|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| The purpose of this checklist is to provide support for the HIPAA Research Privacy Officer and/or their designee to document a waiver or alteration of HIPAA authorization. This checklist will be uploaded in the HIPAA Concurrent Compliance Review activity. The Chair, Vice Chair and/or convened IRB reviews the checklist to confirm the criteria have been met. The IRB Office retains this checklist in the protocol file. | | | | |
| **IRB Number:** | | | |  |
|  | | | | |
| 1. SCOPE (Check all that apply) | | | | |
|  | Waiver of HIPAA authorization for recruitment | | | |
|  | Waiver of HIPAA authorization for conduct of study | | | |
|  | Alteration of HIPAA authorization to not require signature of the individual and date (e.g. verbal) | | | |
|  | Alteration of HIPAA authorization (include specifics of alteration below in “Notes” section; refer to HRP-330 - WORKSHEET - HIPAA Authorization) | | | |
| 1. DOCUMENTATION OF WAIVER OR ALTERATION APPROVAL (Check if “Yes”. All must be checked.) | | | | |
|  | | The description of the PHI that will be used and/or obtained is included in the protocol summary and is necessary for the research. | | |
|  | | The use or disclosure of PHI 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 PHI 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 PHI 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 PHI. | | |
|  | | | | |
| **Notes:** | | | | |