



Application for Human Research Review and/or DSHS Data Release Request

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Reason for Submission:	
New Project <input type="checkbox"/>	DSHS IRB #:
Renewal <input type="checkbox"/>	DSHS IRB #:
Renewal with Amendment <input type="checkbox"/>	DSHS IRB #:
Response to Stipulations <input type="checkbox"/>	DSHS IRB #:
Amendments <input type="checkbox"/>	DSHS IRB #:
Adverse Event Report <input type="checkbox"/>	DSHS IRB #:
Project Dates	
Original Project Start Date: / /	
Estimated Project End Date: / /	

IRB# _____

For IRB Office Use Only

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

Name: _____

Organization: _____

Mailing Address: _____

City, State Zip: _____

Phone Number: _____ Ext: _____

E-Mail: _____

Are you a student? Yes No

DSHS Program Contact(s):
(List additional Program Contacts, as needed, in the Project Description)

	Contact #1	Contact #2	Contact #3
Name			
DSHS Program			
Phone			

Submission Title:

I am Requesting

Hospital Discharge or Outpatient Data Yes No Birth and/or Death Records/Certificates Yes No Bloodspots Yes No

Funding Source
(List name & address as appropriate – If None, state "NONE")

Grant Number: _____ Grant Amount: _____ No Grant Involved

If the study will be funded by a federal agency, include one copy of the full grant proposal or a detailed summary.

Federal: _____

State: _____

Other: _____



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Required Subject Characteristics

(Check all that apply)

Age: 17 Years & Under 18 Years & Older

Vulnerable Categories:

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

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

Subjects **Must be Fetuses** to be selected as a subject: No Yes

Subjects **Must be Pregnant** to be selected as a subject: No Yes

Subjects **Must be Prisoners** to be selected as a subject: No Yes

Subjects **Must be Impaired** to be selected as a subject: No Yes Physically Cognitively Both

Review by other Institutional Review Boards

(List additional boards/panels in Project Description – If None, state "NONE")

(Name)	(Telephone Number)	(Determination)

Project Partners

List any other agencies, organizations, and/or parties collaborating with you in this project

(List additional partners in Project Description – If None, state "NONE")

(Name)
(Name)
(Name)
(Name)

Principal Investigator/Data Requestor Statement & Signature

By initialing each item and signing this application, I certify that:

<input type="checkbox"/>	I have communicated with the Program Contact to ensure their support and the availability of any data I might need,
<input type="checkbox"/>	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:

<input type="checkbox"/>	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 shall be made 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.)
<input type="checkbox"/>	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.
<input type="checkbox"/>	All results of a study shall be restricted to aggregate data and shall not identify any individual, (or institution, or firm, unless allowed by the



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	<i>program releasing the data).</i>
	At the conclusion of the research, all data received from DSHS shall be destroyed. CDs provided must be shredded 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.

Signature: Principal Investigator/Requestor

Date Signed

DSHS Program Contact(s) Statement & Signature

By initialing each item and signing this application, I certify that:

	Conducted initial scientific review and established proposal validity
	Meets legal requirements of program to release the data (Consulted with designated program attorney, if needed)
	Data/specimens (circle one) are in DSHS possession and/or clients are served by DSHS
	Program has sufficient resources to meet time commitment of request w/o compromising agency function
	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
	I am authorized to act as the DSHS Program Contact for this study, and approve the Program's participation in/release of data to this study, as outlined in the Synopsis

DSHS Program Contact(s) Additional Information – for NEW submissions only

Data Related Questions

If this submission is approved, will program data be released? Yes No – If 'No,' go to Attorney Review Section (below)
 How many records and data elements will be released? Records - _____ Data Elements - _____

HIPAA and other Statutes/Policies

Is your program a covered entity as defined by HIPAA? Yes No
 If your program is not a covered entity, does your program apply HIPAA or other rules, statutes, or policies to data requests?
 Yes No

If Yes, describe

Is your program a business associate of a covered entity requesting the data? Yes No

If Yes, describe _____

Do other relevant provisions allow, prohibit, or limit the release of data or protected health information? Yes No

If Yes, list

Compensation to DSHS

Is there a charge to the researcher or other DSHS compensation? Yes No

If yes, describe:

List relevant provisions related to DSHS Compensation



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DSHS Role

Describe DSHS role and/or level of participation:

- Providing only program data. Will the researcher/requester receive only de-identify the data? Yes No
- Other (describe):

Attorney Review

The Program Contact affirms that the request meets all the legal requirements of the program to release the requested data and/or specimens, as determined through consultation with the Office of General Counsel (OGC) designated attorney.

The DSHS OGC Attorney was consulted Yes No

If Yes,

Attorney's Name	Consultation Date	Briefly describe OGC guidance and/or determination
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If No,

Justification/Explanation

Signature: DSHS Program Contact #1 _____ Title _____ Division/Unit _____ Date Signed _____

Signature: DSHS Program Contact #2 _____ Title _____ Division/Unit _____ Date Signed: _____

Signature: DSHS Program Contact #3 _____ Title _____ Division/Unit _____ Date Signed: _____

Assistant Commissioner or Designee Statement & Signature

By initialing each item and signing this application, I certify that:

<input type="checkbox"/>	Completed a Division Review
<input type="checkbox"/>	Forwarded to the Program, to be included in the submission, a list of any potential risks, other than to the human subjects, that concern me, if appropriate (use separate sheet)
<input type="checkbox"/>	Forwarded to the Program, to be included in the submission, a list of other DSHS organizational units/staff with whom I consulted, including their name, title, DSHS Division, and date of consultation, if appropriate (use separate sheet)
<input type="checkbox"/>	Forwarded to the Program, to be included in the submission, additional comments/considerations, as needed (use separate sheet)

Assistant Commissioner or Designee Signature _____ If not AC, give Title _____ Division/Unit _____ Date Signed _____