**HRP-441 - Checklist - HIPAA Waiver of Authorization**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study ID: | | | PI: | |
| Covered Entity: | | | | |
| Alteration to the individual authorization  Waiver of the individual authorization  ***Note: all responses below must be “yes” to approve the alteration or waiver of authorization.*** | | | | |
| Specific individual health information that is needed: | | | | |
| Yes  No | Involves **no more than minimal risk to privacy** of subjects (PHI subjects) | | | |
| Yes  No | Plan to protect the identifiers from improper use and disclosure is adequate. | | | |
| *If “No”, changes required:* |  | | | |
| Yes  No | 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. | | | |
| *If “No”, Changes required:* |  | | | |
| Yes  No | 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 protected health information would be permitted by law. | | | |
| *If “No”, Changes required:* |  | | | |
| Yes  No | The research could not practicably be conducted without the waiver or alteration. | | | |
| Yes  No | The research could not practicably be conducted without access to and use of the PHI. | | | |
| **Review Procedures:** *The alteration or waiver of authorization has been reviewed and approved under either normal or expedited procedures:* | | | | |
| *Expedited*  *Normal* | | | *Date of meeting:* | |
| *Date approval letter sent to IRB:* | | | | |
| Date of approval: | | Signature: | | Name: |
| Comments: | | | | |