**Purpose:** This appendix is designed to provide information to the IRB when using Protected Health Information (PHI).

**Instructions:** Use this form to request **access** to identifiable health information without prior written permission from the subject.

***Identifiable Health Information = Protected Health Information (PHI)***

*Using this form – To check/uncheck the checkboxes, click once on the box. To enter test in text boxes, click once of the box and then type your response.*

* Save this form to your computer before proceeding.

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| **Part 1: General Information** | | | |
| Principal Investigator (PI): | Name | Date: | Enter date |
| Primary Contact Name:(if applicable) | Name | | |
| Project Title: | *Title* | | |

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| **Part 2: Application for:** *(choose one)* | | |
|  | **Waiver of Authorization** | Authorization will not be sought for some or all subjects. The researchers plan to use/access the identifiable health information (PHI) in order to obtain and record data without ever receiving subjects’ written permission (e.g., chart reviews or verbal consent for research) |
|  | **Partial Waiver of Authorization** | Used to identify eligible subject for recruitment in this research. Continued access to PHI will be limited to those who later volunteer for the project and provide written authorization. |
|  | **Alteration of Authorization** | Some or all of the elements of authorization are changed or omitted.  [Specify excluded element(s)] |

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| **Part 3: Protected Health Information (PHI)** | | | | | | | |
| 1. **Explain why is not practical to carry the research without this waiver:**  * *Select all that apply* | | | | | | | |
|  | **Identify/recruit** – access to records is needed to identify eligible subjects (e.g., chart reviews, partial waiver for recruitment, etc.) | | | | | | |
|  | **Limited Means/Resources** – resources needed to identify and contact eligible subjects for recruitment are limited. | | | | | | |
|  | **Large number of subject projected** – potential subject population includes a large number of records to review, and it is not feasible to attempt contact with all subjects. | | | | | | |
|  | **Outdated records** – this is a retrospective project involving subjects who may have moved or expired and researchers cannot feasibly attempt to contract required sample. | | | | | | |
|  | **Risk of breach of confidentiality** – the only record linking the subject, and the research would be the signed authorization, and a breach of confidentiality is the principal risk in the project (e.g., verbal consent to research). | | | | | | |
|  | **Other:** | | | [enter text here] | | | |
| 1. **Which institutions (or covered entities) maintain the records/health information you will be accessing?** | | | | | | | |
|  | **Cape Fear Valley Health System** – insert site/clinic/department below:  [enter text here] | | | | | | |
| 1. **Provide details of the information to be accessed, collected or disclosed without written authorization.** | | | | | | | |
| **3a** | | **Institution/Covered Entity** | | | **3b** | | **Type of materials being used**  *(List the type(s) of materials to be used, such as electronic medical records (e.g., EPIC), paper records, etc.)* |
| [Institution Name] | | | | | [enter text here] | | |
| **3c** | | **Nature of the Health Information**  *Provide a summary of the actual health information you will be accessing and/or collecting under this waiver/alteration* | | | | | |
| [for example “”current medications, treatment and medical history relating to hypertension”] | | | | | | | |
| **3d** | | **Will you assign a code(s) to allow the research team to link subjects to the health information listed above or collect other information allowing you to re-identify subjects?**  *Note: Keeping a SlicerDicer report in EPIC is considered directly identifiable information* | | | | | |
| **NO** | | | **Skip to Question 4** | | | | |
| **YES** | | | **Complete 3e, then answer 4** | | | | |
| **3e** | | **Identifiers Collected with Health Information**  *Using the 18 HIPAA identifiers below, select those collected* ***than can also be linked*** *to the health information in 3c.* | | | | | |
| Any unique identifying number, characteristic or code (e.g., assigned project code/number)  Names  Address  Dates (exempt year)  Ages over 89 (except those grouped as age 90 or older)  Phone numbers  E-mail addresses  Social security numbers\*  Medical record numbers | | | | | | Fax numbers  Account numbers  Certificate/license numbers  Health plan beneficiary numbers  Vehicle identifiers and serials numbers, or license plate numbers  Device identifiers and serial numbers  Web Universal Resource Locators (URLs)  Internet Protocol (IP) address numbers  Biometric Identifiers, including finder and voice prints  Full face photographic images and any comparable images. | |
| \*Pursuant to North Carolina law, social security numbers are not permitted to be collected in reliance on this waiver of authorization. Unless social security numbers are required by law to be collected, the research subject must be given a written disclosure which (i) states that providing social security number is not required; and (ii) describes the purpose for which the social security number will be used. | | | | | | | |

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| **Part 4: Protection Plan**  *Describe the plan to protect he identifiable health information and indicate where it will be stored and who will have access to it. Indicate all safeguards which will be used to protect identifiers to ensure minimal risk of improper use or disclosure of the subject’s identifiable information.* | | | | | |
| **4a** | **DURING ACCESS TO SOURCE RECORDS:**  **Describe the measure to project health information during the time the research will viewing health records.**   * *Select all that apply* | | | | |
|  | All HIPAA regulations as well as institutional privacy policies will be followed during the time the researcher have actual access to the source data (health records) | | | | |
|  | Information (paper and/or electronic) will be viewed in a private/secure area (i.e., medical records room, behind covered entity firewall, etc.) | | | | |
|  | Only personnel authorized by the covered entity will access health record data. These individuals are also approved to review PHI as part of the research project by the IRB. | | | | |
|  | **Other:** | | [enter text here] | | |
| **4b** | **RECORDED DATA:**  **Measures to protect recorded data:** | | | | |
| The information obtained will be stored in the following location: | | | | [on a password/(encrypted) protected spreadsheet and file located on a secured CFVHS server] | |
| Only personnel approved in this research project will have access to the recorded identifiable data | | | | *Check to confirm you understanding* | |
| The identifiable data collected will no be disclosed to persons outside of the covered entity unless: | | | | Required by law  Approved by the IRB as part of the protocol  Other: [explain here] | |
| The key to decipher the code/identifiers will be permanently destroyed a the earliest opportunity consistent with the conduct of the research which is *(select)* | | | | Upon completion of the project  After publication acceptance  Other: [explain here] | |
| **4c** | **DISCLOSURE OF DATA:**  **Protection measures while transmitting PHI (disclosing) from one covered entity to another location:**  Will you disclose the recorded identifiable information outside the covered entity?  *(i.e., identifiable health data sent to sponsor, etc.)* | | | | |
|  | | NO – this project is not collecting identifiable health information | | | |
|  | | NO – this project is not disclosing PHI collected under this waiver/alteration | | | |
|  | | YES – Describe steps taken to securely transmit identifiable health information (PHI) outside the covered entity. | | | [enter text here] |

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| **Part 5: Minimum Necessary**  HIPPA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. **Are you obtaining only the minimum information necessary to complete the waived activities?** | |
| YES |  |
| NO | [explain/justify why not here] |

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| **Part 6: Length of Time**  How long do you need access to PHI (without subject authorization) under this waiver?  *Note: this Waiver is effective beginning on the date is approved. You will only be permitted to access PHI beginning on the approval date and ending at the time you select below.* | |
|  | Upon completion of recruitment |
|  | Upon completion of subject participation |
|  | Upon completion of data collection and/or specimen processing |
|  | Upon completion of data analysis |
|  | Upon project publication acceptance |
|  | Upon FDA approval |
|  | Other: [enter text here] |
| Identifiers will be retained indefinitely because: | |
|  | The project is longitudinal |
|  | Federal requirements: [explain here] |
|  | Other: [enter text here] |