

Institutional Review Board

Review Preparatory to Research Form

This form is for a **Trinity Health Fresno** researcher (only) to request permission to review a limited number of records that contain protected health information (PHI) *prior* to conducting research in order to formulate a research question or hypothesis, assess the feasibility of a project, or determine the availability of data.

* Researchers ***may not*** remove the patient’s name, contact information, or other identifiers from the

THNY premises.

* No contact of potential research subjects is permitted as part of this Review Preparatory to Research request.
* If you are wishing to screen the medical record for the inclusion and exclusion criteria, refer to the New Project Application, Exempt Determination form, or Waiver of HIPAA Authorization form.
* Submit this form to the Research Compliance Department at: **stephanie.lopez001@samc.com** Need help? Call 559-450-7790

|  |  |  |
| --- | --- | --- |
|  | **Investigator:** | **Coordinator:** |
| Name: |  | N/A |
| Affiliation: |  |  |
| e-mail: |  |  |
| Phone number: |  |  |
| Address for IRB  correspondence: |  |  |

Working Title of Research Idea:

**Purpose for accessing Protected Health Information (PHI)**

* 1. You and others who will review the PHI must be part of the covered health entity’s workforce in order to be granted a Review Preparatory to Research.

I am/we are I/we am not- STOP, you will not be permitted to undertake this

activity.

* 1. Describe why access to review the requested PHI is necessary and why this is needed in order to prepare a research protocol? *Note: PHI may only be used to prepare a research protocol or similar preparatory-to-research activities.*
  2. Indicate the PHI you must access in order to conduct your review of data Preparatory to Research:

Name

Geographic information smaller than state (i.e., city, county, zip code) Elements of dates including birth date, admission date, date of death, and all ages > 89 years of age

Telephone numbers Fax Numbers

Account numbers (credit card, etc.) Certificate or license numbers Vehicle identifiers and serial numbers including license plate

Device identifiers and serial numbers Website URLs

Internet Protocol (IP) addresses Medical Record numbers

E-mail addresses Social Security number

Full face photographic images and comparable images

Biometric identifiers, including finger and voiceprints

Health plan beneficiary numbers Any other unique identifying number, characteristic, or code

* 1. Is this the minimum necessary use of PHI?
  2. Approximately how many records will you review?
  3. What is the source of PHI to be reviewed? electronic medical record

other – what is the name and owner of database?

* 1. List everyone and their affiliation who will be reviewing the information:
  2. In the course of the review you will not collect data for conducting actual research and will not remove data or protected health information from the SAMC premises.

I will comply I do not agree- STOP, *you are not permitted to undertake this activity You are responsible for complying with Trinity Health Fresno Policies and seeking approval for (prior to*

*beginning) the eventual proposed research from the SAMC IRB/Privacy Board.*

# Signature of researcher: Date: Printed Name:

The approval to access PHI for Review Preparatory to Research ***will expire three months from the date of IRB approval***.

**Use and disclosures made under a *Preparatory to Research* are subject to the HIPAA disclosure accounting requirement.** A centralized database in which disclosure of data is reported by the Investigator or his/her designee is use by Trinity Health Fresno. Contact the HIPAA Privacy Officer to submit an accounting disclosure related to your use or disclosure of PHI.



**Please return this completed form via e-mail** [**to:**](mailto:aasjirbsubmissions@stjoeshealth.org)[irb.irb@samc.com](mailto:irb.irb@samc.com)