circumstances ● The investigator is not a researcher or collaborator on the specimen or data provider's research. For use of specimens, the research must not be testing a drug or biologic in support of an IND application.	NO

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
	Use of specimens or data may require HIPAA compliance review.	
	Analysis of coded human specimens or coded private human data where: ● The data/specimens were not collected for the currently proposed research, ● The investigators ***can*** link the coded data/specimens back to individual subjects either using direct identifiers or indirect identifiers. ● There is no agreement between the data/specimen provider that prohibits the release of the identity of the subjects and/or the code key linking list. ● The investigator is not a researcher or collaborator on the specimen or data provider's research.	YES
Research Using Publicly Available Data Sets*	Use of publicly available data sets that do not include information that can be used to identify individuals. "Publicly available" is defined as information shared without conditions on use or access restrictions.	NO *(see below for additional information)*
	Data requiring a data use agreement, confidentiality agreement, etc. may not be considered publicly available. The data provider may consider the data identifiable or the risk of deductive disclosure such that human subjects research review is required.	YES
Secondary Use of Research Data	Projects that involve only the secondary analysis of data collected as part of a different research project, if: ● The data were collected anonymously, or ● The data set has been de-identified - any data elements that could be used to identify an individual have been stripped. And there is no linking list/key that can be used to re-identify participants. ● For health-related data, all 18 HIPAA identifiers must be removed.	NO
Research on Organizations	Information gathering about organizations, including information about operations, budgets, etc. from organizational spokespersons or data sources. Does not include identifiable private information about individual members, employees, or staff of the organization.	NO

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Oral History	Interviews concerning the past that collect, preserve, and interpret the voices and memories of people, communities, and participants in past events as a method of historical documentation. The intent is to document a particular past or unique event in history. ● focus exclusively on past events; ● are conducted to understand or explain a particular past or unique event in history; and ● the anonymity of the narrators is not preserved. Conform to the Principles of Best Practices of the Oral History Association: http://www.oralhistory.org/about/principles-and-practices	NO *(meet professional and ethical standards)*
Journalism	Activities focused on the collection, verification, reporting, and analysis of information or facts on current events, trends, issues or individuals involved in such events or issues. There is no intent to test hypotheses, and activities cannot reasonably be characterized as comprising systematic investigation. Code of Ethics of the Society of Professional Journalists http://www.spj.org/ethicscode.asp	NO *(meet professional and ethical standards)*
Case Study	When there is clear intent to generalize the findings. May include activities that would not ordinarily be collected in the course of daily life or treatment/care.	YES
	Analysis and publication of treatment, experiences, or observations provided in a single case where research is not prospectively planned, and no procedures are performed or information collected beyond what would be done for regular (or innovative) clinical care and treatment. There is no intent or plan to develop or contribute to generalizable knowledge. Not involving biospecimens. Not involving FDA regulated products that have not been approved for use in humans. Must still comply with HIPAA requirements (Health Insurance Portability and Accountability Act)	NO
Pilot Studies	Pilot studies used to determine if a study is feasible. Data and findings may be foundational to a thesis, dissertation, or larger study. Data will be used in thesis, dissertation, or other publication (grant application). Although the data derived from a pilot activity may not be included in the full-scale research project, the activity would still need IRB review prior to conducting the activity.	YES

***Research Using Publicly Available Data Sets**

Research projects involving analysis of unrestricted secondary data from the following data sets/repositories will NOT require prior IRB approval, unless the archive hosting the data restricts access to certain data sets or elements and/or explicitly requires prior IRB approval before releasing the data for use.

- Inter-University Consortium for Political and Social Research (ICPSR)*
- National Center for Health Statistics*
- National Center for Education Statistics*
- National Election Studies
- Roper Center for Public Opinion Research
    - Does not include Social Capital Community Surveys restricted data
- The University of Michigan Health and Retirement Study (HRS)*
- U.S. Bureau of the Census
- Panel Study of Income Dynamics (PSID)*
- Survey of Consumers (SCA)
- Demographic and Health Surveys (DHS)
- General Social Survey

*certain data sets may have restricted-use or limited use data available to researchers. IRB approval may be needed. Researchers should consult with the Office of Research Protections and Integrity when restricted use or limited use data will be used.

Notes:
If the research design includes merging more than one public data set, which may increase the risk of identification of individual research participants, contact the Office of Research Protections and Integrity and IRB for guidance.

Researchers should consider University Policy 311.9. This policy may apply if data access requires that the researcher agree to contractual or legally binding terms. Policy 311.9 may be applicable even when IRB approval is not required.

****Quality Assurance, Quality Improvement, Program Evaluation**

Quality improvement and program evaluation activities are done to improve quality of programs, improve services, or improve the provision of medical care, customer service, etc. Generally, these types of projects are done for internal purposes only. However, some quality improvement and program evaluations may fall under the federal definition of human subjects research and therefore, IRB review is required.

Quality assurance, quality improvement and program evaluation may be funded or unfunded and are evaluations of a specific program (formative, outcome, needs assessment, cost analysis, etc.) where the data and results will only be shared with the organization/sponsor/client/requesting party or used for internal decision making or informational purposes. In this case, the work would not be considered "research" for IRB purposes.

	Research	**Quality Assurance/Quality Improvement/Program Evaluation**
Purpose	To test a hypothesis, produce new knowledge, to establish clinical practice standards where none are already accepted. Intent to use data to contribute to generalizable knowledge.	To assess or improve a process, program, or system. To improve performance as judged by established/accepted standards
Mandate/Motivation	The activity being studied is not generally mandated by an institution or organization. The project is a result of individual professional goals and requirements.	The activity under review is mandated by the institution or organization as part of standard operations.
Population	May include a subset of people or a sample size sufficient to answer research questions	Generally, includes people receiving or experiencing the service, program, or practice.

	Research	Quality Assurance/Quality Improvement/Program Evaluation
	and apply it to groups or populations beyond those being studied	The project is not designed to apply to populations beyond that which is studied.
Benefits	Knowledge sought may or may not benefit current subjects, but may benefit future subjects. Benefits are to society.	Knowledge sought directly benefits a process/ program/ system, and may or may not directly benefit subjects.
Risks	May put subjects at risk. Risk is more than minimal risk.	Does not increase risk to patients, with exception of possible privacy/confidentiality concerns
Methods	Systematic data collection. Standard procedures or normal activities may be altered by an intervention. Random assignment of participants to compare outcomes.	Systematic data collection. Activity generally does not alter the timing or frequency of standard procedures.
Analysis	Statistically prove or disprove hypothesis	Compare a program/process/system to an established set of standards, or to establish internal benchmarks
Result	Answer a research question. Results may be generalized to a population beyond those participating in the study. Results will be used to apply knowledge to other programs outside the institution.	Improves or creates a program/ process/system that results in greater safety, efficiency or satisfaction. Results are shared internally and are not disseminated outside of the organization.
Dissemination	Intent to publish or present generally presumed at the outset of the project as part of professional expectations, and obligations; Occurs in research or scientific publications; Results fill a gap in scientific knowledge, develop further hypotheses, or support, refine, or refute results from other research studies.	Dissemination to program stakeholders. May be shared publicly (e.g. website) as part of institutional transparency of results. Publication may occur in evaluation or QI publications. However, the intent is to suggest potentially effective models, strategies, and assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge.

Examples: Quality Assurance, Quality Improvement, Program Evaluation

Example 1: A researcher is conducting a program evaluation for an agency, program, or other organization. The work may include drawing a sample or sampling the entire population affected by the program; data collection, data analysis, and a written report. The organization may also require the PI to present the results at meetings with stakeholders or constituents. The PI has no intention of presenting results from this evaluation in any academic or professional publication or presentation other than that required by the organization. The PI also has no control over what the funding organization may do with the written report. In this case, the work would *not* be considered "research" for IRB purposes. Although the results may be intended to be generalized beyond the specific study sample, findings are not intended to be used or presented as generalizable beyond the scope of the particular program that is being evaluated. In this situation, **no IRB application** would be required.

Example 2: The situation is the same as in Example 1. However, in addition to sharing results with the organization, the researcher also intends to present the findings in an academic or professional setting other than that required by the agency. Depending on the content of the project, it may be considered **"research"** rather than solely "program evaluation," and **an IRB application *may* be required**.

Example 3: A faculty member collects data to evaluate an academic program. The data and results will only be used by faculty within the department or School for internal decision-making or information sharing regarding the specific program. In this situation the work **would not be considered "research"** for IRB purposes, and **no IRB application** would be required.

Example 4: The situation is the same as in Example 3. However, the faculty plans to share evaluation data and results with an accrediting body or present the results from this evaluation in an academic or professional publication or presentation. As above, depending on the content of the data gathered, the project may be considered **"research"** rather than solely "program evaluation," and **an IRB application may be required**.

Adapted from:
University of Michigan
University of Kentucky
Medical University of South Carolina
UNC Greensboro
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University of California at Los Angeles