**BROWN UNIVERSITY**

**APPENDIX G**

**USE OF PROTECTED HEALTH INFORMATION (PHI) ACCESSED, USED OR DISCLOSED FROM A COVERED ENTITY**

Complete this form when the proposed research includes plans to access, use, or disclose [Protected Health Information (PHI)](https://www.brown.edu/research/hipaa-privacy-rule-guidance). The Privacy Rule permits several methods by which PHI may be used in research.

**Study Title:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text.

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| To use PHI in research you must have approval through one of the following methods:1. An authorization signed by the research participant which meets HIPAA requirements;
2. An IRB waiver of the HIPAA authorization requirement;
3. An IRB alteration of the HIPAA authorization requirement; or
4. Use of a limited data set under a data use agreement.

Check below to indicate which method of approval you are proposing:

|  |  |
| --- | --- |
| [ ]  | Research participants in this study will sign an Authorization to Use or Disclose Protected Health Information for Research Purposes. A [HIPAA Authorization](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates#Consents) (Authorization to Use Protected Health Information in Research) must be presented to the study participant for review and to provide permission for access to their PHI.  |
| [ ]  | IRB waiver of the authorization requirement [ ]  Partial Waiver (Recruitment only) [ ]  Full Waiver (Recruitment + Data Collection) |
| [ ]  | IRB alteration of the authorization requirement  [ ]  Alteration (Alter/remove some of the required elements of authorization as described in the Human Subjects Research Application).  |
| [ ]  | I will access a [Limited Data Set](https://www.brown.edu/research/glossary#L) by signing a data use agreement with the party that releases the PHI. An Authorization or documentation of a waiver or alteration of Authorization is not required for Brown / a researcher to receive a Limited Data Set when the data is accompanied by a [Data Use Agreement](https://www.brown.edu/research/glossary#dua). A limited data set must have all the identifiers listed below removed from the data. It is the responsibility of the researcher and the party releasing the PHI to have in place and maintain a copy of a data use agreement which meets HIPAA requirements. A copy of the data use agreement must be included with the IRB submission.  |

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| A. |

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| Provide information below about the PHI accessed in the research. Check all that apply: |
| [ ]  | Names | [ ]  | Medical Record numbers |
| [ ]  | Addresses (including any part of street address, city, state, or zip code) | [ ]  | Health plan beneficiary |
| [ ]  | Dates directly related to an individual (except year), please list: Enter text. | [ ]  | Device identifiers and serial numbers |
| [ ]  | Age information for those over 89 | [ ]  | Account numbers |
| [ ]  | Telephone and/or fax numbers | [ ]  | Certificate/license numbers |
| [ ]  | Email addresses | [ ]  | Biometric identifiers — including finger and voice prints. |
| [ ]  | Web URLs | [ ]  | Full face photographic images and any comparable images. |
| [ ]  | Internet protocol (IP) address numbers | [ ]  | Vehicle identifiers and serial numbers, including license plate numbers |
| [ ]  | Social Security Numbers | [ ]  | Any other unique identifying number, characteristic, or code (Describe below): |
| Enter unique identifiers. |
|  |

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| B. | The research could not practicably be conducted without access to and use of the PHI noted above **and** the research could **NOT** practicably be conducted without the waiver or alteration.[ ]  **Yes** [ ]  **No If you answered No, the study is not eligible for a waiver of the HIPAA authorization requirement.**  |
| C. | The use and disclosure of the PHI identified above involves no more that minimal risk to the privacy of individuals based on the presence of all of the following (please check each item to confirm): |
| [ ]  | a. An adequate plan to protect health information identifiers from improper use and disclosure. |
| [ ]  | b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so). |
| [ ]  | c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule. |
| [ ]  **Yes** [ ]  **No If you answered No, the study is not eligible for a waiver of the HIPAA authorization requirement.** |
| D. | Explain why a waiver or alteration (instead of written authorization) is needed to conduct the research.Click here to enter text. |