**INSTITUTIONAL REVIEW BOARD PROTOCOL REVIEW REQUEST:**

**CHART REVIEW**

**Please delete these instructions before submitting to the IRB.**

The TCU Institutional Review Board (IRB) is responsible for protecting the welfare and rights of the individuals who are participants of any research conducted by faculty, staff, or students at TCU. Approval by the IRB must be obtained prior to initiation of a project, whether conducted on-campus or off-campus. While student research is encouraged at both the undergraduate and graduate level, only TCU faculty or staff may serve as Principal Investigator and submit a protocol for review.

Please submit this protocol electronically to [IRBSubmit](mailto:IRBSubmit@tcu.edu) (MS Word preferred). Also submit a consent document, HIPAA form if applicable, Protecting Human Research Participants Training certificates, recruitment materials, data collection sheets (MS Excel) and any questionnaires or other documents to be utilized in data collection. **We prefer that you submit protocol and informed consent materials as separate Word documents**. You may include other related documents as a pdf. A template for the consent document and HIPAA form, instructions on how to complete the consent, and a web link for the Protecting Human Research Participants Training are available on the [TCU IRB webpage](https://research.tcu.edu/research-compliance/irb/).

Criteria to meet retrospective status (Exempt/Expedited) for review:

* Protocol must be research involving materials (data, documents, records or specimens) that have already been collected solely for the non-research purposes (such as medical treatment or diagnosis).
* Protocol must include specific dates/information etc. that will be used.
* All data must be in existence at the time of IRB submission.

\* *Note: If all data are recorded in a de-identified manner, then the study would be exempt. However, if a link to other sources needs to be recorded with the data, then the study would be expedited and waiver of consent and HIPAA would be required.*

Criteria to meet prospective status (only Expedited) for review:

* Protocol must be research involving data that does not yet exist at the time of IRB submission
* For Prospective studies to meet criteria for a Waiver of Consent, "not practicable" doesn't mean "inconvenient". If a study is planning on collecting data or specimens that are already being collected during clinical care for an ongoing prospective period, consider the following 2 scenarios
* Study involves a large number of patients, seen at multiple locations, with multiple diagnoses.......consent is likely not practicable.
* B- Study involves a single specialty clinic on a smaller set of patients who are regularly seen on a routine basis......consent could be seen as practicable. This scenario, however, would likely meet criteria for a Waiver of Documentation of Consent, but it is feasible that the patients and families could be consented.

1. **Date:**
2. **Study Title:**
3. **Principal Investigator (must be a TCU faculty or staff):**
4. **College/School:**
5. **Other Investigators: List all faculty, staff, and students conducting the study including those not affiliated with TCU.**

1. **If you *have internal or* external funding for this project –**

**Funding Agency:**       **Project #:**       **Date for Funding:**

1. **If you *intend to seek/are seeking* internal/external funding for this project –**

**Funding Agency:**       **Amount Requested From Funding Agency:**

**Due Date for Funding Proposal:**

1. **Please indicate if this is a retrospective and/or prospective chart review:**

**Retrospective Chart Review (Data already existence when the project is submitted to the IRB for initial review)**

**Prospective Chart review (Prospective means the data is not in existence when the project is submitted to the IRB for initial review)**

1. **Provide the date range of the data set (if this is a retrospective chart review, the end date must come before the IRB submission date) *mm/dd/yyyy to mm/dd/yyyy***

1. **Purpose: Describe the primary and/or secondary objectives and hypotheses of the study and what you expect to learn or demonstrate:**
2. **Background: Describe the theory or data supporting the objectives of the study and include a bibliography of key references as applicable.**

1. **Location: Specifically describe where the research will take place (the source location of records to be reviewed). If on TCU campus please list the exact location. If off campus please describe the exact location(s) where you plan to conduct your research.**

1. **Subject Population: Describe the characteristics of the participant population, including age range, inclusion criteria (List the disease or disorder under the study, how will it be documented, and demographic characteristics) and exclusion criteria (list the specific clinical contraindications and specify and specific grades of signs/symptoms) and the total number of participants/charts you plan to review:**

1. **Recruitment Procedure: Describe how the charts to be reviewed will be identified and describe who will identify charts to be reviewed.**

1. **Consenting Procedure: If you need to request consent or HIPAA waivers you can do so in this section. For information to include in this section please view the procedures section of the consent and HIPAA policies, respectively. If this is a prospective chart review you must obtain consent or provide justification for not obtaining consent.**

1. **Study Procedures: Describe the methods for identifying participants for the study. Describe the procedure for obtaining data. Describe the type of data to be collected and timeframe, i.e., lab test, procedure outcome, length of stay etc. Attach a data collection form (MS EXCEL) and list all elements or identifiers to be collected as a part of the study.**

1. **Data Analyses: List the statistical methods to be used to address the primary and secondary objectives. Specify any confounding variables for which it is anticipated adjustment will be made. Explain how missing data and outliers, will be handled in the analyses.**

1. **Potential Risks: A confidentiality breach is a risk associated with chart review research. Please indicate this risk and specify the procedures implemented to minimize this risk.**

1. **Procedures to Maintain Confidentiality: Describe how the data will be collected, de-identified, stored, used, and disposed to protect confidentiality. If protected health information is to be re-identified at a later date, describe the procedure for doing so. All hard data must be stored for a minimum of 3 years in a locked filing cabinet (and locked room) in the principal investigator’s office, lab, or storage closet at TCU. Your professional society may recommend keeping the materials for a longer period of time.**

1. **Potential Benefits: Describe the potential benefits of the research to the participants, to others with similar problems, and to society.** **The subject’s whose charts are reviewed are not likely to receive any benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.**

1. **Check List for the Items That Need to be Submitted: Please submit protocol and consent documents separately in MS word, supplemental documents (interview guides, surveys etc. can be submitted as pdfs) before submitting the materials electronically to the IRB. To prevent any delay in the approval of your protocol, use the most recent template for the protocol, consent document, and HIPAA form by downloading them from** <https://research.tcu.edu/research-compliance/irb/irb-forms-templates/> **each time you prepare your materials.**

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| 1. Protocol |  |
| 1. Consent waiver request |  |
| 1. HIPAA waiver request |  |
| 1. Protecting Human Research Participants Training certificate for each investigator |  |
| 1. Data Collection sheet |  |

**Principal Investigator Assurance**

1. **By signing below, I certify to the following:**

* The project described herein will be conducted in accordance with applicable TCU policies and procedures, as determined by the IRB of record. All Human Subject Research projects occurring at TCU must be conducted in compliance with the Office of Human Protection (“OHRP”) regulations at 45 CFR 46 and all other applicable federal and state laws and regulations (collectively “Applicable Law”)
* I have a working knowledge of Applicable Law
* All personnel who work with human participants under this protocol have received, or will receive, appropriate training in protocol procedures and protection of human subjects prior to working with humans.
* All experiments involving human participants will be performed only by the qualified individuals listed in this protocol and individuals not listed in this protocol will not participate in the protocol experiments.
* Procedures on experimental subjects described in this IRB protocol accurately reflect those described in the funding applications and awards, if externally supported.
* I and all personnel have read and will comply with any pertinent safety information, IRB requirements, and security procedures.
* I will maintain records of all human participants and the procedures carried out throughout the entire term of my project.
* As Principal Investigator, I am aware that I have the ultimate responsibility, on a day-to-day basis, for the proper care, treatment, and protection of the human participants.

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Signature of Principal Investigator Date