E90: Human ~~Beings as~~ Subjects in Research

Policy

The following operating policy governs the participation of human ~~beings as~~ subjects in research:

POLICY AND PROCEDURES CONCERNING RESEARCH INVOLVING HUMAN SUBJECTS
(Revised ~~November 15, 1966~~July 1, 2015)

The University of New Mexico recognizes research as one of its chartered enterprises and shares with its individual faculty ~~members~~member's responsibility for promoting and defending this activity when conducted under its auspices. 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/her the right to reasonable freedom of inquiry. The policy does make explicit the criteria ~~, largely self-evident,~~ by which the propriety of an action should be judged.~~:~~ T~~t~~he procedure is designed to protect human subjects who participate in research and the University (including faculty, students, and the administration) against alleged violation of these criteria.

Policy

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 to be followed, and the possible risks involved must be explained to the~~informed consent must be obtained from all human subjects prior to their participation in research. The investigator must be satisfied that the explanation of participation has been understood, and consent must be obtained without duress, coercion, or~~,~~ undue influence.~~ 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 results.~~

3. It is the responsibility of the individual investigator to have adequate knowledge of the possible consequences of his/her research, or of research done under his/her 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~~ subject's personal privacy and the confidentiality of information received from ~~her/~~him/~~-~~her must be protected.

7. ~~An individual~~The subject'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, a~~All University of New Mexico faculty members are presumed to behave responsibly ~~,~~and in accordance to applicable local, state, and federal regulations, laws, and statutes. ~~and all experimental research subjects should be willing to contribute to the advancement of knowledge, provided their personal rights are respected.~~

Procedures

The policy described above shall be implemented as follows.

1. ~~Several Human Research Review Committees~~All Institutional Review Boards (IRBs) shall be established ~~in the manner described below~~in accordance with relevant federal regulations (45 CFR 46.107, 21 CFR 56.107). ~~:~~ In addition:

(a) The ~~dean~~ Dean of each school or college, or the ~~chief administrative officer of each UNM division or agency~~Chair of each department involved in human research ~~of this type~~, is ~~directly~~ responsible ~~that a Human Research Review Committee exist~~for establishing procedures to evaluate the scientific merit of 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~~an IRB, the term of ~~office~~membership, and the type of faculty representation and expertise on such a committee would be ~~at the discretion of those responsible for establishing these committees~~consistent with the policies and procedures developed by the respective IRB ~~O~~office. However, each ~~Human Research Review Committee~~IRB must include in its membership one or more non-scientists and at least one person~~s~~ ~~outside~~ unaffiliated with

the college, school, or agency it specifically serves. FDA-regulated p~~P~~rojects ~~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~~at least one licensed physician.

2. The ~~Human Research Review Committees~~IRBs shall evaluate ~~procedures~~ proposals against the Policy described above and the specific standards ~~described in item 4 below~~of the federal regulations and/or IRB policies, as well as such additional standards as may be appropriate to the research area. All federally funded research shall be reviewed according to relevant federal regulations (45 CFR 46.111, 21 CFR 56.111). In so doing, ~~they~~ the IRB ~~shall~~ can 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~~IRB shall maintain formal records of its decisions for at least ~~five~~ three 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~~conduct continuing review of federally funded non-exempt research at ~~six-month intervals~~least annually and according to IRB policies, although the ~~committee~~ IRB may require more frequent reporting on some research and may make inspections or take other such ~~other~~ actions as found necessary to insure compliance with the polic~~y~~ies and procedures herein stated.

4. The investigator shall be responsible for obtaining approval from ~~a Human Research Review Committee~~an IRB prior to conducting any research involving human subjects. Application for approval is submitted according to the IRB's policies and procedures. ~~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~~in risk or any unexpected ~~consequences~~ problems adversely affecting the subjects or others will be ~~brought~~ reported promptly to the ~~attention of the Human Research Review Committee involved~~IRB.

5. The investigator shall obtain c~~C~~ontinuing IRB 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~~for all non-exempt studies.

~~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~~6. A faculty member must retain adequate records concerning the procedures described above. ~~Specifically,~~Research records, including those ~~indicating~~ documenting 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~~the study is closed with the IRB. Sponsors and federal agencies may have other retention requirements beyond three years that must be adhered to.

~~9~~7. Whenever a ~~procedure~~ study has been disapproved by ~~either a department chairperson or a Human Research Review Committee~~the IRB, the investigator may appeal ~~to the department chairperson, or the college dean~~the decision to the IRB, 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 IRB has 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~~regarding disapproval and this cannot be appealed to or overturned by any Institutional Official.

~~10~~8. 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 (including student research) and second-line responsibility resides with the department chair~~person~~ who should remain cognizant of the research activities within ~~her/~~his/her department.