Preparatory to Research Activities:

Preparatory to research activities are those taking place before the research or quality improvement project has received IRB Approval or Acknowledgement as QI. Examples include:

- Developing a research question or hypothesis
- Preparing a research protocol
- Writing a grant application
- Assessing the feasibility of conducting a study
- Determining and developing eligibility criteria for study participation for specific individuals
- Calculating sample size

There are several restrictions:

1. All data should be de-identified, if possible. If not possible, a valid reason should be given.
2. As per HIPAA, patients/subjects may not be contacted based on this data, nor can any of the data be disclosed outside of TriHealth.
3. Minimum necessary principle must be followed (i.e. only data necessary to accomplishing the goals of the project should be selected).

Data Privacy Attestation (DPA) Guidance:

Data elements requested on a data privacy attestation (DPA) must be consistent with data elements specified in the research or quality improvement protocol submitted to the IRB for review and approval / acknowledgement.

- **Data Minimization:**

Only collect the minimum necessary data elements required to achieve the research objectives.

- **Data De-identification:**

Where applicable, identifiable data will be de-identified using appropriate methods to protect participant privacy.

- **Secure Storage:**

Research data will be stored securely using appropriate access controls and encryption measures to prevent unauthorized access.

- **Data Sharing:**

Any data sharing with third parties will be conducted in accordance with institutional policies and relevant privacy laws, including obtaining necessary approvals and data use agreements.

- **Compliance with HIPAA:**

I will adhere to all relevant regulations regarding the handling of protected health information or personal data.

- **Data Access and Usage:**

Access to research data will be limited to authorized research personnel directly involved in the project.

Data will be used solely for the purposes outlined in the research protocol and informed consent document.

- **Data Disposal:**

Upon completion of the research project, all identifiable data will be securely destroyed or de-identified according to institutional guidelines.

- **Breach Notification:**

I will immediately report any suspected data breaches to the appropriate institutional authorities and take necessary corrective actions.

REQUEST FOR REVIEW OF PROTECTED HEALTH INFORMATIONPREPARATORY TO RESEARCH

Reviews Preparatory to Research *– Complete this form for one or more of the following preparatory to research activities: 1) developing a research question or hypothesis, 2) preparing a research protocol, 3) writing a grant application, 4) assessing the feasibility of conducting a study or 5) determining eligibility of potential individual research participants. This form is necessary if the investigator is accessing PHI. If the feasibility can be determined without the investigator accessing PHI (i.e., # of patients with a specific diagnosis) this form is not necessary. The access to and use of protected health information in a review preparatory to research does not permit the continued use, or subsequent disclosure, by the researcher after it is determined that there is sufficient basis for a clinical trial or research study.*

Principal Investigator:

Department:

Phone: **Email:**

Institution Releasing Information/Covered Entity:

A. **List members of the study team who are authorized to review health information on behalf of, or in addition to, the principal investigator:**

B. **Identify the source of the data:**

C. **Will the data be accessed remotely?** ☐Yes ☐No

If "Yes", you cannot print, download, copy, save, or otherwise retain PHI at the remote site.

D. **Briefly describe the purpose of the review and/or data collection:**

E. **If applicable, describe where the identifiers (master subject key that links patients to the de-identified data) will be kept and the details of the secure location:**

F. If applicable, explain the plan to destroy the identifiers (the master subject key) at the earliest opportunity consistent with the conduct of the research once data entry and analyses are completed:

I certify that:

1. Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
2. No protected health information will be removed from the covered entity by the researcher in the course of the review;
3. The protected health information for which use or access is sought is necessary for the research purposes;
4. The protected health information that will be reviewed is the minimum necessary for the preparation of this research.

_____ _____

Signature of Principal Investigator Date

Please submit this completed form to irb_hrpp@trihealth.com.