



TEXAS
Health and Human
Services

**Texas Department of State
Health Services**

**Texas Department of State Health Services (DSHS)
Institutional Review Board (IRB)
Memorandum of Understanding (MOU)**

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Institutional Review Boards

DSHS IRB

- Social, behavioral, educational, and health science research

HHSC IRB

- Mental health, intellectual disability, and substance abuse research



IRB Functions

1. IRB for Human Subject Protection (Research)
2. Committee for Requests on Personal Data (Vital Event Data)
3. Scientific Review Panel (Hospital Data)



IRB Application Types

- Initial
- Renewal
- Amendment
- Renewal with Amendment



IRB Review Types

- Full Board
 - Convened meeting once each month
- Expedited
 - Outside of the full board
 - Minimal Risk
 - Fits one of [nine expedited categories](#)
 - Administrator Expedited
- Exempt
 - Not Human Subjects Research or Public Health Practice
 - Fits one of the [six exemption categories](#)



IRB Process

1. Program Review
2. IRB Review
3. Research Executive Steering Committee Review
4. Contract Management Section Review (MOU)



IRB Process




Contract Management Section Process

- Upon approval by the Research Executive Steering Committee, the IRB will package IRB application documents and send them to the Contract Management Section
- Contract Management Section will work with the researchers and their institution to get an MOU signed and approved
- When all MOU documents are signed, the Contract Management Section will contact the IRB who will send approval letters to the researchers and program staff
- Contract Management Section will contact the researchers when an MOU needs renewal (typically every 5 years)



MOU Contract

DEPARTMENT OF STATE HEALTH SERVICES



This Memorandum of Understanding (MOU) is entered into between the Department of State Health Services (DSHS) and **Contractor Name** (Contractor) who are collectively referred to as the "Parties."

I. **Purpose of the MOU**

DSHS agrees to provide Contractor certain confidential data for research studies or data projects approved by the DSHS Institutional Review Board (IRB). The Parties agree to the intended utilization of the data as outlined in Attachment A of this MOU. No personally identifiable or non-public data will be shared or released by Contractor without specific statutory authority and the prior written consent of DSHS.

II. **Term of the MOU**

Unless terminated as provided for in Section V(C), this MOU will become effective on the signature date of the latter of the Parties to sign this MOU, and end on **XXXXXX**. The Parties may renew this MOU for one additional three-year term by executing a written amendment. Data will not be shared between Parties without a written agreement in place. If the MOU expires or is terminated then data sharing will cease.

III. **Authority**

The Parties enter into this MOU under the authority of (please check all that apply):

- Title 45 Code of Federal Regulations Part 46 Protection of Human Subjects Subpart A (for all research requests involving human subjects);
- Texas Health and Safety Code, Title 3, Section 191.051 & Section 192.002(b); 25 Tex. Admin. Code Sec. 181.1(21) & 181.11 (Vital Event Data);
- Texas Health and Safety Code, Title 2, Section 82.009; 25 Tex. Admin. Code Sec. 91.12 (Data from the Texas Cancer Registry);
- Texas Health and Safety Code, Title 2, Section 87.002; Tex. Admin. Code Sec. 37.306 (Data from the Texas Birth Defects Registry);
- Texas Health and Safety Code, Title 2, Section 92.006; 25 Tex. Admin. Code Sec. 103.3 (Data from the Texas EMS & Trauma Registries);
- Texas Health and Safety Code, Title 2, Section 81.046 (Infectious Disease Registries, Data, or Biospecimens maintained by the DSHS Laboratory and Infectious Disease Section);
- Texas Health and Safety Code, Title 2, Section 33.018 (Newborn Screening Bloodspots and associated data);
- Texas Health and Safety Code, Title 2, Chapter 108; 25 Tex. Admin. Code, Chapter 421 (Data maintained by Texas Health Care Information Collection); and
- Other:

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- Standardized document available on the DSHS IRB webpage
 - Contract Management Services will provide a researcher-specific copy
- Will not be signed until after the Executive Research Steering Committee has approved
- Each institution will have their own MOU contract



Institution-wide MOUs

- Each institution conducting DSHS IRB research will need a signed & executed MOU/DUA
- New research studies will be added to an institution's MOU through an amendment process
- IRB Amendments with significant changes may also require amending the institution's MOU
- All MOU amendments must be approved by all parties (DSHS & the research institution)



How Does This Affect Your Research?

- Initial IRB applications will require additional time after approval by the IRB to attain the MOU
- Program data release will not begin until MOUs have been signed and approved by Contract Management
- Updated IRB forms
 - HRP-301 includes information about the authorized signatory
 - Vendor Information Form
- Contract management will manage the MOUs
- IRB applications will continue to be renewed in 1 or 2 year cycles



Timeline for Implementation

- An MOU is required for all initial (new) IRB applications submitted to a DSHS program on or after November 1, 2022



Contact for Questions

IRB Website:

<https://www.dshs.texas.gov/irb/Default.shtm>

IRB Email:

InstitutionalReviewBoard@dshs.texas.gov

Contract Management Section:

maria.acuna@dshs.texas.gov



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