| The Health Insurance Portability and Accountability Act (HIPAA), along with its privacy regulations and other relevant statutes concerning the confidentiality of health data, regulate how Protected Health Information (PHI) can be used and shared by regulated entities for research activities. PHI represents a category of health information that is personally identifiable. For more details on PHI, refer to <https://irb.beyondbound.edu/submitting-to-the-irb/initial-studies/principal-investigator-eligibility-and-permissions.html>. Generally, HIPAA mandates that a covered entity must secure a research participant's written consent before the participant's PHI can be revealed in relation to the research. Nonetheless, Institutional Review Boards (IRBs) and Privacy Boards are empowered to issue exemptions or modifications to the HIPAA consent requirement, with HIPAA outlining further exceptions to this consent necessity.  Should your research involve the use of Protected Health Information (PHI), it is imperative that this Appendix provides a detailed account of the specific PHI data you intend to access, the origin of this data, and the specific HIPAA guidelines under which you will be accessing the data. |
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**1. Identify every covered entity from which Protected Health Information (PHI) will be acquired.**

**2. A covered entity is permitted to utilize or share PHI for research purposes if the activity is in compliance with HIPAA regulations. Please specify the approach(es) you are employing to request access to PHI for your project:**

☐ Use or disclosure of PHI for research with the authorization of research participants.

NOTE: The consent form template on the IRB website includes HIPAA Authorization language (refer to Consent Template with HIPAA Authorization, HRP-1721).

☐ Authorization from participants with modifications to the use or disclosure.

☐ Complete exemption from participant authorization (commonly applied in research involving the analysis of secondary data).

☐ Conditional exemption of HIPAA Authorization to collect only the contact details of potential research participants for the purpose of recruitment.

☐ Utilization of a limited data set under a data use agreement.

(A Limited Data Set is a form of PHI that does not include 16 types of direct identifiers, which can be used or disclosed for research, public health, or healthcare operations without an individual's Authorization or without needing to obtain a waiver or modification of Authorization, provided a data use agreement is in place.)

☐ Research involving only the information of deceased individuals.

☐ Data received by the research team will be anonymized in accordance with HIPAA’s standards for de-identification. (This option should not be selected if de-identification will be conducted by a member of the research team. For more information on HIPAA’s criteria for de-identified data, refer to the NIH Publication, "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule").

**3. Detail the elements within the PHI data set that you intend to examine, including all 18 identifiers as defined by HIPAA and any additional variables incorporated in the PHI analysis.**

**4. Outline the measures you will take to safeguard HIPAA identifiers (for example, names, patient numbers, birthdates) against unauthorized access or disclosure.**

**5. Describe your strategy for eliminating individual identifiers as soon as it is feasible in the context of the research project. If you intend to keep the identifiers, provide a justification for their retention.**

A full exemption from HIPAA Authorization is frequently sought for studies that analyze secondary data, in which case the Institutional Review Board (IRB) may also dispense with the need for consent. A limited exemption of HIPAA Authorization is appropriate when the research team intends to acquire a roster of patients who fulfill specific eligibility criteria, as well as their contact details for the purpose of contacting potential participants about joining the study. In this scenario, the research team will not examine any additional PHI beyond that necessary for contacting potential participants, nor will those who decide to participate be asked to provide HIPAA Authorization afterward.

**6. If you are seeking either a limited or full exemption from HIPAA Authorization:**

A. Justify why the study could not feasibly be carried out without the ability to access or use PHI.

B. Provide reasons why the study could not feasibly be conducted without an exemption from Authorization.

NOTE: By seeking either a complete or partial exemption from the HIPAA authorization prerequisite, you are affirming to the Institutional Review Board (IRB) that the identifiers being requested will solely be utilized for the stated research purposes and will not be shared with any individuals or entities outside of the research team members identified in this application, except as mandated by law or for approved supervision of the research project.