**Application for a Waiver of HIPAA Authorization for Research Purposes**

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| **IRB Project#:**  **(Office use only)** |

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| **PROJECT INFORMATION** |
| **Title of Project:** |
| **Name of Principal Investigator:** |
| **Department:**  **Institution: UNTHSC**  **OR JPS** |
| **Name of Each Co-Investigator (Study Personnel):** |
| **Name, Address, and Phone Number of Study Sponsor (if any):** |

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| **Purpose of the study/objective of the research:** |

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| **1. Protocol/Plan** |
| **a) How, and or from where, do you plan to gather the health information?** |
| **b) What is the source(s) of the Protected Health Information (PHI)\* (choose all that apply):**  Medical Records  Billing system records  Laboratory results  Pathology results  Radiology results  Interviews/surveys/questionnaires  Databases or tissue repositories that were created for operational (i.e. non-research) purposes  Other (describe)  \* **Protected Health Information (PHI) under HIPAA is any information about health status, provision of health care, or payment for health care that can be linked to a specific individual.** |
| **c) Describe the health information that you will collect (attach a copy of your data collection sheet if applicable):** |
| **d) State the anticipated beginning and end dates of the research (or approximate length of data gathering activities):** |
| **e) Give an estimate of the number of records that will be involved in the project**: |
| **f) Necessity of PHI:**  **This research could not practicably be conducted without access to and use of the Protected Health Information (PHI)** *(i.e. Basically, you are unable to do the research without the PHI. For Example, the health information in the medical record is necessary for the case report or retrospective chart review).*  **Please explain why the PHI is necessary for the proposed research related activity:** |
| **g) Is this a retrospective chart review?**  **Yes**  **No\***  **\*If you answered no, can you get Authorization from the research subjects?**  **Yes**  **No**  **\* If you answered no, explain why it is not feasible to get authorization for this research:** |
| **h) Is the risk to individuals whose information you are using minimal?** *(i.e. the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)*  **OR**  **More than minimal?**  **Minimal risk**  **More than minimal risk\***  **\*If you answered more than minimal, please explain what the risk is:** |

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| **2. Protection of Data**  *HIPAA requires that there be an adequate plan to protect the identifiers from improper use and disclosure, that there be an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, and that there be adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, unless required by law or by oversight of the research by a regulatory agency.* | |
| **a) What security measures will you take to protect the PHI from improper use or disclosure or reuse?** *(e.g. they are kept in a locked file cabinet only available to researchers, or they are maintained in a password-protected database and only the researchers have access to the password.)* **Also: List all of the entities that might have access to the study’s PHI such as UNTHSC, JPS, sponsors, FDA, data monitoring boards, any others given authority by law.** |  |
| **b) When and how do you plan to destroy the PHI? If you do not plan to destroy the PHI, please give your rationale.***(e.g. there is a plan to break any links to identifiable information, unless links need to be maintained, in which case a reason should be given.)* |  |
| **c) What security measures will you take to assure that the PHI will not be reused?** *(e.g. “the information will not be used or disclosed for any purpose other than this specific research project”)* |  |

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| **Investigator’s Certification/Assurance** |
| **I certify that the information provided in this request for Alteration to/or a Waiver of Individual Authorization under HIPAA 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.**  **Signature of Principal Investigator Date**  **\_\_\_\_\_ (please initial) I agree that subjects will not be identified by name in any presentation or publication related to this research project.** |