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IRB Application Process

THCIC Program

- **Hospital Discharge Data**
- **Outpatient Surgical / Radiological Procedures**
- **Emergency Department Events**

Research Data RDF vs PUDF



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Two type of research data files

Research Data File (RDF)

Public Use Data File (PUDF)

Select the data file that best benefits your research needs

Public Use Data File PUDF



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- No DSHS IRB approval required
- PUDF released within days of payment
- PUDF has under 300 variables included
- Some variable masking or suppression

Order the PUDF at:

<http://www.dshs.state.tx.us/thcic/hospitals/Inpatientpudf.shtm>

<http://www.dshs.state.tx.us/thcic/OutpatientFacilities/OutpatientPUDF.shtm>

Research Data File RDF



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- RDF requires DSHS IRB approval
- Approval process and data release can take several months
- The RDF has over 300 variables available
- Cost is based on the number of variables and data quarters or years selected
- Justification for each selected variable must be provided
- IRB application must be detailed and clear
- Dates, data years, and data variables must match throughout all forms
- Data must be destroyed after one year or must be renewed annually through the DSHS program and DSHS IRB

Getting Started



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The THCIC program requires an applicant to review:

- Program Data Order Form(s)
- Program User Manual/Data Dictionary
- IRB Forms
- Then contact THCIC to set up a discussion about your research study at THCICHELP@dshs.texas.gov

RDF Program Order Forms User Manuals and Data Dictionaries



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Download the Program

Order Form(s) and review the User Manual/Data Dictionary

Inpatient Order Form and User Manual are posted at:

http://www.dshs.texas.gov/thcic/hospitals/RDF_IP_OrderForm.pdf

User Manual 1999-2003

http://www.dshs.texas.gov/thcic/publications/hospitals/IP_RDF_DataDictionary1999_2003.pdf

User Manual 2004-3 Qtr 2015

http://www.dshs.texas.gov/thcic/publications/hospitals/IP_RDF_DataDictionary2004_Present.pdf

User Manual 4 Qtr 2015-Present

http://www.dshs.texas.gov/thcic/publications/hospitals/IP_RDF_DataDictionaryQ42015.pdf

Outpatient Order Form and Data Dictionary are posted at:

http://www.dshs.texas.gov/thcic/hospitals/RDF_OP_OrderForm.pdf

Data Dictionary 2010- 3 Qtr 2015

http://www.dshs.texas.gov/thcic/publications/hospitals/OP_RDF_Dictionary.pdf

Data Dictionary 4 Qtr 2015-Present

http://www.dshs.texas.gov/thcic/publications/hospitals/OP_RDF_DictionaryQ42015.pdf

Emergency Department Order Form and Data Dictionary are posted at:

https://www.dshs.texas.gov/thcic/RDF_ED_Orderform.pdf

Data Dictionary 2016-Present

<https://www.dshs.texas.gov/thcic/ED-RDF-Data-Dictionary-2016-to-present.pdf>

DSHS IRB Checklist and Forms



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Download the IRB Application forms at:

<http://www.dshs.texas.gov/irb/applirb.shtm>

Review the "Checklist" section for the type of application forms that are required.



FORMS (NOTE: WORD forms expand to fit text; PDF forms do not expand)	WORD	PDF
Application (Required with every submission)		
New Submission Detail		
Renewal Submission Status Report		
Data Request Application (Check with appropriate DSHS Program to see if they have one)		
Request for Exemption from Review of Research (Use to request a Public Health Practice exemption) <i>(NOTE: Federal regulations do not allow research involving prisoners, fetuses, pregnant women, or human in vitro fertilization to be exempted. Also, requests for Hospital Discharge/Outpatient Data and Vital Statistics Data/Certificates cannot be exempted.)</i>		
Request for Expedited Review of Research <i>(NOTE: In IRB terminology, an "expedited review" means a review of proposed research by the IRB Chair or a designated voting member or group of voting members, rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. In the context of research review by an IRB, expedited does not necessarily mean quick or fast. Also, requests for Hospital Discharge/Outpatient Data and Vital Statistics Data/Certificates cannot be expedited. This includes renewals and amendments.)</i>		
Waiver of Informed Consent (If not submitting consent documents)		
Amendment Request		
Final Report (May be e-mailed without an Application)		
CHECKLISTS	WORD	PDF
Initial Submission		
Renewal Submission		
Amendment		



DSHS IRB Required Training



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Take the required course: Human Participant Protection Education

DSHS IRB Forms Page

System13 Login DSHS Online Home DSHS Home DSHS Find a Licensee NPPES NPI Registry MSN CNN

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Advanced Inicio en español Text Size: + -

Topics: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z All

Home About Us News I am a... I'm looking for... Resources Online Services Contact Us

IRB Home Page [Home](#) > Forms & Instructions: To Submit a Request to the DSHS IRB#1

Forms/Instructions **Forms & Instructions: To Submit a Request to the DSHS IRB#1**

Add'l Resources **Prior to Submitting an Application**

Schedule/Deadline The first step in submitting an application is to contact the appropriate DSHS Program Contact. ([Alphabetical list of Programs and Contacts](#)).

Subject Rights

Board & Staff

Contact Us

Required Courses (external links) **Submission Deadline**

Human Participant Protection Education See the [Meeting Schedule & Submission Deadline](#) page. Applications received on or after the submission deadline, that cannot be exempted or examined using an expedited review procedure, will be scheduled for a full board review in the following month. Send your complete submission, original and copies, to the program contact listed on the first page of the application. The program contact will need time to review and sign the application and forward the submission to the IRB Office before the submission deadline.

Human Subject Assurance Training

PDF Viewing

External links to other sites are intended to be informational and do not have the endorsement of the Department of State Health Services. These sites may also not be accessible to persons with disabilities.

An exemption or an expedited review can be requested.

Instructions

Contact InstitutionalReviewBoard@dshs.texas.gov for questions



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Draft Application

Email DRAFT application packet to the THCIC Program

Application packet includes:

- Completed IRB forms
- Human Participant Protection Education Certificate
- Completed Program Order Form(s)
- Initial and sign all forms
- Attach individual forms to one email. Forms may be zipped.
- Email individual documents to the THCIC program at:
thcichelp@dshs.texas.gov
- List the Email Subject as: "Draft IRB – (Name of Applicant)"

Program Response on Draft Application



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Program review of Draft Application packet

The program will review the draft application and respond to the applicant (Principal Investigator (PI)) by email within 5 to 10 business days.

The program will review the draft application for:

- Completeness of responses and forms
- Authorization to receive the requested data
- Special considerations or understandings of data process issues will be noted or presented to the Principal Investigator about their proposal. For example: Possible under-reporting patients listed for Medicare and Medicaid on payment source codes. Or issues regarding "Patient_Unique_Index" variable request. Projects using this variable will not be accurate enough to use if the project is examining issues with patients under two years of age.

The program responses are to provide feedback to the PI on areas where the application needs more information or clarity.

Submit Finalized Application Packet



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- Finalize application packet
- Initial and sign all forms
- Attach individual forms to one email. Forms may be zipped.
- Email individual documents to the THCIC program at: thcichelp@dshs.texas.gov
- List the Email Subject as: "Final IRB – (Name of Applicant)"

Program Approval Process



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The following DSHS programs and entities must review and approve the finalized IRB application packet prior to its delivery to the IRB Committee for placement on the meeting calendar. This approval process may take about two (2) weeks.

- DSHS THCIC program
- DSHS Office of General Counsel (OGC)
- DSHS Assistant Deputy Commissioner
- DSHS Executive Steering Committee (ESC)

If any of the above programs or entities disapprove the application, the THCIC program will notify the applicant of the contributing issues.

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If the application is disapproved, the applicant may submit another complete finalized (all documents) application packet with the modifications (plus tracked changes and a clean copy of modified forms).

Follow the instructions for submitting the “finalized” application again.

Program Approval Process



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Once the application packet is approved by the three programs, THCIC will deliver it to the IRB Committee for placement on its meeting calendar.

An approved application packet must be delivered by the THCIC program to the IRB Committee approximately four (4) weeks prior to a scheduled IRB meeting.

The IRB Committee meets the third Thursday of each month. (There are no meetings scheduled for the month of August)

<http://www.dshs.texas.gov/irb/applirb.shtm>

IRB Approval Process



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If the application is approved by the IRB Committee, it is forwarded to the DSHS Executive Steering Committee (ESC) for final approval, if the application is an “Initial IRB Submission”.

The IRB Administrator will email the Principal Investigator (PI) once the application is approved/disapproved. This may take about two or three weeks after the IRB meeting before the PI receives the email determination.

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The IRB Administrator will copy the THCIC program on the approval/disapproval notification emailed to the PI.

Receiving the Data



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If the application is approved by the IRB, THCIC will email the PI a billing invoice (or Memorandum of Understanding, whichever is applicable) within two (2) business days and will wait until payment is received before building the approved research dataset.

THCIC will notify the PI by email when the dataset is ready for download from our secured server.

Questions?



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Data questions

- Contact the THCIC Program at thcichelp@dshs.texas.gov
- IRB FAQs at <http://www.dshs.texas.gov/thcic/IRBFAQs.aspx>

IRB form or required training questions

- Contact the IRB Administrator at InstitutionalReviewBoard@dshs.texas.gov