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| **Application to Conduct Research Using EXISTING Medical Records** | | | | | | | | |
| ***This document is used to request a Waiver of Authorization to Use and Disclose Protected Health Information (PHI) and a Waiver of Consent to Participate in Research. This form CANNOT be used to request waivers to review information that will be collected in the future or for research subject to FDA regulation.*** | | | | | | | | |
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| Date submitted to IRB: | | | | | | | | |
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| 1. **General Information** | | | | | | | | |
| 1. Title of Study | | | | | | | | |
| 1. Sponsor  Investigator-Initiated  Other (Specify) | | | | | | | | |
| 1. Investigators | | Name | E-mail | | | Position | | |
| Principal Investigator | |  |  | | |  | | |
| Sub-Investigator | |  |  | | |  | | |
| Sponsor\* | |  |  | | |  | | |
| \* If the Principal Investigator is a resident or trainee, then this application must be sponsored by a Baptist employee who will be held to the same Assurances as the Principal Investigator. | | | | | | | | |
| 1. Administrative contact. Provide contact information for a person who is knowledgeable about this protocol and who can be contacted readily. This person does not have to be an investigator. | | | | | | | | |
|  | Name | Position | Phone | | | E-Mail | | |
|  |  |  |  | | |  | | |
| 1. Briefly describe the purpose of the study. (attach proposal and a description of the data collection) | | | | | | | | |
| 1. Describe the PHI to be collected and the source(s) of PHI? | | | | | | | | |
| 1. A Brief explanation of why the use or disclosure of PHI involves no more than minimal risk to the subjects? | | | | | | | | |
| 1. Who or what institution is the custodian of this PHI? | | | | | | | | |
| 1. Briefly describe the time frame (be specific) and search criteria for the PHI you propose to review. | | | | | | | | |
| 1. Approximately how many records do you propose to review? | | | | | | | | |
| 1. Where will the review of PHI take place? | | | | | | | | |
| 1. Will the data be taken beyond BMH IT firewall?  **Yes**  No   (If yes, please complete the Baptist Research Project Security Assessment Form) | | | | | | | | |
| 1. Who will collect the PHI and who will use it? | | | | | | | | |
| 1. Briefly describe what you will do with the information. | | | | | | | | |
| 1. Beside the investigators listed, will the PHI be disclosed to anyone else?   (If Yes, to whom will PHI be disclosed?) | | | | | | | | Yes  No |
| 1. Can this research be practicably conducted without a waiver of consent from the persons whose records you will access?  Yes  No   (If no, please explain) | | | | | | | | |
| 1. Can this research be practicably conducted without access to and use of PHI?  Yes  No   (If no, please explain) | | | | | | | | |
| 1. Does the proposed disclosure or use of PHI involve more than minimal risk to a subject’s privacy? (If yes, please explain) | | | | | | | | Yes  No |
| 1. Does this protocol present any unusual risks to the confidentiality of subjects’ medical information while participating or afterwards? (For example, history of drug use; genetic testing).). If yes, please explain) | | | | | | | | Yes  No |
| 1. Will this protocol collect information about subjects that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation? (If yes, explain) | | | | | | | | Yes  No |
| 1. Briefly describe the plan to destroy identifiers at the earliest opportunity that is consistent with the goals of the study. | | | | | | | | |
| 1. Briefly describe the plan to protect identifiers from improper use and disclosure. | | | | | | | | |
| 1. **Post Submission Steps for Residents and Students** | | | | | | | | |
| ✓For student researchers, make sure that your faculty sponsor and Department Director/Chair have both signed and approved your submission to the IRB.  ✓Monitor your e-mail for communication from the IRB concerning your submission.  ✓Do not start collecting data for your project until you receive an official IRB approval letter.  ***\*\*\*\*\*\*\*\*\*\*\*\**Please note that expedited reviews may take up to 3 weeks to complete\**\*\*\*\*\*\*\*\*\*\*\**** | | | | | | | | |
| 1. **Assurances of Principal Investigator** | | | | | | | | |
| **As principal investigator of the study being submitted for review, I make the following assurances:**   1. **1) PHI used and disclosed under a waiver will be used only for the purpose described in this application and will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project.** 2. **I will maintain appropriate records of patients whose PHI I access and disclose, and I will be prepared to account for these activities.** 3. **If PHI is stored on portable electronic media, then I will use a strong password (at least 14 characters containing at least 1 upper case letter; at least 1 lower case letter; at least 1 number; at least 1 symbol) and NIST 140-2 Level 2 encryption.** | | | | | | | | |
| Signature of Principal Investigator | | | | | Date | | | |
| Signature of Sponsor (if applicable) | | | | | Date | | | |
| ***FOLLOWING SECTION IS TO BE COMPLETED BY IRB CHAIR OR DESIGNATED REVIEWER*** | | | | | | | | |
| 1. **Assessment and Determination** | | | | | | | | |
| 1. Does the research involve more than minimal risk? | | | | | | | Yes  No | |
| 1. Will a waiver of the requirement to obtain informed consent adversely affect the rights and welfare of the subjects? | | | | | | | Yes  No | |
| 1. Is it appropriate to provide subjects with additional pertinent information after their records have been accessed? | | | | | | | Yes  No | |
| ***Conflict of Interest Statement:* I do not have a personal, scientific or financial interest in this project.** | | | | | | | | |
| Approved after expedited review per 45 CFR 46.110(b)(2). 116(d); 45CFR164.512(i)(1)  Approval period is one year unless otherwise specified: | | | | | | | | |
| Referred for review at convened meeting (investigator advised) | | | | | | | | |
| IRB Chair/Designated Reviewer | | | | Date | | | | |