



# IRB2 SUBMISSION PACKET

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

## **Required Forms:**

- IRB2 Application with Signatures
- Human Subjects Training Documentation
- Conflict of Interest (COI) Form with Signatures

## **Additional Forms:**

*\* Some may not apply to your project. \**

- HIPAA Request for Waiver or Alteration of Consent
- Copies of Subject Recruitment Materials (letters, e-mails, advertisements, etc.)
- Copies of Study Instruments (questionnaires, surveys, tests, etc.)

## **Helpful Tips:**

- Use Revision Dates in Header or Footer
- Electronic Signatures Accepted, Scanned Documents w/Signature Preferred

## **For Assistance Contact:**

Abigail Cameron, IRB2 Administrator  
abigail.cameron@hhsc.state.tx.us  
512.206.5730

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES**

**IRB2 INITIAL APPLICATION**

**Project Title**

Protocol #:

**Facility involved in proposed research (mark one):**

DSHS Central Office

Note: Includes Resources of the Mental Health and Substance Abuse Division, including staff, property, and non-public information including: centralized client databases (e.g. CARE, BHIPS) or research proposals in which division employees serve as investigators.

DSHS State Hospital (specify): \_\_\_\_\_

Other: \_\_\_\_\_

**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.
- Health and Human Services (HHS) Office of the Secretary
- Administration for Children & Families (HHS)
- Agency for Healthcare Research & Quality (HHS)
- Centers for Disease Control & Prevention (HHS)
- Food & Drug Administration (HHS)
- National Institutes of Health (HHS)
- Office of Inspector General (HHS)
- Substance Abuse & Mental Health Services Administration (HHS)
- Other (specify): \_\_\_\_\_

I certify that I understand the policies and procedures governing research with human subjects developed by the Department of State Health Services and Department of Aging and Disability Services 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 IRB 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 the DSHS Central Office Institutional Review Board (DSHS IRB2). It is in compliance with the Code of Federal Regulations, 45 CFR 46, and DSHS and DADS' rule governing Research in TDMHMR facilities.

- Expedited Review - under 45 CFR 46.110 (categories 1 to 7)
- Full Board Review
- Exempt Status - under 45 CFR 46.101b (categories 1 to 6)

\_\_\_\_\_  
Signature of DSHS IRB2 Chair or Designee

\_\_\_\_\_  
Date

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

- I have reviewed this proposal and the recommendations of DSHS and support this research proposal being conducted at: \_\_\_\_\_

***DSHS/DADS Facility Name***

- I have reviewed this proposal and the recommendations of DSHS IRB2 and support **this data request.**

\_\_\_\_\_  
Facility Superintendent/Assistant Commissioner

\_\_\_\_\_  
Date

Additional Approval (if required):

\_\_\_\_\_  
DSHS Behavioral Health Medical Director

\_\_\_\_\_  
Date

# DOCUMENTATION OF HUMAN SUBJECTS' TRAINING

INSTITUTIONAL REVIEW BOARD (IRB2)

**Project Title:**

Human subjects training includes CITI training or NIH training. NIH offers free online training and that link can be found at: <http://phrp.nihtraining.com/users/login.php?l=3>. Certificates of completion must be provided with the final IRB2 application package.

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 also assure by signature that all key personnel that become involved in the research will receive training prior to initiating any research activities and be approved by the IRB (through amendment) before initiating any research activities.

**The principal investigator must provide documentation of renewal of human subjects training for key personnel every three years for NIH training or CITI training**

Names of Key Personnel, Principal Investigator, Co-investigators, etc.	Title of Training (NIH, 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

**Project Title:**

DSHS and DADS' Rule Governing Research in TDMHMR Facilities mandates that all research personnel disclose any 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 patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as important as actual conflicts of interest. Financial relationships (such as employment, consultancies, stock ownership, 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 into agreements with study sponsors that interfere with authors' access to all of the study's data or that interfere with their ability to interpret the data and to prepare manuscripts independently. Most investigators have some conflict of interest but 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 sign this form below. A signed Conflict-of-Interest form is required from the principal investigator, faculty supervisor (if student), and all other key personnel for the IRB Submission to be complete. **Therefore, you may need to make additional copies of this document.**

1. Do you have an affiliation with the facility where the research is taking place?

If Yes, please explain.

Yes  No  N/A

2. Is this research being conducted to fulfill an educational requirement?

If Yes, please explain.

Yes  No  N/A

3. Will you (or did) you or your research team receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including grants, manuscript preparation, statistical analysis)?

If Yes, please explain.

Yes  No

<p>4. Do you or research team have financial relationships with entities that could be perceived to influence or give the appearance of influencing this research? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>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 such as government agencies, academic institutions, or charitable foundations need not be disclosed.</p>
<p>5. Are there other relationships or activities that could be perceived to influence (or give the appearance of influencing) your research? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If Yes, please explain.</p>

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

# IRB2 PROTOCOL TEMPLATE

**Title of Study:**

*This application should demonstrate that the proposed project is well-planned, that the sample size is justified by appropriate statistical methodology, that it will be executed properly, documented accurately, and that the results will be analyzed appropriately.*

## 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 DSHS, DADS, 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.  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Protected health information will not be stored on portable devices (e.g., laptops, flash drives, tablets, etc.) unless encrypted. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Identifiable information will be deleted as soon as possible.  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Protected health information will not be transmitted via e-mail and any data transmitted electronically will be encrypted.         | <input type="checkbox"/> Yes <input type="checkbox"/> 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 TDMHMR/DSHS 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 to be extracted from:

Time frame:

**REQUEST FOR WAIVER OR ALTERATION OF CONSENT  
AND HIPAA AUTHORIZATION**

**INSTITUTIONAL REVIEW BOARD (IRB2)**

*\*Optional\**

**Project Title:**

Protocol #:

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 in the research will contain the minimum amount needed to conduct the proposed** research?

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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.

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Written Assurance:

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

\_\_\_\_\_  
Signature of Principle Investigator

\_\_\_\_\_  
Date