

## E90: Human Subjects in Research

Approved By: Faculty Senate

Last Updated: **Draft 4/19/17**

Responsible Faculty Committee: Research Policy Committee

Office Responsible for Administration: Vice President for Research and HSC Vice Chancellor for Research

Revisions to the Policy Rationale, Policy Statement, and Applicability sections of this document must be approved by the full Faculty Senate.

### POLICY RATIONALE

In the oversight of all Human Subjects Research, the University of New Mexico (UNM) as a whole, is committed to protecting the rights and welfare of participants in Human Subjects Research consistent with the ethical principles outlined in the April 18, 1979, report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report”:

- Respect for Persons
- Beneficence
- Justice

### POLICY STATEMENT

UNM aims to promote a culture of compliance with the highest legal and ethical standards for the conduct of human research. UNM recognizes research as one of its chartered enterprises and shares ~~with its individual faculty members~~ responsibility for promoting and managing ~~defending~~ this activity with its individual researchers when conducted under its auspices.

To ensure comprehensive protection of the rights and welfare of subjects in human research across a diverse social-behavioral and biomedical research enterprise, UNM holds two distinct Federal Wide Assurances (FWAs) approved by the U.S. Department of Health and Human Services, one for the University Main Campus and a separate FWA for the Health Sciences Center (HSC). Under these agreements, UNM assures that all of its activities related to human subjects in research (“Human Subjects Research”) are conducted in accordance with all applicable federal regulations (e.g., 45 C.F.R. § 46, 21 C.F.R. § 50, 21 C.F.R. § 56, 21 C.F.R. § 312, 21 C.F.R. § 812).

~~The following policy is not intended to relieve the individual scientist of his/her ultimate responsibility for moral and ethical conduct nor to deny her/him the right to reasonable freedom of inquiry. The policy does make explicit~~

the criteria, by which the propriety of an action should be judged. The procedure is designed to protect the University (including faculty, students and the administration) against alleged violation of these criteria.

1. In considering the participation of humans as research subjects, the guiding principle is that no one should be exposed to risk to health or well-being without being given all reasonable protection and without being adequately informed. The rights and welfare of the study subjects are of paramount importance.

2. In general, the purpose of the study, the procedures followed, and the possible risks involved must be explained to the subject. The investigator must be satisfied that the explanation of participation has been understood, and consent must be obtained without duress or deception. Such an explanation may be postponed or even omitted where there are no risks to the subject, and a full account of the purposes and procedure in advance might bias the result.

3. It is the responsibility of the individual investigator to have adequate knowledge of the possible consequences of his research, or of research done under his direction.

4. Whenever possible, any hazards to health or well-being of each procedure must first be investigated with animals.

5. Whenever medication or physical intervention is used, or whenever the subject is exposed to unusual environmental conditions, proper protection and supervision must be provided.

6. The individual's personal privacy and the confidentiality of information received from him/her must be protected.

7. The individual's time should not be invaded to the extent that the participation creates conflict with other obligations.

8. Remuneration may be offered for the time involved in a study, provided the remuneration is not so large as to constitute an improper inducement to participate.

9. Any individual may request termination of his/her participation at any time and this request will be honored promptly and without prejudice.

10. The review procedures as described below are intended to help maintain a positive attitude toward scientific research. Unless there are reliable indications to the contrary, all University of New Mexico faculty members are presumed to behave responsibly and all experimental subjects should be willing to contribute to the advancement of knowledge, provided their personal rights are respected.

---

## - APPLICABILITY

---

All academic and research UNM units, including the Health Sciences Center and Branch Campuses.

Revisions to the remaining sections of this document may be amended with the approval of the Faculty Senate Research Policy Committee, Policy Committee, and Operations Committee.

---

## DEFINITIONS

---

**[HRRC refers to UNM HSC's Human Research Review Committees \(HRRC\)](#)**

[IRB](#). Refers to the UNM Main Campus Office of the Institutional Review Board (IRB)

[Human Research Subject](#). The [United States Department of Health and Human Services \(HHS\)](#) defines a human research subject as a living individual about whom a research investigator (whether a professional or a student) obtains data through 1) intervention or interaction with the individual, or 2) identifiable private information (32 C.F.R. 219.102(f))

---

## WHO SHOULD READ THIS POLICY

---

- [Faculty, staff, and students conducting research](#)
- [Members of the Faculty Senate and the Research Policy Committee](#)
- [Academic deans or other executives, department chairs, directors, and managers](#)
- [Administrative staff responsible for sponsored research management](#).

---

## RELATED DOCUMENTS

---

*UNM Regents' Policy Manual*

[Policy 5.1](#) "The Faculty's Role in UNM's Academic Mission"

[Policy 5.14](#) "Human Beings as Subjects in Research"

[Policy 5.13](#) "Research Fraud"

*Faculty Handbook*, [Policy E40](#) "Research Misconduct"

---

## CONTACTS

---

Direct any questions about this policy to Office of the Vice President for Research or the HSC Office of the Vice Chancellor for Research.

---

## PROCEDURES

---

[All Principal Investigators and involved researchers engaged in Human Subjects Research are required to:](#)

[1. Obtain approval from the IRB or HRRC following the procedures established by the Main Campus Office of the IRB \(OIRB\) and the Main Campus IRB; or the HSC Human Research Protections Office and the HSC's Human Research Review Committees \(HRRC\), depending on the Principal Investigator's primary appointment. Procedures are posted on the respective websites and are regularly and continually updated to comply with federal regulations and accreditation standards.](#)

[2. Monitor ongoing research and teaching activities under their supervision to ensure that they continue to be conducted in accordance with approved protocols.](#)

[3. Ensure that all personnel involved in Human Subjects Research under their supervision are appropriately trained on the applicable laws, rules, and regulations regarding Human Subjects Research as well as the Main Campus IRB's or HRRC's policies and procedures, as the case may be, with respect to Human Subjects Research.](#)

#### 4. Comply with and ensure compliance with all determinations and additional requirements of the IRB and/or HRRC, as the case may be, with jurisdiction over the research.

The policy described above shall be implemented as follows.

1. Several Human Research Review Committees shall be established in the manner described below.

(a) The dean of each school or college, or the chief administrative officer of each UNM division or agency involved in research of this type, is directly responsible that a Human Research Review Committee exist to evaluate proposals which may come from her/his faculty or professional staff.

In carrying out this responsibility, the administrative officer may establish a Human Research Review Committee to serve his/her particular school, college or agency. Or, if deemed desirable and feasible, she/he may cooperate with another dean or administrative officer in setting up a joint committee to serve more than one group. (In any case, any proposed research involving human beings as subjects would have to be reviewed in advance by some Human Research Review Committee.)

(b) The number of persons to serve on a Human Research Review Committee, the term of office, and the type of faculty representation on such a committee would be at the discretion of those responsible for establishing these committees. However, each Human Research Review Committee must include in its membership one or more persons outside the college, school, or agency it specifically serves. Projects involving investigational new drugs (INDS) must be reviewed by a committee quorum that includes not less than two members who are licensed to administer drugs, and one who is not so licensed.

2. The Human Research Review Committees shall evaluate procedures against the Policy described above and the specific standards described in item 4 below, as well as such additional standards as may be appropriate to the research area. In so doing, they shall call upon specialists, including, where appropriate, consultants not on the University faculty, and may interview the investigator and his/her staff. Decisions shall be reached in executive session by the MANN rule (majority aye, no nay).

3. Each Human Research Committee shall maintain formal records of its decisions for at least five years. It shall receive and, where deemed appropriate, verify reaffirmations by the researcher that her/his methods are essentially unchanged and that no adverse consequences have occurred. Such reaffirmation must be made at six-month intervals, although the committee may require more frequent reporting on some research and may make inspections or take such other actions as found necessary to insure compliance with the policy and procedures herein stated.

4. The investigator shall be responsible for obtaining approval from a Human Research Review Committee prior to conducting any research involving human subjects. Application for approval is submitted in the form of a memorandum approved by the department chairperson or other appropriate person and must contain complete and explicit information concerning each of the following:

(a) Name of the responsible faculty member.

(b) Name(s) of any others who will make contact with human subjects. In the case of continuing research programs with standard procedures, it may be sufficient to indicate the type of assistants to be used (e.g., graduate research assistant) and the method used to insure that they are properly trained.

(c) Title of the research. Also indicate its status (e.g., grant supported dissertation, independent study, etc.).

(d) Objectives of the research. Indicate the type of conclusions anticipated. Especially when any risks are involved, the description of the objectives should be sufficiently detailed so that the potential benefits of the research can be weighed against those risks.

(e) Methods of procedure. Interest here is in those procedures that make actual contact with the human subject. Specifically, if any medications are to be used, list their names and dose ranges. If "deception" is involved, describe the extent of deception and why it is deemed necessary. If remuneration is involved, state how the level was arrived at. In general, describe the nature of the experiences that the subjects will encounter. Include also the methods for selecting and screening subjects, and the amount of time expected of them.

(f) Protection measures. Give the techniques used to protect the subject against unnecessary risk in relation to the procedures just described. For example, if medication is used, for how long will observation be maintained to insure that no residual effects are present? If electric stimulation is involved, how will the subject be protected from the chance of a serious shock? If deception or stress is involved, how will the subject be relieved of these after the experiment? If personal or private information is to be revealed, how will security of such information be guaranteed? In general, describe the precautions that will be taken to preclude physical, social, or psychological harm. Where possible, include reference to similar procedures previously used either by the investigator or in other laboratories.

(g) Consent. The matter of consent involves three issues: 1) is consent necessary? 2) if so, who is the appropriate consenting agent? and 3) what information is necessary to insure that consent is adequately "informed"? In her/his application, the investigator must deal with these issues so as to justify the procedure according to the following guidelines:

(1) Where no risks or harmful disclosures are involved, where the research is a by-product of ordinary training or treatment, and where no permanent effect upon the subject is anticipated, consent is not required. Where some degree of deception, stress, or discomfort is involved, where the research requires specific participation, or where significant changes in health or well-being are intended by the use of procedures that are controversial, or not proved, consent may or may not be required depending upon the particular study proposed. Where risk or invasion of privacy is involved, where abnormal conditions will be encountered, or where treatment is proposed by new methods, consent is required.

(2) The consenting agent shall normally be the parent or guardian of minors, except that the consent of college students may in some cases be acceptable. Consent by an adult is acceptable provided there is no question about the soundness of her/his understanding of the information given in obtaining consent; where such question exists, the next of kin or legal guardian is appropriate.

(3) The amount of information necessary for consent to be adequately "informed" varies with the nature of the research and the amount of risk involved. The investigator must submit in writing an account in lay language of what he/she intends to tell the subjects in soliciting their participation, in instructing them as to procedures, and in insuring them their right to withdraw without prejudice. The experimenter may, but is not required to, obtain consent in writing from the subjects. In any event, she/he is required to maintain a record identifying the subjects, to note therein that each subject was informed in the manner described in the written account, and to sign his/her name indicating that the subject understood the research to the extent indicated and agreed to participate.

(h) Changes. Any changes in methods or procedure from those described above or any unexpected consequences adversely affecting the subjects will be brought promptly to the attention of the Human Research Review Committee involved.

5. Continuing approval may be granted when the essentials of methods of procedure remain unchanged over an extended series of studies; in this case, reassurance must be provided at six-month intervals. Minor modifications of procedure may be approved as a supplement to prior general approval.

6. Where relatively standardized methods and procedures have been developed (e.g., ethnographic field studies, learning of paired associates, etc.), the appropriate department chairperson or other persons responsible for the agency or division in which the research is being conducted may, on application, be granted blanket authorization

to approve such studies without further review. The semi-annual report must include a listing of specific approvals granted in sufficient detail to permit the Human Research Review Committee to review this standing authorization.

7. A student's advisory committee may authorize preliminary pilot research.

8. A faculty member must retain adequate records concerning the procedures described above. Specifically, records indicating informed consent should be held for at least three years after a subject has participated, and especially where invasion of privacy might be at issue, after the results have been published and the final disposition of the original protocols has been made.

9. Whenever a procedure has been disapproved by either a department chairperson or a Human Research Review Committee, the investigator may appeal to the department chairperson, or the college dean, as appropriate. The mechanism for reconsideration, if warranted, is discretionary. The committee may be asked to reconsider; an ad hoc committee of the faculty may be appointed to act as an appeal group; experts not on the faculty may be consulted. The final decision should rest with whatever appeal mechanism is established in the individual case. If the appeal should result in approval, the records of the disapproval shall be retained but, in the case of an application for grant support, only the record of approval shall be forwarded to the granting agency.

10. All faculty members share the responsibility for compliance with the policy as herein stated, but first-line responsibility resides with the individual faculty member for all work done under his/her direction and second-line responsibility resides with the department chairperson who should remain cognizant of the research activities within her/his department.

---

## HISTORY

---

### Effective:

Revised November 15, 1966

---

## DRAFT HISTORY

---

February 20, 2017—draft highlights all changes between current policy and proposed policy.

December 7, 2016—RPC Endorsed draft was revised by Policy Committee to include definitions and clarify Item 1 of Procedures. Draft endorsed by Policy Committee to submit to Operations for endorsement to send to faculty for review and comment.

April 4, 2016—Draft revised by the Faculty Senate Policy Committee and submitted to the Faculty Senate Research Policy Committee (RPC) for review.

September 6, 2015—Proposed revised draft placed in new policy format for review by the Faculty Senate Policy Committee

July 1, 2015-- Revised draft prepared by HSC

COMMENTS TO:  
[handbook@unm.edu](mailto:handbook@unm.edu)

[FACULTY HANDBOOK HOME](#)

[TABLE OF CONTENTS](#)

[TABLE OF POLICIES](#)

[UNM HOME](#)