



# **IRB Handbook (Revised 5/2019)**

**Office of Research Integrity and Compliance**

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# Preface

## Conflict of Interest – Ethical Conduct

### (New Mexico State University Administrative Rules and Procedures)

#### 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. It does so 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. The community should never condone an unethical practice because it is “customary” or 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 they use funds and assets received ethically. 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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## Acknowledgment:

The NMSU Office of Research Integrity and Compliance thanks 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 on research involving human subjects and the processes of the Institutional Review Board (IRB), as well as commonly cited ethical principles and federal regulations.

Readers can address comments or questions about the information in this guide to the Office of Research Integrity and Compliance at [ovpr@nmsu.edu](mailto:ovpr@nmsu.edu). Additional information and educational materials may be found online at <http://compliance.nmsu.edu/irb/>

# I. Human Subjects Research: Basic Expectations

Research involving human subjects conducted at New Mexico State University must be reviewed and approved by the IRB **before** initiating research activities. All investigators are required to follow federal and state regulations, university policies, and ethical principles when conducting research involving human subjects.

All investigators must adhere to the study procedures approved by the IRB. Investigators must promptly report any deviations, violations or unanticipated problems to the IRB.

Changes to an IRB-approved research study must be reviewed and approved by the IRB **before** implementation unless subjects are at immediate risk of harm. Always ensure the safety of subjects and assure appropriate protection of data. Changes are submitted to the IRB using the **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. A consent form template is available for your guidance in the MAESTRO System or at <https://compliance.nmsu.edu/irbregulations/>.

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](mailto:care@research.nmsu.edu) or the Office of Research Integrity and Compliance at [ovpr@nmsu.edu](mailto: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 protection 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 the 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 that the description of the proposed study in the IRB application is accurate and complete before 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 an immediate risk of harm to the subject
- Submitting required status reports or continuing review forms as necessary 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 <https://compliance.nmsu.edu/irbtraining/>
- Agreeing to meet with faculty advisor/chair regularly to monitor study progress.

### **A) Faculty Advisor's Assurance: Core Principles**

The following principles reflect the 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 below. By submitting a protocol for IRB review, the Faculty Advisor to a Student Principal Investigator/Trainee accepts responsibility to monitor and verify that the Student Principal Investigator/Trainee complies with the following:

- The information provided in an 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 training related to the research study.
- Only the currently approved, IRB approved 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 participants or their legally authorized representatives unless these requirements have been waived by the IRB.
- Timely written reports of unanticipated events 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, the Faculty Advisor will:

- Arrange for another faculty member to accept responsibility in his/her absence, if unable to supervise this research personally, as when on leave or vacation.
- Keep him or herself informed of current developments that may affect the research, and will immediately notify the IRB if he or she becomes aware of any information that may materially alter the risk/benefit ratio.
- Meet with the trainee/student regularly to monitor study progress.

### **B) Student Principal Investigator/Trainee Assurance: Core Principles**

Likewise, the Student Principal Investigator/Trainee must accept the responsibilities and roles of Student Principal Investigator and Trainee, and comply with the following:

- Review the conflict of interest section of my application and verify that the information disclosed is correct.
- Verify that the information provided in any IRB application represents an accurate description of the study.
- Assure that all project personnel will conduct the study in compliance with all applicable federal, state, and local regulations and IRB and institutional requirements and policies, and assure that all project personnel will be properly trained in their respective responsibilities, and have completed all appropriate training related to the research study.
- Ensure that only the currently approved IRB informed consent documents and recruitment scripts will be used.
- Agree to make no changes to the protocol without prior IRB approval except when necessary to eliminate immediate hazards to the subject. In the latter case, he or she agrees to notify the IRB as soon as possible after such an occurrence.
- Obtain valid informed consent/assent from all research participants or their legally authorized representatives, unless these requirements have been waived by the IRB.
- Provide timely written reports of unanticipated events involving risks to subjects or others to the Office of Research Compliance according to its reporting guidelines.
- Keep informed of current developments that may affect the research, and notify the IRB if he

or she becomes aware of any information that materially alters the risks/benefits ratio.

- Maintain all required research records in accordance with applicable regulations and IRB policy
- Notify the IRB will be immediately 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.
- Ensure that the minimum necessary data needed is being requested from participants to achieve the goals of the research described in any application, as per HIPAA Privacy regulations.
- Will consult with Faculty Advisor if unable to direct this research personally regarding an appropriate option to consider for the continuation or discontinuation of the research, as when on leave or vacation.

### 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, the Declaration of Helsinki, the Belmont Report, and the United States Code of Federal Regulations (CFR). Although we outline these documents briefly below, investigators will become more aware of their importance as they complete the required IRB training. Although many of these documents are not laws or regulations per se, the relevant sections of the CFR are formal regulations the violation of which can have substantial legal ramifications.

#### 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.

#### B. Declaration of Helsinki

In June 1964, the World Medical Association (WMA) adopted [the Declaration of Helsinki](#) in Helsinki, Finland, as ethical guidelines 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 multiple times, with the last revision in 2013.

#### C. Belmont Report

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued [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**. Respect for persons requires that researchers treat individuals as autonomous, that is, as having the capacity to make their own choices and that they protect persons with diminished autonomy. Research demonstrates beneficence when subjects are protected from harm, specifically, by maximizing possible benefits and minimizing possible harms from study participation. Justice refers to the equitable selection of subjects for a study without undue burden of risks or exclusion from likely benefits of a particular population.

#### D. Code of Federal Regulations: Federal Policy for the Protection of Human Subjects (AKA The Common Rule/Revised 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 provided the 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.” Revisions to the common rule were enacted in 2019 (“Revised Common Rule”).

#### **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.

NOTE: The FDA has not accepted changes made under the Revised Common Rule

#### **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 an 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.

#### **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 many 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.

## IV. What Is Human Subjects Research?

Researchers may wonder whether their project fits the definition of **human subjects research**. To do so, the project must meet the federal regulatory definitions of both **research** and **human subjects** to require IRB approval. Those definitions are below.

The revised common rule (45CFR46.102 (d)) defines *research* as

(l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The revised common rule (45CFR46.102 (d)) defines *human subject* as

(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

The CFR provides additional information and descriptions to supplement these definitions.

### Determining if a Study is Human Subjects Research

As a general rule, NMSU IRB staff--not investigators—have the responsibility to make determinations of whether research activities constitute human subjects research. The same staff is charged with determining whether some classes of human subjects research are exempt from IRB review under federal guidelines. The following chapter describes the exempt categories and review process.

Any investigator who is unsure whether his/her project constitutes human subjects research” should complete a ***Determination of Human Subjects Research*** form and submit it to the Office of Research Compliance. The Chair and/or designee will determine if the study is Human Subjects Research and therefore requires submission of an IRB protocol. Federal regulations do not allow investigators to make this determination themselves.

## 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 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. They may also include medical professionals, theologians, and representatives from vulnerable populations (e.g., prisoners).

The IRB's primary function is to protect human subjects participating in research by reviewing for compliance with legal and ethical standards such as those outlined in the code of federal regulations (Title 45 CFR 46) and the Belmont Report, among others. 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. Research involving human subjects cannot be conducted without the approval of the IRB.

IRB members must have the necessary experience and expertise to evaluate proposed research projects. IRBs must also be diverse in terms of race, gender, and cultural backgrounds. Current IRB members can be found here: <https://compliance.nmsu.edu/irbmembers/>

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

### What does the IRB do?

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

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.**

## VI. Types of IRB Review

Federal regulations provide for three types of IRB review: **exempt, expedited, and full-board** [CFR 45; Part 46](#). The following chapter explains 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 the use of such collections meets certain conditions.

### Exempt Review

The IRB – not the researcher – must determine when a research project falls under one of the eight exempt categories. There are eight exempt categories listed in the federal regulations (45 CFR 46.104(d)).

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 an annual status report in order to comply with NMSU institutional policies 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. An exemption cannot be granted for research that uses prisoners. If the IRB finds the study is not exempt, it must go through an expedited or full board review.

While research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from 45 CFR 46 regulations, they must still be submitted to the IRB for their review and approval.

### Exempt Review Categories:

1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects; financial standing, employability, educational advancement, or reputation; or
- c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § \_\_.111 (a)(7).

NOTE: Exempt category two (2) can include children only when the investigators do not participate in activities being observed.

3. **(i)** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
  - a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
  - b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
  - c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § \_\_.111 (a)(7).

**(ii)** For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

**(iii)** If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

NOTE: Category three (3) does not allow children to participate.

4. Secondary research for which consent is not required: Secondary research uses of

identifiable private information or identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- a. The identifiable private information or identifiable biospecimens are publicly available;
  - b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
  - c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those in terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512 (b); or
  - d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 USC 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 USC 552a, and if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 USC 3501 et seq.
5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
- a. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
6. Taste and food quality evaluation and consumer acceptance studies, if
- a. Wholesome foods without additives are consumed; or
  - b. 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.

**NEW MEXICO STATE UNIVERSITY IS CURRENTLY NOT USING THE CATEGORIES BELOW (EXEMPT CATEGORY 7 AND 8) BECAUSE THEY REQUIRE BROAD CONSENT. IF INVESTIGATORS WANT TO CONDUCT THESE KINDS OF STUDIES, THEY SHOULD CONTACT THE IRB.**

7. Storage or maintenance for secondary research for which broad consent is required: storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §\_\_\_\_.111(a)(8).
8. Secondary research for which broad consent is required: research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
  - a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §\_\_\_\_.116 (a)(1) through (4), (a)(6), and (d);
  - b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §\_\_\_\_.117;
  - c. An IRB conducts a limited IRB review and makes the determination required by §\_\_\_\_.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section;
  - d. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

## **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 protocols in several categories 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.

8. Continuing review of research previously approved by the convened IRB as follows:

- a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- b. Where no subjects have been enrolled and no additional risks have been identified; or
- c. Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. `

NOTE: NMSU will use expedited categories 8 and 9 only when a research protocol receives or will receive a *convened full board review* (see below). Under these circumstances, investigators will still be responsible for submitting continuing reviews. The IRB will decide the frequency of the continuing reviews (e.g., six months, one year).

## 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. All protocols requiring review by the full IRB shall be reviewed at convened meetings which will be held at timely intervals. If an emergency meeting is necessary in order to comply with any aspect of the Federal regulations, such a meeting will be called by the IRB Chair. The Principal Investigator (PI) may be invited to attend a convened meeting at which their protocol is to be reviewed. In such cases, the IRB reserves the right not to review the research study if a representative of the research team knowledgeable about the study design is not 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 the 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.**

## **IRB Review Exceptions**

**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.

As noted above, the NMSU IRB—not investigators—has the responsibility to make determinations of whether research activities constitute human subjects research or are *not human subjects research*. Any investigator who is unsure whether his/her project constitutes human subjects research” should complete a ***Determination of Human Subjects Research*** form and submit it to the Office of Research Compliance. The Chair and/or designee will determine if the study is Human Subjects Research and therefore requires submission of an IRB protocol. Federal regulations do not allow investigators to make this determination themselves.

# 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).
- Consult with the IRB regarding the appropriate level of IRB review (NHSR, coded data, exempt, expedited). Investigators who are unsure whether his/her project constitutes human subjects research” should complete a *Determination of Human Subjects Research* form and submit it to the Office of Research Compliance. 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 [https://dept-wp.nmsu.edu/maestrohelp/files/2019/01/Maestro\\_V2\\_Help\\_Documentation.pdf](https://dept-wp.nmsu.edu/maestrohelp/files/2019/01/Maestro_V2_Help_Documentation.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 involving human subjects is expedited or exempt

The federal regulations allow for eight exempt and nine expedited review categories of human subjects research (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. Investigators can always consult with IRB staff about the proper classification of their protocols. Moreover, IRB staff may modify submitted protocols to fit within more appropriate review categories without returning the protocol to the investigator for formal modification.

One approach to determining whether your protocol is exempt or expedited is to review the eight exemption categories identified in Chapter VI and decide if the protocol matches the category description. If the protocol appears to fit an exempt category, you might consider the following questions:

- Does the research include vulnerable populations, such as children or prisoners?
- Will the investigator collect personally identifying information?
- Is there any possible risk to participants stemming from their participation in the study?

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

If the project is not exempt, investigators should 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 determine whether the protocol requires 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. The link and instructions for the CITI Human Subjects Training can be found at <https://compliance.nmsu.edu/irbtraining/> .

### 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 are 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 HS. Human Subjects; RI: Research Instruments; CF: Consent form; OE: 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” (see procedures for making this determination above), 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 the 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 approves 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. Status Reports, Continuing Reviews, and 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 status report or continuation form, as necessary, via MAESTRO.

The Revised Common Rule eliminated the need for continuing reviews. Researchers working with agencies that did not adopt the changes in the Revised Common Rule must continue to follow the agency's specific guidelines