Policy Number	AP-900
Policy Title	Institutional Review Board
Effective Date	9/1/2004
Revision Date	3/24/2025
Subject Matter Expert	Review Committee Coordinator
Policy Authority	Medical Director for Center for Public Health Policy and Practice
Signed by: Stephen J. Pont, M.D., M.P.H.	

1.0 Purpose

1.1 The purpose of this policy is to ensure 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 such research is conducted in accordance with applicable sections of state laws, federal laws, and agency policies so appropriate management review is part of the process.

1.2 It is the policy of DSHS for the Institutional Review Board to review all proposed human subject research involving 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

2.1 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.

2.2 Authorized Institutional Official (AIO): 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.

2.3 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 (45 CFR §46.107).

2.4 Data: Information provided for research or to assist with research or public health practice (see definition of **Research**), which is to be obtained from DSHS. Examples of DSHS data are vital events, patient claims, cancer registry, and birth defects registry.

2.5 Exemption/Exempt Research: Term used in the Federal Regulations (45 CFR §46.104) to describe eight categories of research that do not require comprehensive IRB review.

2.6 Expedited Review: Review of proposed research by the IRB Chair, 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 nine 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.

2.7 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 (45 CFR §46.102(e)(1)).

2.8 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.

2.9 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:

2.9.1 At least one member whose primary concerns are in scientific areas;

2.9.2 At least one member whose primary concerns are in non- scientific areas;

2.9.3 At least one member not affiliated with DSHS;

2.9.4 At least one member from the Office of General Counsel;

2.9.5 At least one member who is familiar with vital event data;

2.9.6 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

2.9.7 Non-voting members may include a representative from the DSHS Laboratory Services, prisoner representative, or physician consultant.

2.10 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 (45 CFR §46.102(j)).

2.11 Program Contact: Employee of the DSHS program who possess and manage 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.

2.12 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.

2.13 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.

2.14 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.

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

2.16 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 entity 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 Surveillance Activities).

2.17 Public Health Research: Research that relates to the science of protecting and improving the health of people and their communities the benefits of which include study participants, the public, and contributes to general knowledge.

2.18 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 as defined in of 45 CFR §46.102.

2.19 Review: There are four types of IRB Review:

2.19.1 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).

2.19.2 Expedited Review - A review by the DSHS IRB Chair (or by one or more experienced IRB members designated by the Chair) 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) are eligible for expedited review per federal guidelines (see Expedited Review definition).

2.19.3 Chair Review – A review by the IRB Chair outside a full board meeting to determine if a study meets one of the exemption categories, to determine if a study is an activity reviewable by the DSHS IRB, or to review as an expedited review.

2.19.4 Administrative Review - Review of proposed administrative changes to research by the Review Committee Coordinator rather than by an expedited reviewer or the entire IRB. Administrative changes that may be reviewed by the Review Committee Coordinator include addition and/or deletion of co-investigators or key study personnel after ensuring no conflicts of interest have been indicated.

3.0 Persons Affected

3.1 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 are responsible for reviewing requests 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 required approvals and/or signatures before it is submitted to the DSHS IRB. Review processes are provided in the IRB Procedures document.

4.2 DSHS Authorized Institutional Official - This individual must be authorized to: act and speak for DSHS; ensure DSHS effectively fulfills its research oversight function; provide oversight for IRB functions; and select the Chair of the IRB. The Authorized Institutional Official selects the IRB Chair and Vice Chair, and approves recommendations for appointing new IRB members.

4.3 DSHS Commissioner - The DSHS Commissioner shall appoint an individual to serve as the DSHS Authorized Institutional Official (AIO).

4.4 IRB Chair - The IRB Chair (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 that meets the requirements of NIH Notice OD-00-039. The course must be completed for the initial appointment to the board and is good for three years. The Chair, 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 Chair, or designee, will actively establish and review IRB policies and procedures and resolve any issues that arise during the work of the board. The Chair must have thorough knowledge of all federal and state human subjects research regulations. The Chair serves a three-year, renewable term. The Chair must be a DSHS employee.

4.5 IRB Vice Chair - The IRB Vice Chair assumes all responsibilities of the IRB Chair in his or her absence. When the IRB Chair has a conflict of interest concerning a protocol under

review, the Vice Chair conducts proceedings for that protocol's review. The Vice Chair must complete a course in human subject protection that meets the requirements of NIH Notice OD-00-039. The course must be completed for the initial appointment to the board and is good for three years. The Vice Chair serves a three-year, renewable term. The Vice Chair 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 Chair. IRB members must complete a course in human subject protection that meets the requirements of NIH Notice OD-00-039. 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 subject protection that meets the requirements of NIH Notice OD-00-039. The course must be completed for the initial appointment to the board and is good for three years. Alternate members serve as replacements for IRB Primary members who are unable to attend a convened IRB meeting. Alternate members may be paired to a specific primary member and assume the duties of the matched 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: coordinating meetings, screening protocols, conducting administrative reviews of personnel amendments, assigning protocols, managing the IRB database, maintaining the Federal wide 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, communicating with researchers and program

contacts, and conducting education activities related to the IRB. The Review Committee Coordinator must complete a course in human subject protection every three years that meets the requirements of NIH Notice OD-00-039.

5.0 Procedures

5.1 Procedures for the Institutional Review Board can be found here.

6.0 History

Date	Action	Section
6/14/2024	Clarified the definition of Exempt Review. Updated the types of IRB reviews to include Administrative Review, renamed Exempt Review to Chair Review, and clarified the review duties of the IRB Chair. Removed outdated links to Human Subjects protection training websites. Removed the correspondence duty from the IRB Chair. Removed term limits from roles. Amended the duties of IRB Alternate members. Amended the duties of the Review Committee Coordinator to include Administrative Reviews.	2.0 4.4 4.5 4.6 4.7 4.8
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 Chair"	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
AA-1008	Open Records Policy
TBD	Data Governance Policy (new - pending)
C-055	Employee Data Request, Research and Publication Policy
C-061	External (Non-Agency) Data Request, Research and Publication

8.0 Associated Requirements and Documentation

Requirements/Document Name
IRB Procedures Manual