IRB Application Process
THCIC Program

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

April 26, 2021

Research Data RDF vs PUDF

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

- 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

- 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

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

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

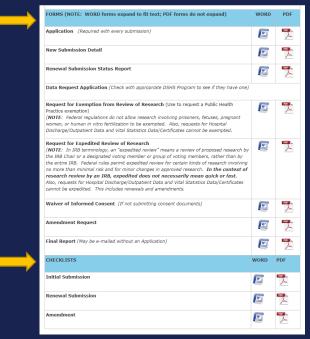https://www.dshs.texas.gov/thcic/ED-RDF-Data-Dictionary-2016-to-present.pdf

DSHS IRB Checklist and Forms

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.

DSHS IRB Required Training

Take the required course: Human Participant Protection Education

Contact InstitutionalReviewBoard@dshs.texas.gov for questions

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

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

- 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

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.

Program Approval Process

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

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

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.

IRB Approval Process

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

Receiving the Data

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?

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