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| The purpose of this checklist is to provide support for the Privacy Board Member designated to conduct Privacy Board Reviews to document a waiver or alteration of HIPAA authorization. This checklist or equivalent is to be used. This checklist or equivalent needs to be retained. | | | | | | |
| **IRB Number:** | | |  | | | |
| **Protocol Name:** | | |  | | | |
| **Investigator:** | | |  | | | |
|  | | | | | | |
| 1. DOCUMENTATION OF WAIVER APPROVAL (Check if “Yes”. All must be checked) | | | | | | |
|  | A description of the PHI to be accessed or used has been reviewed and the PHI to be accessed or used is the minimum necessary to meet the aims of the research. | | | | | |
|  | The procedures required to meet any conditions placed on the waiver are described in the protocol. | | | | | |
|  | The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:(Check if **“Yes”**. All must be checked) | | | | | |
|  | An adequate plan to protect the identifiers from improper use and disclosure. | | | | |
|  | An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. | | | | |
|  | Adequate written assurances that the protected health information will not be reused or disclosed to 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 protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512. | | | | |
|  | The research could **NOT** practicably be conducted without the waiver or alteration. | | | | | |
|  | The research could **NOT** practicably be conducted without access to and use of the protected health information. | | | | | |
| 1. REVIEW PROCESS (Select one) | | | | | | |
|  | Review was conducted using the Expedited Procedure. | | | | | |
|  | Review was conducted at a Fully Convened meeting. | | | | | |
| 1. DETERMINATION (Select one) | | | | | | |
|  | Approval of a Waiver of HIPAA Authorization | | | | | |
|  | Approval of an Alteration/Partial Waiver of HIPAA Authorization (Selection one) | | | | | |
|  |  | For Recruitment Purposes Only | | | | |
|  |  | Other: | | | | |
|  | | | | | | |
| The IRB Chair or designated privacy board member signing below has determined that the above requirements are met, access to the protected health information described in the protocol is necessary, and waived or altered the requirement for authorization. | | | | | | |
| Chair or Designee Signature: | | | |  | Date: |  |