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

**Instructions:** Complete and attach this supplement to your research plan if (a) you are **conducting** research at a HIPAA covered component at the University of Oregon, or (b) a HIPAA covered entity or if you will be **accessing** “Protected Health Information.”

* This appendix is a part of the Research Plan and must be included with each Research Plan submission.
* Respond to every question on this application. Incomplete applications will be returned, and will result in a delay of your study being reviewed.

Save this form to your computer before proceeding.

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| 1. General Information | |
| **Principal Investigator:** | **Version Date:** |
| **Faculty Advisor:** | **Protocol Number:** |
| **Study Title:** | |

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| 1. Definitions |
| * The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. |
| * ***Protected Health Information (PHI)***: Individually identifiable health information held by a health care provider or health plan covered by HIPAA (e.g., University of Oregon’s Health Center, Counseling and Testing Center, etc.). * In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. Research Use/Disclosure without Authorization. |

| 1. Protected Health Information (PHI) |
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| **Describe the PHI and how it will be obtained for this research**: |
| * Complete the applicable sections below. If not applicable, check "N/A". |

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| Part III: HIPAA Authorization  N/A |
| A Privacy Rule Authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. Please complete this section if an Authorization will be obtained from individuals for use and/or disclosure of their PHI. |
| **Authorization will be obtained** |
| Researchers requesting HIPAA Authorization can either include language in their regular informed consent form or can include a separate authorization form during the consent process. In either scenario, HIPAA Authorization must be written in plain language and include 6 core elements and three required statements.  Additional information and an Authorization Template can be found at the Research Compliance Services website.  Please attach a copy of the Authorization that will be used for this research to your submission. |

| 1. Waiver Request  N/A | | | | |
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| The HIPAA Privacy Standard at 45 CFR 164.512(i) requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Protected Health Information. In addition to these criteria, the federal Common Rule (45 CFR 46 section 116(d)) stipulates that “whenever appropriate, the subjects will be provided with additional pertinent information after participation.”  This request is for (chose one): | | | | |
| **Total Waiver** | | | | |
| When you request a total waiver of the HIPAA Authorization, you are requesting permission to access, use or disclose a research subject’s PHI for your research study without seeking the subject specific authorization for that use or disclosure. | | | | |
| **Partial Waiver** | | | | |
| When a partial waiver is requested, you may request that certain required elements of the HIPAA authorization be altered or that the HIPAA authorization be waived for a portion of the study. [For instance, you may request a waiver for subject identification or recruitment purposes but not for enrollment purposes. For example, you may request a waiver of the HIPAA authorization requirement so that a treating physician may obtain verbal permission from the patient/parent so that the physician can notify the study coordinator of the patient’s/parent’s interest in the study. Once the study coordinator has discussed the study with the interested patient and parent, they will consent the participant and parent and obtain a full authorization.] | | | | |
| **Specify what you are requesting the waiver (total or partial) for**: | | | | |
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| * 1. Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of the individual? Indicate whether the research meets the following criteria: | | | | |
|  | Yes  No | * + 1. There is a plan to protect the identifiers from improper use and disclosure (e.g., encryption of electronic files, other confidentiality procedures etc.). | | |
|  | Yes  No | * + 1. There is a plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law. | | |
|  | Yes  No | * + 1. Adequate written assurances that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted can be provided (e.g., agreement with covered entity for disclosure of PHI, etc.). | | |
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| * 1. Describe the plan to protect the identifiers (names, addresses, telephone numbers, social security numbers, medical record numbers, photos, and other identifying information etc.) from improper use and disclosure? | | | | |
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| * 1. Describe the plan to destroy the identifiers at the earliest opportunity, or provide justification for retaining the identifiers? | | | | |
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| * 1. Will a waiver adversely affect the privacy rights of the individual? | | | | |
|  | Yes  No | If "No", please explain: | | |
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| * 1. Could the research be practicably done without the waiver? | | | | |
|  | Yes  No | If "No", please explain: | | |
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| * 1. Could the research practicably be done without access to, use or disclosure of the PHI identified below? | | | | |
|  | Yes  No | If "No", please explain: | | |
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| * 1. Please identify the PHI that will be used under this waiver request. | | | | |
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| * 1. Are the privacy risks to individuals whose PHI will be used or disclosed reasonable in relation to the anticipated benefit, if any, to the individuals? | | | | |
|  | Yes  No | Describe the risk/benefit analysis relating to the waiver request: | | |
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| * 1. Will the Principal Investigator be the only member of the research team who will access, use or disclose PHI? | | | | |
|  | Yes  No | If "No", name all of the individuals who will have access to PHI during the research study, including students. | | |
|  | **Name** | | **Job Description/Role in Study** |  |
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| 1. Limited Data Set  N/A |
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| A covered entity is permitted to use or disclose PHI for research purposes if it provides a *limited data set* and enters into a data use agreement with the recipient.  Please complete this section if the PHI used or disclosed for this research is a part of a limited data set and will be or is covered by a data use agreement. |
| **The PHI used or disclosed for this research is/will be a part of a limited data set** |
| A *limited data set* is protected health information from which direct identifiers have been removed that may be used and disclosed for research purposes pursuant to a data use agreement.  Please attach a copy of the data use agreement that will be applied to this limited data set to your submission. |