THE UNIVERSITY OF MICHIGAN POLICY ON THE USE OF HUMANS AS SUBJECTS IN RESEARCH AND INSTRUCTIONAL INVESTIGATIONS

THE POLICY

1. It is the policy of the University to respect and safeguard the rights and welfare of all individuals who may be involved in i. ctivities. In the conduct of its research and instructiona. ogram, the University's action will conform with the te. rinciples known as the Nuremberg Code (see Appendix A) to tent that they or their basic objectives are applicabl. rally or in principle, and other applicable codes to th. exte.t that they are not in conflict with the Nuremberg Code.

Applicability

2. This policy and its procedures will be applicable to all situations and activities of the University where human beings may be "at risk" as a consequence of participating as a subject in investigation, research, experimental procedures in instruction, or other activities--regardless of the source(s) of support. It applies equally whether the supporting funds are from outside or from within the University, whether separately budgeted or unbudgeted. For the purpose of this policy, the University accepts the definition of "at risk" as stated in the Institutional Guide to DHEW Policy on Protection of Human Subjects. "An individual is considered to be 'at risk' if he may be exposed to the possibility of harm--physical, psychological, sociological, or other--as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs." It is the responsibility of the principal investigator to refer his plans to an appropriate review committee if humans are subjects even if he, the principal investigator, does not consider the subject to be "at risk."

Responsibility for Implementation and Administration

3. Responsibility for the implementation and administration of this policy where investigations, either in instruction or research, involve humans as subjects rests with the Vice-President for Research. He will be assisted in the resolution of policy questions by a committee composed of the chairmen of the several review committees established by the schools, colleges, and research units. The Vice-President for Research is responsible for approving the makeup of the review committees. While he may impose stricter limitations on the conduct of the investigation than approved by a committee, he may not relax any limitation imposed by a committee.

REVIEW COMMITTEES

4. The general procedure for implementation of this policy will be the review of the plan of any investigation involving

Implementation Procedure

humans as subjects by a committee in accordance with the provisions of this policy. If the committee, after reviewing a written plan for the investigation or interviewing the principal investigator(s), is convinced that all the provisions of this policy will be met, the Vice-President for Research will be so informed in writing, with a copy to the principal investigator. The investigator's copy of this communication will be his authorization to conduct the proposed investigation when and if all other University requirements are met.

Unit Committee

5. It will be the responsibility of each school, college, and research unit of comparable level having a significant volume of activity involving human beings as subjects in investigations to establish a review committee. Each review committee is to be composed of sufficient members with varying backgrounds and possessing the professional competence pertinent to the judgments that are to be made in the implementation of this policy. In addition to persons qualified in the appropriate disciplinary and professional areas, committees should include, when appropriate, persons whose primary concerns lie in the areas of law, standards of professional conduct and practice, and community attitudes. These peripheral area representatives are a requirement where the review committee is concerned with new drug studies. The makeup of the committee need not be restricted to members of the specific unit of the University and may be drawn from any part of the University to ensure that the committee includes professionals appropriate to judgments concerning: (1) the rights and welfare of the individual or individuals involved; (2) the appropriateness of the methods used to secure informed consent; (3) the determination of the risks to the subjects and the relationship of those risks to the benefits to the subject or the importance of the knowledge to be gained; and (4) the confidence that the committee can repose in the principal investigator in matters related to the policy objectives. A member of a committee having a vested interest in an investigation being reviewed must be disqualified from participating in the decision.

Drug Studies

Makeup of Committees

Judgments to be Rendered

Disqualification of Committee Member

Units Not Having Committees

Appeals

6. Units of the University whose volume of activity involving human beings as subjects may not justify unit committees will be served by a committee reporting directly to the Vice-President for Research or by one of the existing unit committees as assigned by the Vice-President for Research. The committee reporting to the Vice-President for Research will be composed of the chairmen or alternate of appropriate unit committees and other members possessing competence pertinent to the judgments that are to be made. This latter committee is also available should appeal be considered necessary.

Establishing New Committees

7. Any unit of the University not having a review committee may, with the approval of the Vice-President for Research, establish one when the dean or director deems it appropriate.

Submission to Review Committees

8. Before an activity involving humans as subjects may be undertaken or a proposal for its support or continuation submitted to a prospective sponsor, in or outside the University, the plan of the investigation must be submitted to the appropriate review committee with due regard to the lead time required by that committee. The committee will review the plan and procedures to ensure compliance with the specifications (1) through (4) in paragraph 5 above and, if necessary, will conduct interviews with the project director, principal investigator(s), or individuals directing the investigation, instruction demonstrations, or activity. The committee is required to review the material in the form in which it will be submitted to the sponsor. When the committee is satisfied after this review that the University's policy and the rights of individuals will not be compromised, the chairman of the committee will confirm approval of the project in a memorandum to the Vice-President for Research with copies to the principal investigator and the dean or director of the investigating unit. The memorandum, in addition to indicating favorable review, will call to the attention of the principal investigator: (1) that he is required to advise the review committee before making any change in protocol which might bring into question the involvement of human subjects in a manner at variance with the consideration on which the prior approval was based; and (2) that every 12 months from the date of the approval, or at shorter intervals if the risks are such that in the opinion of the committee a shorter period would be appropriate, a re-review is required. The memorandum to the Vice-President for Research will also indicate whether the approval is for the protocol as originally proposed or as altered as a result of the review. Any additional instruction to the principal investigator(s) considered appropriate may be included in the memorandum.

Committee Action

Committee Memorandum

Changes in Protocol Review

Alteration of Protocol

Additional Instructions in Memorandum

Processing the Memorandum

9. When the review is related to a sponsored project or training grant, the original copy of the memorandum from the chairman of the review committee to the Vice-President for Research is to accompany the proposal as it is processed within the University. The Vice-President for Research will retain the memorandum in his files. In the case of other activities, as covered in paragraph 2 above, the review committee memorandum will also be sent to the Vice-President for Research. In these cases, the memorandum will be accompanied by a brief description identifying the program or activity involving the human subjects. All review committee memoranda of approval will be retained in the Office of the Vice-President for Research as a part of the University's record of administration of this policy.

Instructional or Other Activities

Quorum

10. A simple majority, plus one if necessary to provide an odd number, will be considered a quorum for purposes of committee work. In cases where the investigation relates to new drugs, the quorum must include at least two persons licensed to administer drugs and one who is not so licensed.

Committee Files

11. The files of the several review committees must contain records of the review process for individual cases including, but not limited to, minutes of discussions of substantive issues and a sample of the form for written consent as approved by the committee.

Basic Elements of Informed Consent

12. This policy recognizes as essential the following six basic elements* of informed consent:

"1. A fair explanation of the procedures to be followed, including an identification of those which are experimental;

2. A description of the attendant discomforts and risks;

3. A description of the benefits to be expected;

4. A disclosure of appropriate alternative procedures that would be advantageous for the subject;

5. An offer to answer any inquiries concerning the procedures;

6. An instruction that the subject is free to withdraw his consent and to discontinue** participation in the project or activity at any time,"

Retention of Consent Agreements

and requires that the investigator, where appropriate, retain in his file a complete set of written consent forms signed by the subject(s) or his (their) authorized representative(s). This treatment of informed consent records may be altered when retention of written consent may more appropriately be in clinical files.

Exculpatory Language

13. The informed consent agreement, written or oral, entered into by the subject or other qualified third party(s) representative of the subject's interests, should include no exculpatory language through which the subject is made to waive, or appears to waive, any of his legal rights, or to release the University its agents from liability for negligence.

When t onduct the Re.

14. An essential feature and requirement of this Policy Procedure is that approval of an appropriate review committee be obtained before any investigation or activity involving humans as subjects is started or a proposal for support from the outside or from within the University is processed.

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*Quoted from the Institutional Guide to DHEW Policy on Protection of Human Subjects, DHEW Publication No. (NIH) 72-102, Dec. 1, 1971.

**The committee will recognize instances where the subject may not be at liberty to withdraw at will where such withdrawal would be hazardous.

15. The Office of the Vice-President for Research will provide each committee with guidelines and instructions that may become available from time to time from such sources as: professional organizations, the Department of Health, Education, and Welfare, the Department of Agriculture, and other agencies of the federal government.

APPENDIX A

Nuremberg Code[1]

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

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[1] II Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, The Medical Case 181 (U.S. Government Printing Office, 1949).

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.