

SECTION 5: GENERAL IRB POLICIES

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SECTION 5.1 APPLICABILITY

The procedures set forth in this document are applicable to all faculty, staff, employees, and students at the University of North Texas Health Science Center who propose to use humans as subjects in research, development, and related activities.

SECTION 5.2 FUNCTIONS AND RESPONSIBILITIES

- A. Safeguarding the rights and welfare of subjects at risk in any research activity, whether financially supported or not, and irrespective of the source of any supporting funds, is primarily the responsibility of the institution. In order to provide for the adequate discharge of the institutional responsibility, no research activity involving human subjects may be undertaken by any faculty, staff, employee or student at the University of North Texas Health Science Center unless our IRB has reviewed and approved the research prior to commencing the research activity.
- B. The review will determine whether the subjects will be placed at risk and, if risk is involved, that:
1. Risks to subjects are minimized (This is an essential condition for approval);
 2. The risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;
 3. The rights and welfare of any such subjects will be adequately protected;
 4. Legally effective informed consent/authorization will be obtained by adequate and appropriate methods in accordance with the provisions of Section 4 of this manual; and
 5. The conduct of the activity will be reviewed at intervals determined by the IRB, but not less than annually.
- C. The determination of when an individual is at risk is a matter of the application of common sense and sound professional judgment as it relates to the circumstances of the research activity in question.
1. The IRB will carefully weigh the relative risks and benefits of the research procedures to be applied to the subject.

2. Research activities designed to yield fruitful results for the benefit of individual subjects or society in general may incur risks to the subjects provided such risks are outweighed by the benefit to be derived from activities.
 3. The degree of risk involved in any activity should never exceed the humanitarian importance of the problems to be solved by that activity. Likewise, compensation to volunteers should never be such as to constitute an undue inducement to the subject.
 4. There is a wide range of medical, social and behavioral research projects and activities in which no immediate physical risk to the subject is involved; e.g., those utilizing personality inventories, interviews, questionnaires, or the use of observation, photographs, taped records, or stored data. However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy.
 5. There may also be projects that involve tissues, body fluids, and other materials obtained from human subjects. The use of these materials obviously involves no element of physical risk to the subject. However, their use for research, training, and service purposes may present psychological, sociological, or legal risks to the subjects. In these instances, application of the policy requires IRB review to determine that the circumstances under which the materials are to be procured are appropriate and, if the subject is deemed to be at risk, that adequate and appropriate consent will or can be obtained for the use of these materials for research purposes.
 6. Similarly, some studies depend upon stored data or information that was often obtained for quite different purposes. Here, the IRB will determine whether the use of these materials is within the scope of the original consent/authorization, or whether consent/authorization should be obtained or waived.
- D. If the proposed activity involves an investigational drug, biological material, or device, it is the policy of the University of North Texas Health Science Center IRB that before these test articles may be tested on humans at this institution, or before an FDA-approved drug can be used for unapproved indications, the sponsor must obtain a Food and Drug Administration exemption [Investigational new Drug (IND) or Investigational Device Exemption (IDE)] before the activity will be approved by the IRB.
- E. The Institutional Review Board shall not approve any activity involving human subjects unless the principal investigator is a faculty member, staff or student of The University of North Texas Health Science Center or unless a faculty member at the above institution agrees in writing to assume responsibility for the subjects involved.

- F. Any activity involving the use of radioactive materials must have approval by the Radiation Safety Committee before it can receive final approval by the IRB.
- G. Compliance with this policy or the procedures set forth herein will in no way render inapplicable pertinent laws of the State of Texas, any local law which may bear upon the proposed activity or the Rules and Regulations of the Board of Regents of the University of North Texas Health Science Center.

SECTION 5.3 TYPES OF PROTOCOL REVIEW

Three types of review may be conducted by the Institutional Review Board to ensure that all research involving human subjects conforms to Federal Regulations: (1) Ascertain that research meets the criteria for exemption from full board review; (2) Ascertain that research meets the criteria for expedited review; and (3) full Board review of research at a convened meeting.

SECTION 5.4 PROCEDURE TO BE FOLLOWED BY THE IRB FOR DETERMINING WHICH PROJECTS NEED VERIFICATION FROM SOURCES OTHER THAN THE INVESTIGATORS

- A. To determine that no material changes have occurred in a project since previous IRB review, the IRB will utilize some or all of the following criteria;
 - 1. Review of randomly selected projects;
 - 2. Review of complex projects involving unusual levels or types of risk to subjects;
 - 3. Review of projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB;
 - 4. Review of projects where concerns about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.
- B. If it is determined that material changes have occurred in a project without IRB notification, review or approval, the IRB will meet and take appropriate action depending on the seriousness of the noncompliance.
- C. Any action taken by the IRB shall be reported to the Senior Vice President of Research or designee, the Department Chair, the appropriate Dean, and if indicated, the President of UNTHSC. All material noncompliance will be reported to the cognizant federal agency.