***University of North Texas Health Science Center***

***Office of Research Compliance Institutional Review Board***

***Protocol Synopsis for Research Involving Chart Reviews***

**Instructions: To assist with timely and appropriate reviews of projects involving analysis of (more than one patient’s) medical records and/or charts, please fill out this document. Note that this protocol must list a full-time (not adjunct or part-time) UNTHSC Faculty or Staff member as the Principal Investigator.**

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| **PROTOCOL INFORMATION** | **IRB# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **(OPHS Only)** | | | |
| ***Title of Project*:** |  | | | |
| ***Name of Principal Investigator:***  ***Department:***  ***Phone:*** | | | ***Email:*** | |
| ***Name of Co-Investigator (s), students, medical residents, etc:*** | | |  | |
| **CATEGORY OF REVIEW (check one)**  **EXEMPT**: Study procedures involving de-identified data or health information (usually a one-time chart collection) | | **EXPEDITED**: Study procedures involving identifiable data or health information (usually done for longer term studies that involve tracking or follow-up stages) | | |
| **Purpose of the Study-** *State the scientific objectives of the research (attach additional page if needed).* | | | | |
|  | | | | |
| **Background & Significance** **–** *Briefly describe the background leading to the present proposal (add page if needed).* | | | | |
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| **RESEARCH PLAN** (check all that apply) | | | | |
| Retrospective Chart Review (records already in existence will be studied) - **EXEMPT Review**  Prospective Chart Review (medical information/records not yet collected will be studied) – **EXPEDITED Review**  BOTH Retrospective / Prospective Chart Review - **EXPEDITED Review** | | | | |
| **RESEARCH PLAN (continued)** | | | | |
| The information in the chart/record to be used for research purposes, dates from (Month/Year)       through Month/Year)  **[Do NOT indicate *your* personal time frame for conducting this research record review]** | | | | |
| Name of Facility (hospital, clinic, private practice, etc.) where the records will be/were obtained: | | | | |
| How **many** individualpatients’ charts will be reviewed? | | | | |
| How **often** will the researchers review the records (once per record, repeatedly, etc.)? | | | | |
| **Who** will review the records/charts? *List anyone who will have access to the personal identifiers collected for research.* | | | | |
| What is the source of medical information that will be reviewed / studied? (Check all that apply):  Entire Medical Record  Billing Records  Laboratory Results  Pathology Records  Radiological Records  Interviews / Surveys / Questionnaires  Other (describe): | | | | |
| What data items will be collected for research purposes? *Provide specific data fields****,*** *attach a data collection sheet, or* ***a brief narrative describing what information will be recorded for research purposes****.* | | | | |
| **PROTECTED health information AND WAIVER OF INDIVIDUAL HiPAA AUTHORIZATION [45 CFR 164. 512 (i) (2) (i) - (v)]: *Medical Data that are connected to an identifiable person are considered protected health information (PHI) and subject to HIPAA regulations. In order to use such information (PHI) in research, the following section must be completed.*** | | | | |
| The use or disclosure of PHI must not involve more than minimal risk to the privacy of the individuals. Is the risk to subjects:  Minimal or  More than Minimal  [Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/ tests.] | | | | |
| Will personal identifiers be recorded or linked by a code (or “master list”) to the research data? Yes  No  If so, please list all of these identifiers:  How long will you keep the link (identifying code or “master list”) to the personal identifiers?  *State in terms which relate to the study timeline, such as: “after data entry is complete”, “until close of study”, “six years after study completion”, etc. State N/A if no link will be kept. State “indefinitely” if the link will never be destroyed. If the link will be kept indefinitely, explain why the identifier must be retained, including whether it is needed for a health purpose, legal or institutional requirement, or another reason.* | | | | |
| **PROTECTED health information AND WAIVER OF INDIVIDUAL HiPAA AUTHORIZATION (Cont.)**  **There must be an adequate plan to protect the identifiable health information from improper use or disclosure.**  What security measures will be taken to protect the PHI? (e.g. identifiers are kept in a locked file cabinet only available to researchers; they are maintained in a password-protected database and only the researchers have access to the password.) | | | | |
| How will the confidentiality of the research data be maintained? | | | | |
| Do you plan to destroy the PHI that you have transferred/collected for research purposes after the completion of the research study? Yes  No  If so, when and how? If not, please give your rationale. | | | | |
| **DATA SECURITY:**  Will the PHI that you transfer or collect for research purposes, be transmitted to another institution/facility and/or person(s)? Yes  No  If so, describe the precautionary measures you have in place to protect the confidentiality of the research PHI: | | | | |
| Describe how the research data will be stored and protected. Note: Research data are the subset of data extracted from the subject’s clinical data (e.g., medical records) for research purposes.   1. *For* paper-based information include the following information: where the data will be stored, who has access to the storage area, and how access will be monitored: 2. For electronic information: how electronic security will be maintained, what password protection and virus software are enabled, etc.: | | | | |
| Is the Principal Investigator the data steward? Yes  No  [*A data steward is the individual who creates, maintains and/or stores a file, which contains PHI and is responsible for that database*]*.*  If NO, who will be responsible? | | | | |
| List all of the parties or persons that might have access to the study’s research data: | | | | |
| **RISK/BENEFIT assessment** | | | | |
| **Potential Risks-** *Describe any* ***informational risks*** *(including breach of privacy, confidentiality risk, document access, risk of embarrassment, and other “risks” related to how sensitive information is stored, accessed, and managed):* | | | | |
| **Potential Benefits-** *Describe any potential benefits to the subjects, society and/or science that may result from this research project.* | | | | |
| **REQUEST FOR WAIVER OF INFORMED CONSENT [45 CFR 46. 116 (d) (1 – 4)]:**  Informed consent refers to a process whereby the researcher obtains the willingness of the participant to be included in research once all the necessary elements of consent (specified in federal regulations) have been disclosed. In order for the UNTHSC IRB to grant this waiver for a chart review, all of the following conditions must be met. The **Principal Investigator** (PI) must certify each of these items by **initialing ALL of the statements.** | | | |
| **THE PI MUST INITIAL ALL STATEMENTS!**  \_\_\_\_\_\_ (initial) The research involves no more than minimal risk to the participants.  \_\_\_\_\_\_ (initial) The waiver will not adversely affect the rights and welfare of the participants.  \_\_\_\_\_\_ (initial) The research could not practicably be carried out without the waiver. “Practicably” means there is no practical way to either implement a consent document or disclose all the elements of consent without jeopardizing the validity of the study.  \_\_\_\_\_\_ (initial) Whenever appropriate, the participant will be provided with additional pertinent information after participation. | | | |
| **INVESTIGATOR’S CERTIFICATION / ASSURANCE**  I certify that the information provided in this request for protocol review is complete and correct. I understand that I have the ultimate responsibility for protecting the confidential information of individuals and ensuring the privacy of their protected health information. I agree that subjects will not be identified by name in any presentation or publication related to this research project. Further, I attest that I, and any person listed as key personnel on this protocol has legal and institutional authorization to access and examine the medical records to be studied in this project, and take full responsibility for their access and use of these records. Finally, my signature below is my representation that I and any individual listed as research personnel on this protocol have ***no* financial or other conflict of interest** that could adversely affect a subject or their data in this study. I acknowledge that I am required to notify the IRB within 10 business days if a change in my, or any individual listed as key personnel on the protocol, disclosure status occurs.  **Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of Co-Investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of Co-Investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | |

**ATTACHMENTS**

□ Certificate of Human Subjects Training (such as CITI) for **all** study personnel.

□ Signed letter of permission from the institution/facility (e.g., hospital, clinic, physician) authorizing access and review of the records. **NOTE: If Principal Investigator has authorized access to patient records, this letter need not be provided.**