

Texas DSHS IRB MOU

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TEXAS
Health and Human
Services

**Texas Department of State
Health Services**

Institutional Review Board

DSHS IRB # 1

- Administered by Office of Practice and Learning
- Social, behavioral, educational, and health science research

HHSC IRB # 2

- Administered by HHSC
- mental health, intellectual disability, and substance abuse research



IRB Function

The DSHS IRB serves in three capacities:

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



IRB Application Types

- Initial
- Renewal
- Amendment
- Renewal with Amendment



Texas Department of State
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IRB Review Types

- Full Board
 - Convened meeting held the 3rd Thursday of each month
- Expedited
 - Outside of the full board
 - Minimal Risk
 - Fits one of [nine expedited categories](#)
 - Administrator Expedited
- Exempt
 - NHR or Public Health Practice
 - Fits one of the [six exemption categories](#)

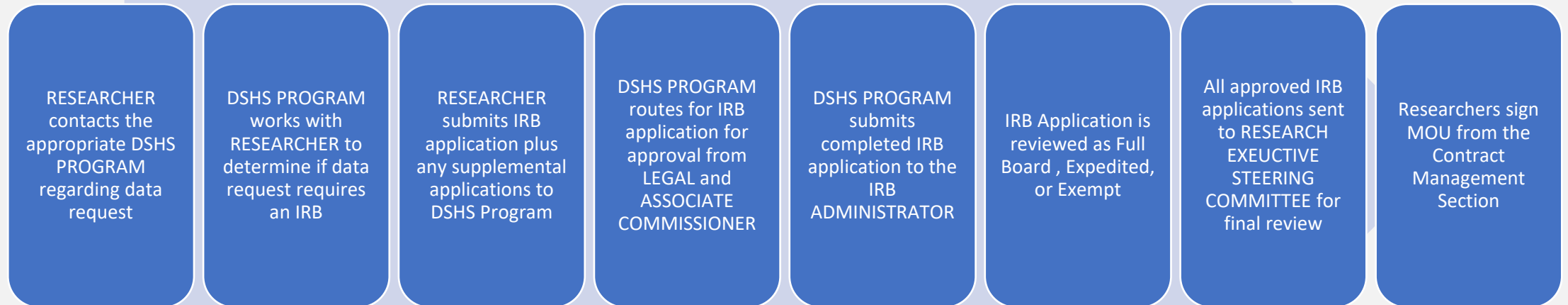


IRB Process

1. Program Review
2. IRB Review
3. Research Executive Steering Committee Review
4. *Contract Management Section Review*



IRB Process



Contract Management Section Process

- Upon approval by the Executive Research 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

- Standardized document available on the DSHS IRB webpage
 - Has a watermark “For Informational Purposes Only”
 - Contract Management Services will provide a researcher-specific copy
- Will not be signed until after the Executive Research Steering Committee has approved
- Each IRB study will have their own MOU contract
- Typically need to be renewed every 5 years



How Does This Affect Your Research?

- Initial IRB applications will take longer to get approved
- Programs will need to educate IRB applicants on the new IRB forms and the MOU documents
 - HRP-301 includes information about the authorized signatory
 - Vendor Information Form
- Program data release will not begin until MOUs have been signed and approved by Contract Management



How Does This Affect Your Research?

- Contract management will manage the MOUs
- IRB applications will continue to be renewed in 1 or 2 year cycles
- IRB amendments and renewals will be attached to the MOU contract, but they likely won't require any update to the contract
- Substantial changes in the scope of an approved IRB application will require either:
 - A new IRB application
 - An amended MOU



Timeline for Implementation

- The process will start for all initial IRB applications (new) submitted to DSHS 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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