TEXAS Health and Human Services

IRB2 APPLICATION

TO BE COMPLETED AFTER THE "APPROVAL-TO-APPLY" FORM IS APPROVED

Checklist:
Required Forms:
☐ • IRB2 Application with Signatures ☐ • Human Subjects Training Documentation for **all** research personnel ☐ • Signed Conflict of Interest forms for **all** research personnel
Additional Forms: * *Some may not apply to your project.* *
☐ • HIPAA Request for Waiver or Alteration of Consent ☐ • Copies of Subject Recruitment Materials ☐ • Copies of Study Instruments
For Assistance Contact:
IRB2 Administrator IRB2@hhs.texas.gov

Project Title:			
IRB2 Tracking Number:			
Facility involved in proposed research (mark one):			
☐ State Hospital (specify): _____			
☐ SSLC (specify): _____			
☐ Other (specify): _____			
Principal Investigator:			
Name:			
Address:			
Phone:		E-mail:	

Co-Investigator(s) and Key Personnel:		
Name	Phone	E-mail

Primary Contact for IRB Communication (if not the Principal Investigator):			
Name:			
Address:			
Phone:		E-mail:	
Faculty Supervisor (if student):			
Name:			
Address:			
Phone:		E-mail:	

Funding Sources:
☐ NOT APPLICABLE: NO FUNDING/SUPPORT RECEIVED FOR THIS PROJECT/ ACTIVITY FROM AN HHS AGENCY OR OTHER SOURCE ☐ A TEXAS STATE AGENCY (SPECIFY): _____ ☐ OTHER (SPECIFY): _____

I certify that I understand the policies and procedures governing research with human subjects and that I fully intend to comply. I further acknowledge my responsibility to report any changes in the protocol, any unanticipated/adverse events, and to obtain written approval to proceed before implementing any study changes. Annual review and continuing IRB2 oversight must be maintained for compliance. If approved for a data request, all data will be secured for the duration of the study and destroyed as soon as possible.

_____ _____
Signature of Principle Investigator Date

_____ _____
Signature of Faculty Supervisor (if student) Date

For IRB Use

This proposal has been reviewed and approved by IRB2. It is in compliance with the Code of Federal Regulations, 45 CFR 46, and TAC Rules.

☐ Expedited Review - under 45 CFR 46.110

☐ Full Board Review

☐ Exempt Status - under 45 CFR 46.101b

_____ _____
Signature of IRB2 Chair or Designee Date

Obtain the signature of the Facility Superintendent where investigator will be conducting research (hospital/SSLC) – OR – a Commissioner (for data request).

☐ I have reviewed this proposal and support this research proposal being conducted at:

_____
Facility Name

☐ I have reviewed this proposal and support **this data request.**

_____ _____
Facility Superintendent/Commissioner Date

Additional Approval (if required):

_____ _____ _____
Name Title Date

TEXAS Health and Human Services

IRB2 DOCUMENTATION OF HUMAN SUBJECTS TRAINING

Project Title:

Human subjects training includes CITI, OHPR and NIH training. NIH training can be found here http://phrp.nihtraining.com/users/login.php?l=3. **Certificates of completion must be submitted for all key personnel. Please e-mail scanned training certificates to: IRB2@hhs.texas.gov.**

Key personnel includes any individuals involved in conducting the research who have direct and ongoing contact with actual or potential research participants or exposure to data, records, or charts. This includes the primary contact/principal investigator, co-investigators and key personnel. Human subjects training should also be listed for the faculty sponsor if the faculty sponsor has direct and ongoing contact with research participants or exposure to data/records. If the faculty sponsor is planning to publish (author or co-author), then the faculty sponsor should be listed as key personnel and list human subjects training below.

The principal investigator must provide documentation of renewal of human subjects training for key personnel every five years.

Names of Key Personnel, Principal Investigator, Co-Investigators, etc.	Title of Training (NIH, OHRP, CITI)	Training Date

I verify that training in the conduct of research with human subjects has been obtained by all key personnel listed on this research project. I assure that any key research personnel that become affiliated with the project after this date will receive the human subjects training prior to conducting any research activities. An amendment application will be requested, completed, and emailed to the IRB2 Administrator prior to any changes in research personnel.

_____ _____

Signature of Principle Investigator Date

_____ _____

Signature of Faculty Sponsor (if applicable) Date

IRB2 DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

TAC Rules Governing Research in legacy TDMHMR Facilities mandate that all research personnel disclose potential conflicts of interest that may occur if the research is conducted. A conflict of interest exists when professional judgment concerning a primary interest (such as patient welfare or research validity) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as equally important as actual conflicts of interest. Financial relationships (such as employment, consultancies, etc.) are the most easily identifiable conflicts of interest and the most likely to undermine credibility. Conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual beliefs. Authors should avoid entering agreements with study sponsors that interfere with authors' access to study data or that interfere with their ability to prepare manuscripts independently. Most investigators have some conflict of interest. A conflict, in and of itself, does not mean that research cannot be conducted ethically and with full protections for research participants.

Please complete and submit this form. **All research personnel including the principal investigator, faculty supervisor (if student), and all co-investigators must sign and submit this document. Refer back to the IRB2 website for submission of additional signed Disclosure of Potential Conflict-of-Interest forms.**

1. Project Title
2. Do you have an affiliation with the facility where the research is taking place?
If Yes, please explain. ☐ Yes ☐ No ☐ N/A
3. Is this research being conducted to fulfill an educational requirement?
If Yes, please explain. ☐ Yes ☐ No ☐ N/A

4. Did your research team receive payment or services from a third party for any part of the proposed research?

If Yes, explain. ☐ Yes ☐ No

5. Do you or research team have financial relationships with entities that could be perceived to influence or give the appearance of influencing this research?

If so, please list below all sources of revenue paid (or promised to be paid) to you or your institution on your behalf over the 36 months prior to the beginning of this research. Public funding sources do not need to be disclosed. ☐ Yes ☐ No

6. Are there other relationships that could be perceived to influence or give the appearance of influencing your research?

If Yes, explain. ☐ Yes ☐ No

I certify that I have provided a full description of any potential conflicts of interest that I can foresee in the conduct of this research protocol. I acknowledge my responsibility to report any future conflicts of interest that may arise to IRB2.

_____ _____

Signature of Key Personnel Date

This application should demonstrate that the proposed project is well-organized, guided by previous literature, and that data will be analyzed in response to hypotheses or guiding research questions.

Title of Study:
1. Background and Significance
Length of this section: 1-3 paragraphs Instructions: State why you are proposing this project and how the results will be used. A LITERATURE REVIEW IS NOT REQUIRED.
A. State the public health purpose of the research.
B. Describe how results will be used (e.g. contract, grant, thesis, dissertation, etc.).

2. Specific Aims

Length of this section: 1 paragraph with bullets

Instructions: Provide a bulleted list of research questions, goals, and/or hypotheses.

3. Methods and Study Procedures

Length of this section: 3-5 paragraphs on the following page

Instructions:

For Data Release, Chart Reviews, or Secondary Data Analyses

- Detail how data will be obtained, transferred, and securely stored.
- List each data element (by variable name) that you plan to extract and specify which ones are protected health information (PHI).
- Identify the maximum number of records you plan to extract from the sources/systems (e.g.,100 clients discharged from facility from January 1, 2005 to January 1, 2006 with a diagnosis of schizophrenia).
- Explain the roles of the key personnel including the tasks they will perform.

For Surveys, Interviews, or Research Activities involving Direct Interaction with Living Individuals

- Describe steps in the recruitment of study participants. Attach copies of recruitment materials such as verbal scripts, advertisements, letters, etc.
- Describe all informed consent procedures. Attach draft informed consent document(s) and/or verbal consent script. A template is provided in this packet.
- Describe how signed consent forms will be securely stored.
- Describe all procedural steps involved in the data collection process.
- Provide details on how instruments/surveys/treatments, etc., will be administered. Attach copies of all instruments, interview guides, surveys, etc.
- Describe how participant data will be stored securely and clarify when it will be de-identified and/or destroyed.
- Explain the role(s) of key personnel.

3. Methods and Study Procedures Continued

4. Inclusion/Exclusion Criteria for Study Participants
Length of this section: 1-3 sentences Instructions: Identify who will be included in the project and the inclusion criteria you intend to use (e.g., males age 20-25 with a diagnosis of schizophrenia). For data requests, include the years you plan to extract (e.g., December 1, 2005 to December 1, 2009).

5. Sample Size and Maximum Number of Records
Length of this section: 1-5 sentences Instructions: Sample size must ensure that there are sufficient cases to ensure a reasonable chance of detecting or ruling out any important statistical effect and no more subjects than necessary are placed at risk. For data requests, indicate the maximum number of records you plan to extract. Specify which years you plan to extract and the specific data element(s) you are requesting in the Appendix. For example: "The researcher will request a maximum of 5,000 records from the CARE client system. The extraction will begin with January 1, 2005 and end with January 1, 2004."

6. Recruitment and Consent Procedures
Instructions: If human subjects will be recruited and informed consent procedures will be used, please explain below. If this section does not apply, please indicate "N/A."

7. Compensation

Instructions:
If subjects will be compensated, describe here. If this section does not apply, please indicate "N/A."

Notes about Compensation:

a. The level of compensation provided to subjects should not be disproportionate to the level of inconvenience and expenses accrued by the subject. In the limited choice environment of a hospital or school, possible compensation may include enhancement of general living conditions, medical care, quality of food, amenities, and opportunity for earnings.
b. Compensation for participation should be provided on a pro-rata basis. This implies that study participants will be paid in direct proportion to his/her actual degree of participation. For example, if a subject completes half of the study, he/she should receive half of what would have been paid for the completing the study.
c. Informed consent must, in the case of compensation, contain a detailed account of the terms of payment, including the amount to be paid and a description of the conditions under which a subject would receive partial payment or no payment.

8. Risks to Study Participants

Instructions: Describe risks to human subjects participating in this research. If there are no risks or this question is not applicable, explain.

9. Minimization of Risks to Participants
Length of this section: 1-3 paragraphs. Instructions: Describe how you will minimize risks to participants including risks of data disclosure.
10. Potential Benefits
Length of this section: 1-3 sentences Instructions: If there are specific benefits to the agency, community/society, and study participants list those below. If there are no specific benefits, state as such.
11. Alternative Treatments
Length of this section: not applicable Instructions: If treatments are being tested, describe any alternative treatments that may exist. If no treatments will be tested on human subjects, indicate "N/A."

12. Confidentiality and Data Security	
Does data analysis include the use of individually identifiable or participant-identifiable information?	☐ Yes ☐ No
If yes, check the appropriate box below to specify which procedures will be used to ensure the confidentiality of participant-identifiable information.	
1. All data collection and storage devices will be password protected.	☐ Yes ☐ No
2. Protected health information will not be stored on portable devices (e.g., laptops, flash drives, tablets, etc.) unless encrypted.	☐ Yes ☐ No
3. Identifiable information will be deleted as soon as possible.	☐ Yes ☐ No
4. Protected health information will not be transmitted via e-mail and any data transmitted electronically will be encrypted.	☐ Yes ☐ No

13. Data Analyses

Length of this section: 1-3 paragraphs.

Instructions: Describe the analyses you will use to answer the research questions in the specific aims section. Indicate if you plan to submit the results for publication or presentation.

14. Use of Placebos

The research protocol should disclose sufficient information so that the IRB can determine if the protocol: a) extends the use of a placebo or washout period unreasonably; b) deprives the human subject of reasonable relief; or c) extends a human subject's use of placebos as the primary medication therapy after the subject is discharged from the facility.

Length of this section: 1 paragraph

Instructions: If this section does not apply, please insert "N/A".

15. Investigational Drugs and/or Devices
If the research protocol extends the use of an investigational medication or device after subjects are discharged from a facility, the process for ensuring continuity of care/communication with any other care providers must be described. A memorandum of agreement with each local authority responsible for continuity of care must state that the local authority will provide appropriate care, as required by TAC rules following discharge from psychiatric hospital, following the conclusion of their participation in the research study. Length of this section: 1-3 paragraphs Instructions: Describe the use of the investigational drug or device. If this section does not apply, please insert "N/A".

Appendix A – Data Elements
Instructions: List data elements requested by source. Include only those being extracted from the electronic system or paper records (e.g., date of admission, gender, ethnicity, diagnosis code, etc.). Specify time frame to be included and any other exclusion conditions (e.g., discharges from January 1, 2005 to January 1, 2006, ages 18-64).
List data elements by data source:
Time frame:

Optional

Project Title:	
IRB2 Tracking Number:	
Describe the risks to subjects involved in this research, including risks to privacy. Explain why **risks to the subjects' privacy are no more than minimal,** if that is the case.	
Please check all that apply: ☐ Request a Waiver or Alteration of Consent Requirements (Complete Part A & B) ☐ Request a Waiver of Signed Consent (Complete Part C) ☐ Request a Waiver of Authorization to Use or Disclose Protected Health Information (Complete Part A & D)	
Part A:	
1. Justify why the research can not be practicably conducted without the waiver.	
2. Justify that the rights and welfare of participants will not be adversely affected by the waiver.	

Part B:

3. Please describe any plan to provide subjects with additional pertinent information after study completion, if appropriate:

☐ Not applicable

Part C:

4. Is there any link between the participants and the research other than the consent form?

☐ Yes (If Yes, go to 6.) ☐ No

5. Describe procedures used in the study and explain why they would not normally require consent outside of the research context.

Part D:

6. List the protected health information (PHI) that will be collected or used. **Explain why the research can not be done without access to this information.**

7. Describe the **plan to protect PHI and other identifying information from improper use and disclosure.** Specify where PHI will be stored and who will have access to it (e.g., IRB, sponsors, research personnel, etc.)

8. Explain how the use of PHI will contain **the minimum amount needed** to conduct the proposed research?	
9. What will happen to the PHI at the conclusion of the study?	
Will PHI be destroyed at the earliest opportunity?	☐ Yes ☐ No
If NO, explain why the data must be retained and for how long.	

Written Assurance:

As Principal Investigator, my signature provides written assurance that identifiable information will not be **reused or disclosed**, except as required by law, and that the data provided and/or collected will not be linked with additional datasets unspecified in the study protocol.

_____ _____

Signature of Principal Investigator Date

If your computer allows email submission, after completing the form click the "Submit" button located below, otherwise submit the form and applicable documentation.
Submit