

IRB Handbook: Making Sense of Human Subjects Research

Office of Research Integrity and Ethics
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New Mexico State University

Conflict of Interest – Ethical Conduct

([New Mexico State University Policy Manual, 3.19](#))

General Statement

Inherent within the responsibility for educating the future leaders of our society is the obligation to adhere to the highest ethical standards and principles. New Mexico State University is committed to maintaining the highest standards of ethics and integrity in all of its academic and administrative operations, by promoting such standards among its regents, administrators, faculty, staff, students and others acting on behalf of the university (including those acting on behalf of university controlled entities) and by striving to ensure a level of accountability appropriate for a public institution.

Principles of Ethical Conduct:

- A. Members of the university community are expected to exercise and demonstrate personal and professional honesty and to respect the rights, values and contributions of others.
- B. Members of the university community are expected to be aware of and comply with relevant laws, regulations, contract requirements and university policies and procedures. An unethical practice should never be condoned on the grounds that it is “customary” or that it serves a worthy goal.
- C. Individuals with access to confidential, proprietary or private information must never use or disclose such information except where authorized or legally obligated to do so.
- D. All members of the university community are responsible for avoiding, where possible, real or potential conflicts of interest and commitment between personal and professional responsibilities, including relationships that have the appearance of a conflict.
- E. The university’s interests should be foremost in all official decision making and employees and others acting on behalf of the university shall remove themselves from decision-making roles that involve them in any personal capacity or which involve their friends or family members.
- F. All individuals acting on behalf of the university have a responsibility to ensure that funds and other assets received are used in an ethical manner. Assets of the university (including personnel), whether tangible or intangible, may not be used for illegal purposes or personal gain.
- G. Members of the university community shall strive to present all information, including financial information and research data and results, completely and accurately.

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The NMSU Office of Research Integrity and Ethics would like to acknowledge the University of Southern California (USC), Office of the Protection of Research Subjects for their approval to modify and adapt their “Student Handbook: Making Sense of Human Subjects Research Faculty Handbook.” (5/16/14).

Introduction to Human Subjects Research Protection

*Conducting research with human subjects is a **Privilege not a right.***

Whether the research is social or behavioral, all research involving human subjects must be conducted responsibly and it must protect the rights, welfare and safety of all human subjects.



The purpose of this handbook is to assist investigators in meeting these obligations by providing guidance on New Mexico State University's policies pertaining to research involving human subjects and the processes of the Institutional Review Board (IRB), as well as commonly cited ethical principles and federal regulations.

Comments or questions about information in this guide may be addressed to the

- Office of Research Integrity at ovpr@nmsu.edu or the
- Office of Research Compliance at ovpr@nmsu.edu

Additional information and educational materials may be found online at:
<http://www.research.nmsu.edu/compliance/IRB/IRB.html>

I. Human Subjects Research: Basic Expectations

Research involving human subjects conducted at New Mexico State University must be reviewed and approved by the IRB **prior to** initiating research activities.

Investigators are required to follow federal and state regulations, university policies, and ethical principles when conducting research involving human subjects whether they are students, faculty or staff.

All investigators must adhere to the study procedures approved by the IRB. Any deviations, violations or unanticipated problems must be reported promptly to the IRB.



Changes to an IRB-approved research study must be reviewed and approved by the IRB **prior to** implementation, unless subjects are at immediate risk of harm. Changes are submitted to the IRB using the ***Continuing Review/Modification of Protocol*** form found in the MAESTRO online system at <https://maestro.research.nmsu.edu/>.

Informed consent is central to the ethical treatment of human research subjects. Investigators must be forthright and realistic when describing the benefits and risks of research participation and when answering questions posed by subjects.

Adverse events and unanticipated problems involving risk to subjects or others must be reported promptly to the IRB in accordance with IRB policy using the ***Adverse Event Report*** form found in the MAESTRO online system at <https://maestro.research.nmsu.edu/>.

When the research study is complete, investigators are expected to notify the IRB of study completion and closure by submitting the ***Final Report of Research Protocol*** form found on the MAESTRO online system at <https://maestro.research.nmsu.edu/>.

Information on how to use the MAESTRO online system can be found at <http://maestrohelp.research.nmsu.edu/>. Comments or questions about the MAESTRO online system may be addressed to care@research.nmsu.edu or to the Office of Research Compliance at ovpr@nmsu.edu or via telephone at 575-646-7177.

II. Responsibilities of Student Principal Investigators/ Trainees and Faculty Advisors

This section of the handbook will explain the duties and responsibilities of the student principal investigator/trainee and the faculty advisor. The application submitted to the IRB via the MAESTRO online system requires both the student principal investigator/trainee and the faculty advisor to sign an assurance affirming their understanding and commitment to fulfilling their research responsibilities and adherence to the NMSU policies and federal regulations pertaining to the conduct of research activities involving human subjects.



The assurance appears at the bottom of the application forms submitted via the MAESTRO online system. A copy of the student principal investigator/trainee and faculty advisor assurance is included at the end of this section.

Both the student principal investigator/trainee and the faculty advisor must also complete the online training course on conducting research involving human subjects. The online training course on research involving human subjects is available at <https://www.citiprogram.org>.

The online training course is required to fulfill the federally-mandated human subjects training requirement.

1. Faculty Advisor (FA)

NMSU faculty who advise students on research projects play an important role in the protections of human subjects. Faculty Advisors bear ultimate responsibility for their students and the ethical conduct of the research. The efforts and commitment of the FA have a significant impact on the success of student projects, the quality of data, and the time elapsed from submission to final IRB approval.

To ensure student projects are successful – Faculty Advisors must:

- adopt an active role in mentoring
- accept responsibility for students' research (both planning and conduct)
- approve study design and methodology
- allocate adequate time for each student
- assure scientific merit in student projects
- know if an informed consent or a waiver is needed
- help students determine the level of risk (less than or greater than minimal risk)

- know whether the research is or is Not Human Subjects Research (“NHSR”)
- know the levels of IRB review: Exempt, Expedited, or Full Board
- anticipate time required for students to secure IRB approval and conduct the research
- fulfill the human subjects’ education requirement by taking the online education training found at <https://www.citiprogram.org>.

2. Student Principal Investigator/Trainee

Under the direction of the Faculty Advisor, the Student Investigator is responsible for:

- ensuring the description of the proposal study in the IRB application is accurate and complete prior to IRB submission
- ensuring the description of the proposal study in the IRB application is accurate and complete prior to IRB submission
- obtaining IRB approval before initiating any research activities (**Do NOT** collect data until IRB approval has been obtained)
- informing the IRB of all proposed changes or additions to the previously approved study before implementing them unless there is immediate risk of harm to the subject
- submitting required continuing review form to the IRB
- reporting unanticipated problems involving risks to subjects or others and adverse events to the IRB
- informing the IRB of study closure or termination through completion of the final report form
- fulfilling the human subjects education requirement by taking the CITI online human subjects education training. More information about education requirements can be found at: <http://www.research.nmsu.edu/compliance/IRB/IRB.html>
- Agreeing to meet with faculty advisor/chair on a regular basis in order to monitor study progress.

A) Faculty Advisor's Assurance

The following is a commitment between the Faculty Advisor and the Student Principal Investigator/trainee. The Faculty Advisor must agree to accept the responsibilities associated with that role, as described in the Faculty Advisor's Assurance, shown on the next page.

Faculty Advisor's Assurance

By submitting the protocol for IRB review, I, _____, as Faculty Advisor to a Student Principal Investigator/Trainee, accept responsibility to monitor and verify that the Student Principal Investigator/Trainee complies with the following:

- The information provided in this application represents an accurate description of the study.
- All project personnel will conduct the study in compliance with all applicable federal, state, and local regulations and IRB and institutional requirements and policies. All project personnel will be properly trained in their respective responsibilities, and have completed all appropriate trainings related to the research study.
- Only the currently approved, IRB stamped informed consent documents and recruitment scripts will be used.
- No changes will be made to the protocol without prior IRB approval except when necessary to eliminate immediate hazards to the subject, in which case the IRB will be notified as soon as possible.
- Valid informed consent/assent will be obtained and documented from all research subjects or their legally authorized representatives unless these requirements have been waived by the IRB.
- Timely written reports of unanticipated problems involving risks to subjects or others and adverse events will be immediately reported to the Office of Research Compliance.
- All required research records will be maintained and will be made available in accordance with applicable regulations and IRB policy.
- The IRB will be immediately informed of any violations of HHS regulations (45 CFR 46), FDA regulations (21 CFR 50, 56), FERPA regulations (34 CFR 99), PPRA regulations (34 CFR 98), HIPAA regulations (45 CFR 164.530), state/local laws, or IRB Policies and Procedures for the protection of human subjects.
- Per HIPAA Privacy Rule regulations (if applicable to the study), only the minimum necessary data to achieve the goals of the research described in this application is being sought.

In addition, I, as Faculty Advisor, will:

- arrange for another faculty member to accept responsibility in my absence, if unable to supervise this research personally, as when on leave or vacation.
- keep myself informed of current development that may impact the research, and I will immediately notify the IRB if I become aware of any information that may materially alter the risk/benefit ratio.
- meet with the trainee/student on a regular basis to monitor study progress.
- certify that I have read and agreed to the foregoing statements and that my submission of this application has the same force and effect as my written signature.

By signing below, I accept these conditions.

Signature of Faculty Advisor

Date

B) Student Principal Investigator/Trainee Assurance

The Student Principal Investigator/Trainee must agree to accept the responsibilities and roles of Student Principal Investigator and Trainee. The Student Principal Investigator/Trainee's Assurance is shown on the next page.

Student Principal Investigator/Trainee's Assurance

By submitting this protocol for IRB review, I, _____, as Student Principal Investigator/Trainee, accept responsibility for the following:

- I have reviewed the conflict of interest section of my application and the information disclosed is correct.
- The information provided in this application represents an accurate description of the study.
- All project personnel will conduct the study in compliance with all applicable federal, state, and local regulations and IRB and institutional requirements and policies. All project personnel will be properly trained in their respective responsibilities, and have completed all appropriate trainings related to the research study.
- Only the currently approved IRB Stamped informed consent documents and recruitment scripts will be used.
- No changes will be made to the protocol without prior IRB approval except when necessary to eliminate immediate hazards to the subject. In the latter case, the IRB will be notified as soon as possible.
- Valid informed consent/assent will be obtained and documented from all research subjects or their legally authorized representatives unless these requirements have been waived by the IRB.
- Timely written reports of unanticipated problems involving risks to subjects or others and adverse events will be submitted to the Office of Research Compliance according to its reporting guidelines.
- I will keep myself informed of current developments that may impact the research, and I will immediately notify the IRB when I become aware of any information that may materially alter the risks/benefits ratio.
- All required research records will be maintained and will be made available in accordance with applicable regulations and IRB policy.
- The IRB will be immediately informed of any violations of HHS regulations (45 CFR 46), FDA regulations (21 CFR 50, 56) FERPA regulations (34 CFR 99), PPRA regulations (34 CFR 98) HIPAA regulations (45 CFR 164.530), state/local laws, or IRB Policies and Procedures for the protection of human subjects.
- Per HIPAA Privacy Rule regulations the minimum necessary data needed is being requested to achieve the goals of the research described in this application (if applicable to the study).
- If unable to direct this research personally, as when on leave or vacation, I will consult with my advisor for an appropriate option to consider for the continuation of the research.
- I certify that I have read and agreed to the foregoing statements and that my submission of the application has the same force and effect as my written signature.

By signing this form, I certify the above assurances and confirm that I will meet with my faculty advisor on a regular basis to monitor study progress. If my faculty advisor is away, I will meet with the arranged alternate faculty member who will assume these responsibilities.

Signature of Student Principal Investigator/Trainee

Date

III. Ethical and Regulatory Framework

The current ethical and regulatory framework for the conduct of research involving human subjects dates from the 1947 Nuremberg Code. A brief summary of the major ethical and legal regulations that pertain to research involving human subjects is provided in this section.



A. Nuremberg Code

The Nuremberg Code was developed following the Nuremberg Military Tribunal convened to bring to trial Nazi doctors who conducted inhumane medical experiments on prisoners without their consent. The Code provided many of the basic principles that still govern the ethical conduct of research involving human subjects.

For example, the Nuremberg Code asserts that **“the voluntary consent of the human subject is absolutely essential” to conducting research involving human subjects.**

The Nuremberg Code further explains that this requirement for the voluntary consent of the human subjects includes:

- Capacity of participants to consent,
- Voluntary participation,
- Freedom from coercion,
- No penalty for withdrawal, and
- Full knowledge of the risks and benefits of participation.

The Nuremberg Code can be found at:

<http://www.hhs.gov/ohrp/archive/nurcode.html>

B. Declaration of Helsinki

In June 1964, the World Medical Association (WMA) adopted the Declaration of Helsinki in Helsinki, Finland, as ethical guidance for medical doctors undertaking biomedical research involving human subjects. While the Declaration of Helsinki is a set of ethical principles regarding human experimentation developed primarily for physicians, the WMA encourages others involved in medical research involving human subjects to adopt these principles. The Declaration addresses international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The Declaration of Helsinki has been

revised in 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008 and 2013.

The Declaration of Helsinki states:

- Research involving medical interventions with humans should be based on results from laboratory and animal experimentation,
- Human research protocols should be reviewed by an independent committee prior to
Initiation,
- Informed consent of research participants is necessary,
- Research should be conducted by medically/scientifically qualified individuals, and
- Risks should not exceed benefits.

The Declaration of Helsinki can be found at:

<http://www.wma.net/en/30publications/10policies/b3/index.html>.

C. Belmont Report

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by the U.S. Congress in response to public outrage over the Tuskegee syphilis study conducted by the U.S. Public Health service in the 1940's, which used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available. The Commission produced "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research."

The Belmont Report sets forth three basic ethical principles for conducting research involving human subjects: **respect for persons, beneficence, and justice**. These terms have specific meaning when applied to human subjects' research as noted below:

1) Respect for persons

Respect for persons requires that individuals be treated as autonomous, that is, as having the capacity to make their own choices and that persons with diminished autonomy be protected. In other words, a person must be capable of making an informed decision whether or not to participate in a human subjects research project and safeguards must be in place for those who cannot make an informed decision on their own. Informed consent of human research subjects is derived from the principle of respect for persons.

2) Beneficence

Beneficence is demonstrated when subjects are protected from harm, specifically, by

maximizing possible benefits and minimizing possible harms from study participation. The “risk-to-benefit” ratio in a study must be acceptable to the IRB in order for the research to be approved.

3) Justice

Justice refers to equitable selection of subjects for a study without undue burden of risks or exclusion from likely benefits of a particular population. For example, exclusive enrollment of a subset of the population for a condition that is not unique to that subset is not just. Additionally, enrollment of a population unlikely to benefit from the results of the research is also unjust.

The Belmont report can be found at:

<http://www.hhs.gov/ohrp/policy/belmont.html>

D. Federal Policy for the Protection of Human Subjects (Common Rule)

In 1991, the U.S. Department of Health and Human Services codified into regulation the Policy for the Protection of Human Subjects (Title 45, Part 46). These regulations, called the “**Common Rule**” (Subpart A), provide the basic foundation for the human subjects’ protection program in use today. This Federal Policy has been codified by all federal agencies that conduct, support, or otherwise regulate human subjects research, hence the title “**Common Rule.**” The Policy in Subparts B, C, D, provides additional protections to “vulnerable populations” such as pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D) involved in human subjects’ research.

The Code of Federal Regulations (Title 45 Part 46) can be found at:

<http://www.hhs.gov/ohrp/policy/belmont.html>

E. FDA Regulations on Protection of Human Subjects (21 CFR 50) and Institutional Review Boards (21 CFR 56)

The U.S. Food and Drug Administration, under the Department of Health and Human Services regulates clinical research seeking approval for drugs, devices, and biologics. Title 21, Part 50 contains the federal definition of human subjects, federal requirements for informed consent and the required safeguards for clinical investigations. Title 21, Part 56 contains specific regulations regarding the composition, organization, and functions of Institutional Review Boards.

The FDA regulates drugs, devices, and biologics through a series of regulations that must also be addressed by researchers and sponsors. They are: Biologics (21 CFR 600), Investigational New Drugs (21 CFR Part 312), and Investigational Device Exemptions (21 CFR 812).

F. Health Insurance Portability and Accountability Act (HIPAA) / (Privacy Rule)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal privacy law that generally prohibits health care providers (such as physicians or other health care

practitioners, hospitals, nursing facilities and clinics) from using or disclosing patients' "protected health information" (PHI) without written authorization.

When a student investigator intends to obtain or release PHI to others (e.g., sponsors, other investigators, collaborators) in connection with their research, he/she must indicate so in the IRB application.

Protected Health Information (PHI) is health information transmitted or maintained in any form or medium that includes ALL of the three following conditions:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
- relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

The Privacy Rule can be found at the HIPAA privacy website of the Office for Civil Rights (OCR):

<http://www.hhs.gov/ocr/hipaa>.

G. International Compilation of Human Subjects Research Standards (2012 Edition)

The International Compilation of Human Research Standards is compiled by the Office for Human Research Protections of the U.S. Department of Health and Human Services. The Compilation enumerates over 1,000 laws, regulations, and guidelines that govern human subjects' research in 103 countries, as well as the standards from a number of international and regional organizations. This Compilation was developed for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in human subjects' research around the world.

The International Compilation of Human Research Standards can be found at:

<http://www.hhs.gov/ohrp/international/index.html>

IV. What Is/Isn't Human Subjects Research?

The first question a researcher should consider with respect to IRB submission is whether the project fits the definition of **human subjects research**. In order to do so, the project must meet the federal regulatory definitions of both **research** and **human subjects** in order to require IRB approval.

Research

Federal Regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102 (d)). "Generalizable knowledge" is information where the intended use of the research findings can be applied to populations or situations beyond that studied.



As described in the Belmont Report, “...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

“Research” generally does **not** include operational activities such as routine outbreak investigations and disease monitoring and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services.

Human Subjects Research generally does not include journalism, political polls, or public health surveillance. However, some of these activities may include or constitute human subjects research in circumstances where there is a clear intent to contribute to generalizable knowledge – and the study collects data about the subjects themselves – then the entire project must receive IRB approval.

Human Subjects

A human subject is defined by Federal Regulations as “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)(1), (2)).

The following list contains brief explanations of the terms found in the definition of human subjects.

- The term **living individual** refers to the state of the subject. The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimen(s) or specimens/information from non-living subjects are not subject to the human subjects protection regulations.
- “**About whom**” indicates that the data received from the living individual is **about** the person. A human subject research project requires that the data received from the living individual is **about** the person.

- **Intervention** includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes.
- **Interaction** includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.
- **Identifiable private information**¹ includes information which has 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) (45 CFR 46.102(f)(2)) and information about behavior that occurs in a context in which an individual can reasonably expect that no recorded observation is taking place (such as a locker room or public restroom).
- **Identifiable** means the information contains one or more data elements that can be used alone or combined with other reasonably available information to identify an individual (e.g. Social Security number).
- **Observational studies** of public behavior (including television and internet chat rooms) are **not** human subjects' research if they do not involve intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may not constitute human subjects research if individuals are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

In light of the potential regulatory consequences of not obtaining IRB review and approval, the investigator should err on the side of caution and consult the IRB when he/she is uncertain if a project is human subjects' research.

¹Disclosure of private information may place subjects at risk of criminal or civil liability and/or damage their financial standing, employability, or reputation. Researchers must use caution with collections of identifiable data of a sensitive nature.

Identifying Studies that Are Human Subjects Research

Certain studies may have the characteristics of research but do **not** meet the regulatory definition of human subjects research. Federal Regulations state that the *definition of human subjects and research* must **both** be met in order *for a study to be considered human subjects research*.

Examples of activities that are Human Subjects Research:

1. Utilizing test subjects for new devices, products, or materials.
2. Collecting data through intervention or interaction with individuals. Examples of this type of research include internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.

3. Using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
4. Using bodily materials such as blood, urine, tissues, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to ~~the key~~-identifying information.
5. Producing generalizable knowledge about categories or classes of subjects from individually identifiable information.
6. Studies that use human beings to evaluate environmental alterations, for example, weather conditions or modifications to their living, working space or research surroundings.

Identifying Studies that Are *Not* Research Involving Human Subjects (Do Not Need IRB Review):

Examples of activities that are Not Human Subjects Research (NHSR):

1. **Data collection** for internal departmental, school, or other university administrative purposes. Examples: teaching evaluations, customer service surveys.
2. **Service surveys** issued or completed by university personnel for the intent and purposes of improving services and programs of the university or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary. This would include surveys by professional societies or university consortia.

Note: *If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.*

3. **Information-gathering interviews** where questions focus on ~~things~~-issues, procedures, products, or policies rather than people or their thoughts regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.
4. **Course-related activities** designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are **not** intended for use outside of the classroom are considered exempt. Example: instruction on research methods and techniques.

Note: The IRB is only required to review studies that meet the Federal definitions of research and human subjects², or “engaged in research”³.

5. **Biography or oral history** research involving a living individual that is not generalizable beyond that individual.
6. **Independent contract for procedures** carried out for an external agency. Examples:

personnel studies, cost-benefit analyses, customer satisfaction studies, public park usage, IT usage, and software development.

7. **Research involving cadavers**, autopsy material or bio-specimens from now deceased individuals.

Note: Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. Please contact the IRB for further information.

8. **Innovative therapies** except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.)

9. **Quality improvement** projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge **and** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice.

Note: Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for further guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

10. **Case histories** which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.

11. **Publicly available data do not** require IRB review. Examples: census data, labor statistics.

Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as "publicly available".

12. **Coded private information** that were **not** collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects' names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator.

Note: Investigators are not allowed to make this determination. These projects require verification from the IRB.

See the [OHRP Guidance on Research Involving Coded Private Information or Biological Specimens](#) for more information.

² <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

³ <http://www.hhs.gov/ohrp/assurances/index.html>

Determining if a Study is Human Subjects Research

Any investigator who is unsure of whether his/her project constitutes “human subjects research” should contact the Office of Research Compliance. The Chair and/or designee will determine if the study is Human Subjects Research. Federal regulations do not allow investigators to make this determination themselves.

If a “Request for Human Subjects Determination” is submitted, an email notification will be sent to the investigator. If a study does not qualify as Human Subjects Research, the IRB will issue a response stating that the project does not require IRB review and/or approval.

Note: Grant offices, faculty advisors, publications, and/or dissertation committee members may require a determination letter from the IRB to verify that the decision was not made by the researchers. Students, who submit a request for determination of their study as “Not Human Subjects Research,” will receive a letter to confirm the decision by the IRB.

V. Institutional Review Board (IRB)



The Institutional Review Board (IRB) is an independent committee established at institutions or organizations where research involving human subjects is conducted or supported.

The IRB is charged with reviewing research projects involving human subjects for compliance with institutional policies and state, local, and federal laws. The IRB will also assess whether the risks posed to subjects are proportional to the benefits.

The IRB is comprised of a minimum of five members from relevant academic disciplines including at least one non-affiliated member. The members include faculty, staff, and members from the local community.

The IRB functions as a surrogate “human subject advocate” whose role is to protect subjects participating in research by reviewing research projects before research is allowed to begin.

IRB members must have the necessary experience and expertise to evaluate proposed research projects. IRBs must be diverse in terms of race, gender, and cultural backgrounds.

The IRB is part of a comprehensive system; responsible for the protection of research subjects. The comprehensive system at NMSU includes the Office for Research Integrity, the Office of Compliance, the IRB, and the Institutional Official.

IRB functions and duties are described in the 1991 Federal Policy for the Protection of Human Subjects (Common Rule - Title [45 CFR 46](#)).

What does the IRB do?

The IRB is responsible for reviewing and approving proposed or continuing human subjects research. The IRB review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, obtaining fully informed consent, minimizing risks, maximizing possible benefits and assuring the maintenance of privacy and confidentiality of persons and data. Human subjects’ research projects cannot be conducted without the approval of the IRB.

The committee has the authority to approve, require changes to study procedures, or disapprove proposed research projects. **Institutional officials can disapprove an IRB approved project but cannot approve a project that has been disapproved, suspended, or terminated by the IRB.**

Even studies that qualify for the “Exempt” category in the regulations must receive an exempt determination by the IRB or a designee of the IRB.

IRB project approval is valid for up to one year. If the research continues for more than a year, a continuing review application must be submitted to the IRB to extend approval for a year.

VI. Types of IRB Review

Federal regulations provide for three types of IRB review: **exempt, expedited, and full-board** CFR 45; Part 46, Section 46.111). 4. The following chapter provides an explanation of each category of review and examples of studies that meet those categories. The IRB conducts reviews using the criteria contained in the Federal Policy for the Protection of Human Subjects.

A unique category, “**Not Human Subjects Research,**” is used when the research does not meet the federal definition of **human subjects** and/or **research** and thus will not require IRB review. This term may also be used for coded **data/specimens** when use of such collections meets certain conditions.



Exempt Review

The IRB staff – not the researcher – must determine when a research project falls under one of the six exempt categories. There are six exempt categories listed in the federal regulations (45 CFR 46.101(b)).

Exempt research is research with human subjects that is “exempt” from the provisions of the Code of Federal Regulations (45 CFR 46). An exempt research project requires a continuing review if it will continue beyond the approved date by the IRB, unless the project is amended in such a way that it no longer meets the criteria under which it was determined to be exempt. Exempt projects involve less than minimal risk.

Exempt Review Categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or comparison of instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless:** (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **AND** (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g, or for the National Center for Education Statistics

under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.

4. Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed or (b) a food is consumed that contains a food ingredient at or below the level found to be safe, an agricultural chemical or environmental contaminant at or below the level found safe by the Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review

Expedited review applies to those research projects that do not fit an exempt category but do not present more than minimal risk. These projects must meet one of the nine categories for expedited review. Expedited review requires the same approval criteria as a full board study but because these studies entail less risk they are reviewed by the IRB Chair or a Designated Reviewer, rather than the convened committee. During this process, IRB reviewers exercise all of the authorities of the IRB except that they may *not* disapprove the research. There are nine expedited review categories in the federal regulations (45 CFR 46.110).

Expedited Review Categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3

ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: Some research in this category may be exempt from the Department of Health and Human Services regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

Full Board (Convened) Review

Studies that involve **more than minimal risk** require full board review at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members.

While federal regulations do not specifically list categories that require full board review, studies such as those listed below are normally sent to full board for review when part of the study design involves greater than minimal risk procedures:

- studies taking place internationally (particularly countries with little or no provisions for the protection of human subjects) where subjects may be at physical, psychological or legal risk;
- studies in which disclosed information could require mandatory legal reporting (e.g., child/ elder abuse, etc.);

- studies involving deception which raise the risk to subjects or others;
- studies in which the IRB staff, chair, member, or designee determines risk to subjects or others to be greater than minimal risk; or
- studies using “vulnerable” populations and thus requiring extra protections.

A Reminder... Student investigators should consult with IRB staff and faculty advisor if they are unsure which level of review is required for their research.

All human subjects research whether conducted by student researchers, faculty or staff must obtain IRB approval prior to initiation of any research activity/study (presuming the study fits the federal definition of human subjects and research and is not solely a classroom exercise).



Retroactive approval for data previously collected for an unapproved study is not allowed, however, in some cases previously collected data, not originally intended for a current study, may qualify for use as existing data. The student researcher can contact the IRB for clarification.

Failure to seek IRB approval for research may invalidate a study and/or result in delayed graduation. Many journals will not accept a human subjects' research paper without proof of IRB approval.

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IRB Review Exceptions

Not Human Subjects Research (NHSR)

Not Human Subjects Research (NHSR) is research that does not meet the federal definition(s) of human subjects and/or research. NHSR studies are not defined in the federal regulations. NMSU policy requires that investigators contact the Office of Research Compliance to review for NHSR.

For more information on NHSR, see Chapter IV of this handbook or [*Is Your Project Human Subjects Research?: A Guide for Investigators.*](#)

VII. Tips for Expedited and Exempt Research

A. Before You Begin:

- Complete the CITI training (required of all study personnel: Student Principal Investigator, Faculty Advisor, and Research Staff).
- Determine appropriate level of IRB review (NHSR, coded data, exempt, expedited). A study may fall under more than one category within that review level (exempt, expedited). Note: Expedited Review is a type of IRB review. **It does not mean a faster review.**
- Allow enough time for the IRB submission and review process. An initial IRB review takes approximately 45 business days.
- *Applications are reviewed by the IRB in the order received.*
- Answer each question on the MAESTRO online application form. Do not leave any questions blank. Use the MAESTRO Training Document found at: <http://www.research.nmsu.edu/compliance/IRB/MAESTROTraining.pdf> Guidance is also available on the right side of each question.
- Request site permission before submitting an IRB application. Some sites/schools/facilities require permission to conduct research on their premises even if the research is exempt from IRB review.
- Adhere to [FERPA](#) (Family Educational Rights and Privacy Act) and [PPRA](#) (Protection of Pupil Rights Amendment) requirements, as applicable.

B. How to decide if a project is Expedited or Exempt

The federal regulations allow for six exempt and nine expedited review categories ([See Chapter VI](#)). Designation of a study in either the expedited or exempt research categories is often a judgment call rather than a hard line regulatory decision. These decisions become clearer with experience and dialogue with others. The following section has been designed to help investigators reflect on the distinction between expedited and exempt studies.

First, look at the abstract and methodology and determine if it meets the federal definition of both human subject and research. If the project does not meet both, then it is Not Human Subjects Research (NHSR). An email request for a NHSR project should be submitted to the Office of Research Compliance and the IRB will confirm the determination.

OR

If the project does meet the federal definition of both human subject and research, then it

must be submitted to the IRB for their review and approval. To submit a project using coded data for review and approval by the IRB, the Application form titled, *Application to Use Human Subjects in Research (Expedited or Exempt)*, must be completed and submitted online through MAESTRO. The online submission system will allow you to provide the appropriate data pertaining to your project on the application form and to submit it for review and approval by your faculty advisor and department

head. Once your application form is approved by the appropriate individuals, it will be submitted to the Office of Research Compliance for review and approval by the IRB.

OR

If the project does not fit either of the two descriptions above, then the project may qualify for an exemption. Look at the six exemption categories identified in Chapter VI and reflect on which exemption category most appropriately fits the project.

Consider the following questions if the project seems to fit an exemption category:

- Will vulnerable subjects be used, such as children or prisoners?
- Will the investigator collect sensitive/private information and keep identifiers for them?
- Is there a risk to participants from the information being collected?

If the answer to any of these questions is “yes”, then the project is **not** exempt and will require an **Expedited** or **Full Board** review.

If the project does not appear to fit any exempt category, or there are “yes” answers to the questions above, complete and submit the application form titled, *Application to Use Human Subjects in Research (Expedited or Exempt)* via MAESTRO for further determination by the IRB. The IRB will do either an expedited or full board review.

C. PROCESS OVERVIEW

1. Principal Investigator (Faculty/Staff/Student) Designs and Submits Study via MAESTRO:

Investigators design their protocol and submit it via the MAESTRO Online application system. Investigators must indicate if the application requires exempt, expedited, or full board review. The final determination of the review category is made by the IRB.

NOTE: Investigators, key personnel and faculty advisors must fulfill the CITI Human Subjects Training requirement before the IRB will give final approval.

2. Faculty Advisor and Department Sign-off:

Once the application is submitted (via the online MAESTRO application system)

the faculty advisor must review and sign off on the application, along with the Department Head. In some cases, a departmental representative must also sign the application. The faculty advisor signs first. This sign-off represents consideration of scientific merit, availability of resources, or other issues at the department level.

3. IRB Office:

After department and faculty advisor approval is obtained, an initial review of the application is conducted by the IRB or IRB designee.

It is most beneficial if the student/faculty/staff takes advantage of using the IRB Submission Checklist at the bottom of the online application as a SELF PREVIEW CHECK before final submission of the application for the review process. Various questions on the MAESTRO electronic application also include a letter designation. The letter designation coincides with the letter(s) on the Submission Checklist application at the bottom of the electronic application. The number/letter combination indicates that the information provided by the student/faculty/staff in the electronic application is consistent with the information provided for A. Human Subjects; B: Research Instruments; C: Consent form; D: Other Elements.

A thorough pre-review of the application by the student/faculty/staff to verify the correct level of review and to evaluate the protocol and supporting documents (e.g., consent form, recruitment materials, etc.) will decrease the probability of errors in the application. If a study is approved as exempt or determined to be “not human subjects’ research,” the P.I. will be notified of such a designation. Any significant changes to the approved study must be submitted and reviewed by the IRB prior to implementation of changes.

For studies designated as expedited or full board, IRB review is required by a designated reviewer or the full board, respectively. **(For more information on the IRB Review categories see Chapter VI: Types of IRB Review).**

The possible determinations/outcomes that can be made on a study are as follows:

- Approved – the application is complete, the risks to subjects are minimal/minimized, and the procedures are appropriate. The IRB gives approval for the research to be conducted.
- Returned for corrections – applications that are found to have deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. The researcher is notified of the necessary changes that must be addressed for approval to proceed. The researcher’s response is reviewed by the IRB and will be approved or deferred until all issues are addressed satisfactorily.
- Disapproved – Applications that are found to have risks that outweigh the potential benefits to subjects and/or society will receive a non-approval and the research will not be allowed. This determination can only be made by the **full**

board at a convened meeting. Institutional administrative officials may not override this decision.

4. Study Approved and PI Notified:

The researcher will be notified through a MAESTRO generated email when the study has been approved.

5. Modifications and Reportable Events

Once the application is approved, the researcher may begin recruiting subjects and conducting the study. The researcher must let the IRB know if any of the following subsequently occur:

- Changes to the original study must be reviewed and approved by the IRB through a Modification form to the study via MAESTRO before they are implemented, unless the subject is at immediate risk.
- Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others (harm to subjects or others resulting from the study must be reported to the Office of Research Compliance immediately).
- Complaints regarding human subjects' research (any complaints from the subjects or the study staff must be reported to the Office of Research Compliance).
- Breach of Confidentiality (Confidential data that has been disclosed by any member of the study staff must be reported to the IRB immediately, for example, the theft of a laptop containing research data with names and addresses of participants).

6. Continuing Review: Progress Report/Study Close Out

All active exempt, expedited or full board (non-exempt) studies that the researcher plans to continue beyond the designated time of approval by the IRB must submit a continuation form via MAESTRO. The investigator must provide a Final Report upon completion of the study or a request for continuance through MAESTRO, if the study is to continue beyond the approved expiration date). The requirement for continuing review applies to all applications approved by the IRB that are to continue beyond the approved expiration date.