UNM | Office of the Institutional Review Board

Activities Requiring IRB Review

(If there are any questions regarding what does or does not require UNM IRB review, contact OIRB at 505-277-2644)

Any activity that meets either (a) the Department of Health and Human Services (DHHS) definition of both "research" and "human subjects" or (b) the Food and Drug Administration (FDA) definitions of both "clinical research" and "human subjects" requires review and approval by the University of New Mexico (UNM) Main Campus IRB (or deferral to an appropriate IRB).

Research: "A systematic investigation designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(d)].

Human Subjects (DHHS): "A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" [45 CFR 46.102(f)].

- Intervention: includes physical procedures such as blood samples, MRI, x-rays; or the manipulation of the environment in order to stimulate certain types of behavior.
- Interaction: includes interpersonal communication between the investigator and subject through surveys, interviews, administration of educational tests, etc.
- Identifiable: the identity of the subject is or may readily be ascertained by the investigator with the information obtained as part of the research.
- Private information: a context in which an individual can reasonably expect that no observation or recording is taking place or information that is provided for specific purposes by an individual and which the individual can reasonable expect will not be made public.

Clinical Investigation: "Involves use of a test article (i.e. drug, device, food substance or biologic), one or more human subjects, meets requirements for prior submission to FDA , or results are intended to be part of an application for research or marketing permit" [21CFR 56.102].

Human Subjects (FDA): "An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient." [21CFR 56.102(e)] (Drug, Food, Biologic)

Human Subjects (FDA for medical devices): "A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease." [21 CFR 812.3(p)] (Medical Devices) NOTE: This definition includes use of tissue specimens even if they are deidentified.

In cases in which any other federal agency apply, institutional oversight of the activity follows the definitions for "research" and "human subjects" as defined by the relevant agency as appropriate. For Department of Defense-supported research, institutional oversight of the activity follows the definitions of "research" and "experimental subject" as defined by Department of Defense regulations [DoD Directive 3216.02].

Examples of What Does and Does Not Require UNM IRB Review and Approval Prior to Initiation of Research

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Repositories (e.g. data, specimen, etc.)	Preliminary activities designed to help the Investigator refine data collection procedures. This data is to be included in the publication.	YES
	A storage site or mechanism by which identifiable human tissue, blood, genetic material or data (transcriptions/audio/video recordings) are stored or archived for research by multiple Investigators or multiple research projects.	YES
	Activities (e.g. review of medical or educational data, queries, etc.) intended only to assess the feasibility of future research. *Note that UNM or other "covered entity" might need to obtain researcher certifications for a review preparatory to research for HIPAA compliance purposes.*	NO
Research Involving Only Decedents	Research involving only data or tissue obtained from individuals who are deceased prior to the conduct of the research. There must not be any interaction or intervention with living individuals, or collection of private data or specimens associated with living individuals. Under HIPAA regulations, researchers with UNM or other "covered entity" must obtain a HIPAA waiver of authorization for review of identifiable protected health information (PHI).	NO *(contact Privacy Officer for HIPAA requirements)*
Standard Diagnostic, Therapeutic, or Teaching 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 standard patient care or assignment for research purposes.	YES
	A diagnostic or experimental 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 student or patient but not for the purposes of research.	NO
Case Report – Clinical	Report about three or less clinical experiences/ observations identified in the course of clinical care (including therapy), not involving biospecimens or FDA regulated products (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. Case reports are generally done by retrospective review of medical records and highlights a unique treatment, case or outcome. Please note: UNM HIPAA policies apply to this project. Contact UNM's Privacy Officer (http://hsc.unm.edu/admin/compliance/HIPAA.html) for assistance in complying with UNM's HIPAA policies.	NO
Case Report – Other	Report about experiences or observations associated with three or less individuals with no intent to generalize information.	NO

Quality Assurance and Quality Improvement Activities – Clinical or Procedures	Systematic, data-guided activities designed to implement promising ways to improve clinical care, patient safety and health care operation. The activity is designed to bring about immediate positive changes in the delivery of health care, programs, or business practices at the University of New Mexico. There must be no plans to disseminate the knowledge beyond UNM.	NO
Quality Assurance and Quality Improvement Activities – Non-Clinical	Data collected with the limited intent of evaluation and improving existing services and programs or for developing new services or programs at the University of New Mexico. There must be no plans to disseminate the knowledge beyond UNM. Examples include teaching evaluations or customer service surveys.	NO
Innovative Procedures, Treatment, or Instructional Methods	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants [more than three (3)]. 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 wellbeing 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.	NO*
UNM functioning as the Coordinating Center for a Multi-Center Research Project	UNM in *not* an enrolling site and the UNM PI has agreed to serve as the coordinating center for a multi-center project, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	YES
	UNM *is* an enrolling site and the UNM PI has agreed to serve as the coordinating center for a multi-center project, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	YES
Establishing Subject Pools	Activities with the purpose of recruiting subjects for future research studies.	YES
Pilot Studies	Pilot studies involving human subjects are considered human subject research studies.	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. This may include data sets that require payment of a fee to gain access to the data.	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

Community Service Projects	Donated service or activity that is performed by someone or a group of people solely for the benefit of the public or its institutions.	NO *(but if human subject data are collected during the activity to be used for research protocols, submission to the IRB is required)*
Secondary use of research data	Analysis of data gathered for a previous research protocol not related to current proposal and the data are de-identified. De-identified means removal of the 18 identifiers recognized by the HIPAA regulations with can be found at the following link: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#standard	NO *(but if data has direct or indirect identifiers, submission is required to the IRB)*
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
Oral History	Interviews concerning the past that collect and interpret the voices and memories of people as a method of historical documentation and that are preserved by placement in some form of repository or archive for access by other researchers. Research activities conform to the Principles of Best Practices of the Oral History Association: http://www.oralhistory.org/about/principles-and-practices	NO *(If interviews are not intended to draw conclusions, inform policy, generalize findings or be used for future research)*
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 a systematic investigation. Research activities should be consistent with the Code of Ethics of the Society of Professional Journalists http://www.spj.org/ethicscode.asp	NO *(but exercise of professional ethics is expected)*
Master's Thesis/Doctoral Dissertation/Capstone	Graduate studies which involve human subjects or a clinical investigation which results in a thesis, a dissertation research or a capstone.	YES
Classroom 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 (e.g. published or disseminated at a capstone or conference).	NO *(instructors have an obligation to ensure students meet professional and ethical standards)*

Student Practicum and Internship (Professional schools within UNM which actively seek opportunities for their students to become involved in "real world" activities or work assignments that will introduce them to and, in some cases, provide practical experiences in their chosen profession)	A practicum/internship that falls within the work scope of a local, state, or federal agency (e.g. Public Health Agency) or employment by private industry involving data collection for non-research purposes. No *a priori* research design or intent.	NO
	Use of or access to human subjects data previously collected for non-research purposes (perhaps through a circumstance like the one above) in a systematic investigation designed to contribute to generalizable knowledge, one indicator of which is publication.	YES
	Independent research project not falling within the scope of a previously approved project.	YES
	Participation with or providing services to a UNM PI conducting IRB-approved research. No work outside the scope of the IRB approval.	YES *(amendment to add student if providing research assistance at level of study personnel)*
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 but data are collected through intervention or interaction with research subjects.	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 but data are collected through intervention or interaction with research subjects.	YES

** 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.*