**THE UNIVERSITY OF TEXAS AT TYLER**

**INSTITUTIONAL REVIEW BOARD**

**APPLICATION FOR PROTECTED HEALTH INFORMATION USE**

**Principal Investigator**: Click here to enter text.

**Email address**: Click here to enter text.

**Phone number**: Click here to enter text.

**Research Staff needing access to protected health information (must also be listed in IRB review application)**: Click here to enter text.

**Study Title**: Click here to enter text.

**TYPE OF HEALTH INFORMATION REQUESTED**

**Which of the following categories of health information is being requested for use in this study (check all that apply)**

[ ]  **Category 1: Health information that is protected, with authorization from participants**

Health information, as defined by the HIPAA Privacy Act can be protected or it can be de-identified. Protected health information (PHI) includes the following:

 "…as individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse. For purposes of the Privacy Rule, genetic information is considered to be health information." [http://privacyruleandresearch.nih.gov/pr\_07.asp]

[ ]  **Category 2: Health information that is a limited data set**

Limited data sets include that all identifiers have been removed except:

* Admission, discharge, or service dates
* Dates of birth, death
* Age (including age 90 or over)
* Five-digit zip code or any other geographic subdivision, such as state, county, city, precinct and their equivalent geocodes (except street address).

Refer to the IRB Handbook for additional information on limited data sets and required information from covered entities.

[ ]  **Category 3: Health Information that is de-identified, none of the identifiers will be linked to the health information.**

De-Identified Health Information: Health information that cannot be linked to an individual and has none of the following identifiers with it:

* Names
* All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geocodes
* All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death
* Telephone numbers
* Fax numbers
* Electronic mail addresses
* Social security numbers
* Medical record numbers
* Health plan beneficiary numbers
* Account numbers
* Certificate/license numbers
* Vehicle identifiers & serial number, including license plate numbers
* Device identifiers & serial numbers
* Web universal resource locators (URLs)
* Internet protocol (IP) address numbers
* Biometric identifiers, including finger and voice prints
* Full face photographic images and any comparable images
* Any other unique identifying number, characteristic or code.

Any code used to link de-identified data to identifiers must be held by the investigator in a secure manner. The code must not be derived from or related to information about the individual, and may not be otherwise capable of being translated so as to identify the research subject. The mechanism for re-identification must not be disclosed to any person outside of UT Tyler or the research setting.

**DATA AND/OR RECORDS NEEDED FOR RESEARCH PROTOCOL**

1. Selection Criteria (e.g.: all hypertensive children seen in Pediatric Clinic)

Click here to enter text.

1. Dates of required records:

Begin: Click here to enter a date.

End: Click here to enter a date.

1. Data fields required (list fields required from an electronic data base, or list fields to be recorded from the paper record by the researcher)

Click here to enter text.

1. Anticipated sources of information (check all that apply)

[ ]  Paper medical records

[ ]  Electronic files

[ ]  Other: Click here to enter text.

5. I certify that the use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals based on at least the following elements:

 a. An adequate plan is in place to protect the identifiers from improper use and disclosure. The plan is as follows (select all that apply):

 [ ]  All electronic study data will be password protected

 [ ]  Passwords will be changed on a regular basis

 [ ]  Access to study data will be restricted to the following authorized personnel only:

 [ ]  All paper study records will be kept in locked file cabinets and access limited to authorized study personnel only.

 [ ]  Other: Click here to enter text.

b. An adequate plan is in place to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

 The plan is as follows: Click here to enter text.

**By submitting this form with the IRB research review application, the PI attests to the following**:

I declare that the requested information constitutes the minimum necessary data to accomplish the goals of the research.

I agree that the protected health information that I am requesting will remain secure and will be accessible only to authorized persons for all categories, and will remain de-identified for Category 3 information.

I attest that the above statements are correct and complete to the best of my knowledge.

**SIGNATURE OF PRINCIPAL INVESTIGATOR**:

|  |  |  |
| --- | --- | --- |
| Click here to enter text. |  | Click here to enter a date. |
| Principal Investigator Signature (Acceptable signatures: Electronic submission from PIs mailbox or electronic signature) |  | Date |