



DSHS Institutional Review Board #1

APPLICATION FOR REVIEW OF RESEARCH, & REQUESTS FOR RELEASE OF DATA, INCLUDING PERSONAL (PROTECTED) HEALTH INFORMATION

Submission of this application to the DSHS IRB #1 constitutes a request for review and approval of: 1) research involving the use of human subjects, and/or 2) request for release of DSHS data, including personal (protected) health informatio.

Principal Investigator/Requestor: (List other Investigators, as needed, in Project Description)

Name: _____
 Organization: _____
 Mailing Address: _____
 Phone: _____ Ext: _____
 E-Mail: _____

IRB# _____

For Official Use Only

Are you a student? Yes No

DSHS Program Contact(s): (DSHS employee; contact with a DSHS Program is required before submission)

Contact 1	Contact 2 (if needed)
Name: _____	_____
DSHS Program: _____	_____
Mailing Address _____	_____
Phone: _____ Ext _____	_____ Ext _____
E-Mail: _____	_____

Application for review of:

- Research Involving Human Subjects and/or Request for the release of data, including personal (protected) health information [IRB]

The human subjects regulations (45 CFR Part 46) define research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” [45 CFR 46.102(d)]. A human subject is “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information” [45 CFR 46.102(f)].

Specific DSHS Program data requiring approval by an independent board to be released or individually identifiable health information about an individual, including demographic information, which relates to the individual's past, present, or future physical or mental health condition, provision of health care, or payment for the provision of health care [protected health information (PHI)].

Submission Type:	Project Start Date: ___/___/___	Project End Date: ___/___/___
New	<input type="checkbox"/>	
Renewal	<input type="checkbox"/> DSHS IRB #:	
Resubmission	<input type="checkbox"/> DSHS IRB #:	
Amendment	<input type="checkbox"/> DSHS IRB #:	

Submission Title:

Required Subject Characteristics (Check all that apply)

Age: 17 Years & Under 18 years and older

Vulnerable Categories: (If subjects must be members of a vulnerable category, check "Yes." Otherwise, check "No.")

Subjects **MUST** be *Elderly/Aged* No Yes to be selected as a subject

Subjects **MUST** be *Fetuses* No Yes to be selected as a subject

Subjects **MUST** be *Pregnant* No Yes to be selected as a subject

Subjects **MUST** be *Prisoners* No Yes to be selected as a subject

Subjects **MUST** be *Impaired* No Yes to be selected as a subject If yes, Physically Cognitively Both

Funding Source (List name & address as appropriate)

Federal _____

State _____

Other _____

Review by Other Institutional Review Board (ethic/research/science boards/panels)

(Name) (Telephone Number) (Review Date)

(Name) (Telephone Number) (Review Date)

Principal Investigator/Data Requestor Statement and Signature

By signing this application, I certify that:

- I have communicated with the Program Contact to ensure their support and the availability of any data I might need,
- The information supplied on this application and all attachments is complete and correct, to the best of my knowledge.

All data provided is subject to the following conditions:

- The data shall be treated as strictly confidential. The data shall not be made available to any other individual; agency, institution, or firm and controls shall be maintained to prevent unauthorized access. Individual information that identifies persons directly or indirectly and individual patient records or any part of them shall not be shared with any individual, institution or firm contacted. No attempt to use the data to discover personal identifiers. (NOTE: Federal agencies which are subject to the Federal Freedom of Information Act and the Federal Privacy Act shall not release confidential identifying data except as is required by those Acts.)
- The data shall not be used for any purpose other than that specifically set forth in this application. The data may not be linked to any other database without the written permission from the DSHS data source.
- All results of a study shall be restricted to aggregate data and shall not identify any individual, institution, or firm.
- At the conclusion of the research, all data received from DSHS shall be destroyed. Computer tapes provided must be "scratched" after serving the purpose set forth in this application unless specific authority is granted for their retention.
- The Texas Department of State Health Services shall be credited as the source of the data. In addition, no statement may be made indicating or suggesting that interpretations drawn from DSHS program data are those of those programs.
- A Final Report of the study shall be furnished to the Texas Department of State Health Services IRB within 60 days of completion of the project.
- Data will be furnished in accordance with established fees, or if applicable, on a cost reimbursement basis. Payment must be received before the release of the data.
- I indemnify and hold Texas Department of State Health Services, Institutional Review Board #1, Texas Healthcare Information Collection, and Committee on Requests for Personal Data members, employees, and contract vendors harmless from any and all losses, claims, damages, liabilities, costs, and expenses (including without limitation, reasonable attorney's fees and costs) arising out of any claim stemming from the use of data received from this agency.

Signature: Principal Investigator/Requestor

Date Signed

DSHS Program Contact Statement and Signature

By signing this application, I certify that:

- I am authorized to act as the DSHS Program Contact for this study,
- I approve the Program's participation in this study, as outlined in the Synopsis,
- Program staff have contacted the Principal Investigator/Requestor to define the responsibilities of the Program concerning this study and any limitation concerning the availability of the data being requested,
- Program staff has informed the Principal Investigator/Requestor that all written communication from the Program may be included in the submission.

Signature: DSHS Program Contact #1

Date Signed

Signature: DSHS Program Contact #2

Date Signed: