



Policy Number	AA-2200
Policy Title	Institutional Review Board
Effective Date	9/1/2004
Revision Date	4/28/2020
Subject Matter Expert	Review Committee Coordinator
Policy Owner	Assistant Deputy Commissioner
Signed by: Dr. Lara Lamprecht	

1.0 Purpose

The purpose of this policy is to ensure that the Department of State Health Services (DSHS) has appropriate policies and procedures in place for the review, approval, and oversight of proposed human subjects research involving agency clients, data, and specimens in the possession of DSHS, to ensure the protection of the rights, privacy, and welfare of human subjects involved in such research. This policy is to ensure that such research is conducted in accordance with applicable sections of state laws, federal laws, and agency policies so that appropriate management review is part of the process.

It is the policy of DSHS that the Institutional Review Board reviews all proposed human subjects research which involves DSHS clients, data, and/or specimens in the possession of DSHS, data requests involving healthcare claims data, and data requests submitted to DSHS programs that involve the use of identifiable information or specimens. This policy is inclusive of research proposed by private or public entities, including research proposed by a DSHS or HHSC program area. This policy applies to the DSHS-managed IRB.

2.0 Definitions

Affiliated with the Texas Department of State Health Services: A DSHS-affiliated activity is conducted by or under the direction of any employee or agent of DSHS in connection with institutional responsibilities, using any DSHS property or facility; or involves the use of DSHS program data, specimens, or clients.

Authorized Institutional Official: An officer of an institution with the authority to speak for and legally commit the institution to adherence to the

requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

Conflicting Interest: Any situation in which financial, professional, or personal obligations may compromise or present the appearance of compromising an individual or group's professional judgment in conducting, reviewing, or reporting research. Members of the IRB may not review, deliberate on, or approve research if they have a conflicting interest related to the research.

Data: Information provided for research and analysis, which is to be obtained from DSHS. Examples of DSHS data are vital event, patient claims, cancer registry, and birth defects registry.

Exemption/Exempt Research: Term used in the Federal Regulations (45 CFR §46.104) to describe [eight categories](#) of research to which the Federal Regulations do not apply.

Expedited Review: Review of proposed research by the IRB Chairperson, a designated voting member, or group of voting members, rather than by the entire IRB. Federal regulations ([45 CFR §46.110](#)) permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research protocols. In the context of research review by an IRB, expedited does not necessarily mean quick or fast.

Human Subject: A living individual about whom an investigator conducting research: 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Institutional Review Board (IRB): An administrative body established to protect the rights and welfare of human subjects in research conducted under the auspices of DSHS and requests submitted to DSHS programs that involve the use of identifiable information or specimens.

IRB Membership: Total membership will include at least five voting members with varying backgrounds, and will always meet the requirements of [45 CFR §46.107](#). IRB membership includes:

- At least one member whose primary concerns are in scientific areas;
- At least one member whose primary concerns are in non- scientific areas;
- At least one member not affiliated with DSHS;

- At least one member from the Office of General Counsel;
- At least one member who is familiar with vital event data;
- At least one member familiar with the Texas Cancer Registry data, HIV/STD data, birth defects data, and/or hospital inpatient or outpatient data; and
- Non-voting members may include a representative from the DSHS Laboratory Services, prisoner representative, or physician consultant.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Program Contact: Employee of the DSHS program that possesses and manages the data and/or specimens that have been requested, who is responsible for reviewing the request before it is submitted to the DSHS IRB. The Program Contact's specific duties related to reviewing such requests are listed in Section 4.1 of this policy, below, and in the DSHS IRB Procedures Manual.

Public Health Authority: An agency (or entity acting under a grant of authority from or contract with such public agency) that is responsible for public health matters as part of its official mandate.

Public Health Entity: An agency (or entity acting under a grant of authority from or contract with such public agency) that is responsible for public health matters as part of its official mandate. The term includes state health department, local health department, and local health authority.

Public Health Practice: Activity intended to identify and control a health problem or improve a public health program or service. Benefits of the project are primarily for the participants or the participants' community; data collected are needed to assess or improve the program or service, the health of the participants or the participants' community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental.

Public Health Purpose: A purpose that relates to the science of protecting and improving the health of people and their communities.

Public Health Surveillance: Involves collecting, testing, analyzing, and using information or biospecimens to improve public health and prevent disease. It provides timely and useful evidence, and it enables public health authorities to be more effective in their efforts to protect and promote public health. The

purpose of the surveillance is to inform the decisions or actions that must be made by a public health authority.

Public Health Research: Research that relates to the science of protecting and improving the health of people and their communities.

Research: A systematic investigation (i.e. the gathering and analysis of information), including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Review: There are three types of IRB Review:

1. *Full Board Review* – A review by the entire DSHS IRB Committee at a convened meeting. The DSHS IRB requires Full Board Review for all new studies (unless they are determined to be Exempt).
2. *Expedited Review* - A review by the DSHS IRB Chairperson (or by one or more experienced IR members designated by the Chairperson) outside of a full board meeting. Studies eligible for expedited review 1) have been determined to be “minimal risk” at their initial (or first review) at a Full Board Meeting; and 2) meet at least one of the [nine expedited categories](#) approved by the US Department of Health & Human Services Office for Human Research Protections.
3. *Exempt Review* – A review by the IRB Chairperson to determine if a study meets the exemption criteria outlined in the Federal Regulations (45 CFR §46.104). This is research that is minimal risk and fits into one of the [eight exemption categories](#). Exempt research does not require IRB approval or oversight.

3.0 Persons Affected

This policy applies to all DSHS programs and employees.

4.0 Responsibilities

- 4.1 **DSHS Programs and Employees** – DSHS Programs and employees in programs that possess and manage data and/or specimens that have been requested are responsible for reviewing requests before they are submitted to the DSHS IRB. This programmatic review includes: conducting an initial scientific review of the proposal's validity; consulting with the program attorney to ensure the submission meets all the legal requirements for the program to release the requested data or specimens; ensuring the data or specimens are actually in the

possession of DSHS; ensuring the program has sufficient resources to meet the time commitments of the request without compromising agency functions; and ensuring the application includes all the required approvals and/or signatures before it is submitted to the DSHS IRB.

- 4.2 **DSHS Authorized Institutional Official (AIO)** – This individual must be authorized to: act and speak for DSHS; ensure that DSHS effectively fulfills its research oversight function; provide oversight for IRB functions; and select the Chairperson of the IRB. The Authorized Institutional Official selects the IRB Chairperson and Vice Chairperson and approves recommendations for appointing new members of the IRB.
- 4.3 **DSHS Commissioner** – The DSHS Commissioner shall appoint an individual to serve as the DSHS Authorized Institutional Official (AIO).
- 4.4 **IRB Chairperson** – The IRB Chairperson (or designee) will conduct full IRB meetings by directing discussions, leading reviews, and serving as a voting member on research proposals. The Chair must complete a [course in human subjects protection](#). The course must be completed for the initial appointment to the board and is good for three years. The Chairperson, or designee, will be responsible for conducting or delegating expedited reviews and making exemption determinations in accordance with [45 CFR §46.110](#) and [45 CFR §46.104](#). The IRB Chairperson, or designee, will actively establish and review IRB policies and procedures and resolve any issues that arise during the work of the board. The Chairperson signs all IRB correspondence and must have thorough knowledge of all federal and state human subjects research regulations. The Chairperson serves a three-year, renewable term, with a maximum of one renewal as Chairperson. The Chairperson must be a DSHS employee.
- 4.5 **IRB Vice Chairperson** – The IRB Vice Chairperson assumes all responsibilities of the IRB Chairperson in his or her absence. When the IRB Chairperson has a conflict of interest concerning a protocol under review, the Vice Chairperson conducts proceedings for that protocol's review. The Vice Chairperson must complete a [course in human subjects protection](#). The course must be completed for the initial appointment to the board and is good for three years. The Vice Chairperson serves a three-year, renewable term, with a maximum of one renewal as Vice Chairperson (this does not count against tenure if appointed as Chairperson). The Vice Chairperson must be a DSHS employee.

- 4.6 **IRB Primary Members** – IRB primary members will review, discuss, and vote on applications submitted to the IRB. Members will assume duties as a primary reviewer as requested. IRB members may also be assigned expedited reviewer duties by the IRB Chairperson. IRB members must complete a [course in human subjects protection](#). The course must be completed for the initial appointment to the board and is good for three years. IRB members may make recommendations for new member appointments, including alternate members. All IRB members (or their alternates) will attend no fewer than nine convened meetings per year. Any member who violates the attendance policy will receive one written warning. If a second violation occurs, they will be asked to resign from their position. IRB members will serve a three-year, renewable term. If a primary IRB member is unable to fulfill their tenure, their alternate member will finish their term.
- 4.7 **IRB Alternate Members** – Alternate members must complete a [course in human subjects protection](#). The course must be completed for the initial appointment to the board and is good for three years. The alternate member is paired to a specific primary member and assumes the duties of the IRB member when he or she is unavailable. If the primary member is unable to fulfill their tenure, the alternate member will finish the term. IRB alternate members will serve a three-year, renewable term.
- 4.8 **Review Committee Coordinator** – The Review Committee Coordinator is responsible for all administrative functions of the IRB including: coordination meetings, screening protocols, assigning protocols, managing the IRB database, maintaining the Federalwide Assurance and IRB Registrations with the US Department of Health and Human Services Office for Human Research Protection, managing and updating the policy and procedures, communications with researchers and program contacts, and education activities related to the IRB. The Review Committee Coordinator must complete a [course in human subjects protection every three years](#).

5.0 Procedures

Procedures for the Institutional Review Board can be found [here](#).

6.0 History

Date	Action	Section
4/28/2020	Policy revision. Policy renumbered.	All
5/1/2011	Changed title of policy from "Institutional Review Board" to "Institutional Review Boards". Added a statement to clarify that the policy covers both DSHS IRBs and future IRBs. New language. Added definition for "Exemption/Exempt Research". Added definition for "Expedited Review". Amended definition for clarity. Added definition for "Public Health Purpose". Clarified responsibilities for "Authorized Institutional Official" and "IRB Chairperson"	Title 2.1 2.2 2.3 3.2 – 3.7 5.3 - 5.4
9/1/2004	Policy issued.	All

7.0 Associated Policies

Policy/Directive Number	Policy/Directive Name
TBD	Open Records Policy (<i>new - pending</i>)
TBD	Data Governance Policy (<i>new - pending</i>)

8.0 Associated Requirements and Documentation

Requirements/Document Name
IRB Procedures Manual