

PLANNING AND DEVELOPMENT 6.0

Institutional Review Board – 6.10

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NOTE: This document summarizes the overall mission and policy of the Tennessee Department of Health (TDOH) Institutional Review Board (IRB). The **detailed** institutional policies and procedures followed by the TDOH IRB are available from the TDOH IRB office (irb-tдох.help@state.tn.us OR (615) 253-5851). The policies and procedures follow the policies outlined in [46CFR45](#), Protection of Human Subjects (1), and are required under the Federalwide Assurance with the Department of Health and Human Services (DHHS) and the Office of Humans Subjects Research Protection (OHRP).

POLICY

Any request to utilize records, patient specimens, or patients to conduct research in local regional or the state health departments must be reviewed by Institutional Review Board (IRB) of the Tennessee Department of Health (TDOH). Policies outlined in 46CFR45, Protection of Human Subjects, will be followed in conducting all research. (1)

PURPOSE

To support research activities designed to develop or contribute to generalized knowledge while minimizing risk and protecting the safety and confidentiality of all health department patients and employees.

APPLICABILITY

This policy applies to all offices under the auspices of the Bureau of Health Services. Research should be distinguished from certain routine public health activity. The

distinction is not always clear cut. CDC has identified three critical areas of public health practice for which confusion exists. These are public health surveillance, emergency responses, and program evaluation. The intent of the activity is a distinguishing feature. The intent of research is to contribute to generalizable knowledge. The intent of public health practice is to conduct programs to prevent disease and injury and improve the health of communities.(2)

PROCEDURE

If an agency or individual requests permission to conduct research in or use records from a the Tennessee Department of Health (local, regional or state) a written request should be directed to the Chairperson of the Institutional Review Board of the Tennessee Department of Health.

The request to conduct research is to be formally submitted on TDH IRB Forms which are available by email irb-TDH.help@state.tn.us OR by phone (615) 253-5851. The forms standardize relevant study information and include, but are not limited to, a concise description of the study, including objectives, design, and methods. The study description must also address potential risks and benefits, details on how risk is to be minimized, informed consent, and confidentiality. An informed consent form must be included with the proposal per the instructions on the TDH IRB Forms and follow the TDH IRB Policy that follows..

All requests to conduct research must be accompanied by written executive level approval from the agency or institution conducting the research and from the agency in which the research is being conducted. The approval letter must indicate if the proposed research has been approved by or exempted from the agency's Institutional Review Board (IRB) and include a copy of the agency's IRB determination. If exempted, an explanation of why the research was exempted must also be clearly stated. There must be written approval from the local, regional or Tennessee Department of Health office participating in the research. The agency must also be directed to provide a detailed description of the specific activities that are to be carried out by both health department staff and the researcher(s).

If the research study involves recruiting members of the TDH community (patients or employees), then an appropriate senior executive member from the TDH community must serve as either Principle Investigator (if appropriate) or Co-Principle Investigator. The Principle Investigator is the person who will personally conduct or supervise the research study. Under most circumstances, this will be either a TDH employee or a faculty member from a collaborating university or accredited academic institution. For IRB communication purposes, a university faculty member or TDH employee must be identified, who holds ultimate responsibility for ensuring that this project complies with all TDH, regulatory, and fiscal requirements.

The Tennessee Department of Health Institutional Review Board will review the request and give final approval or denial or the Chairperson or designee IRB member may be able to exempt the study from IRB review. The types of research that may qualify for exemption include:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices.
2. Research involving the use of educational tests, if data are recorded in such a manner that subjects cannot be identified.
3. Research involving survey or interviewing procedures except where responses include a respondent I.D. and the subject's responses could reasonably place the subject at risk of criminal or civil liability or damage the subject's financial status or employability and the research deals with sensitive aspects of the subject's behavior such as, but not limited to, drug or alcohol use or sexual behavior.
4. Research involving survey or interviewing procedures when the respondent is an elected official or appointed public official or candidate for public office.
5. Research involving the observation of public behavior except where the subject can be identified and the subject's responses could reasonably place the subject at risk of criminal or civil liability or damage the subject's financial status or employability and the research deals with sensitive aspects of the subject's behavior such as drug or alcohol use or sexual behavior.
6. Research involving the collection or study of existing data documents, records, pathological specimens or diagnostic specimens if the sources are publicly available and the subjects cannot be identified.
7. Unless specifically required by statute, research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services and which are designed to study programs under the Social Security Act or other public benefit service programs; to study procedures for obtaining benefits or services under those programs; to study changes in or alternatives to those programs; or to study changes in the methods or levels of payment for benefits or services.
8. Research being conducted by another agency within the Department of Health for official business of the Department of Health.

If the Chairperson or designee Institutional Review Board Committee member identifies components of the proposed research which require approval by the IRB, the request will be forwarded to that committee. The types of research which require review by the IRB include:

1. Research that requires access to identifiable private information where the identifiers are to be included in the data maintained by the researcher*.
2. Research that involves obtaining information through intervention or interaction with the individual other than the types of intervention and interaction previously listed as qualifying for exemption. Intervention includes performance of physical procedures to obtain data and manipulation of the subject or the subject's

environment for research purposes. Interaction includes communication or interpersonal contact between the researcher and the subject.

If the research does require review by the IRB, generally, the following criteria must be met by the researcher:

1. The risks to subjects are minimized.
2. The risks to subjects are minimized in relation to anticipated benefits.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented.
6. Adequate provisions are included for monitoring the data to insure the safety of subjects.
7. Adequate provisions exist to protect the privacy of patients and to maintain the confidentiality of data.
8. If any of the subjects are likely to be vulnerable to coercion, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Informed consent requires the researcher to provide the following information to subjects:

1. A statement that the study involves research, the purpose of the research and the expected duration of the patient's involvement in the research, a description of the procedures to be followed and identification of any procedures that may be experimental.
2. A description of any foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject.
4. A disclosure of any alternative treatments that might be advantageous to the subject.
5. A statement of the extent to which confidentiality of the data will be maintained.
6. For research that involves more than minimal risk, an explanation of whether any compensation and of whether any types of medical treatments might be available to the subject if injury occurs and if so what they consist of or where further information may be obtained.
7. An explanation of whom to contact for further information.
8. A statement that participation is voluntary, and refusal to participate or discontinuing participation at any time will not result in penalty or loss of benefits to which the subject is otherwise entitled.

The IRB may waive the requirements for informed consent if the consent form would be the only record linking the subject to the research or if the research presents no more than minimal harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.

EXCEPTIONS

Any records for which access is specifically allowed by Tennessee Law will not be covered by these guidelines. For example, confidential vital records and other registries and databases may be released to researchers without review by the Institutional Review Board in accordance with the Vital Records statute, regulations and Institutional Review Board policies such as the policies of the Health Data Policy Committee.

Sharing of medical records between the health department and an individual patient's private physician requires no review, but does require the permission of the patient or the patient's legally authorized representative in accordance with official policy established by the Bureau of Health Services.

OFFICE OF PRIMARY RESPONSIBILITY

Bureau of Health Services, irb-tdoh.help@state.tn.us OR (615) 253-5851

*[T.C.A. 10-7-504\(a\)\(1\)](#) states "...the medical records of persons receiving medical treatment, in whole or in part, at the expense of the state shall be treated as confidential and shall not be open for inspection by members of the public."

References:

1. [Office for Protection from Research Risks, National Institutes of Health. Protection of Human Subjects. CFR Title 45, Part 46. Bethesda: OPRR; Revised 2005.](#)
2. [Snider, DE, Stroup, DF Defining Research When It Comes to Public Health. Public Health Reports 1997; 112:29-32.](#)

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