Guidance on Completion of Request for Waiver/Alteration of HIPAA Authorization

This document is intended to be guidance for waivers/alterations of HIPAA authorization that will allow for potential identification of subjects. A waiver/alteration of authorization must be approved by CGIRB ***prior*** to the collection, use, and disclosure of PHI when the information is used preparatory to research or in conjunction with waiver or alteration of informed consent. Requests for waivers are not required if the covered entity and investigator are one and the same when used preparatory to research.

CGIRB does not require a Waiver/Alteration of HIPAA Authorization Form or Non-covered Entity Statement for certain subject recruitment activities including, but not limited to, telephone scripts, call center materials/activities, and "dear patient letters."

CGIRB has confirmed with the Office for Civil Rights, the official enforcement agency for all HIPAA-related issues, that this policy is appropriate.

In general, a covered entity's site-specific Privacy Notice is not sufficient for the specifics requested in the Waiver/Alteration of HIPAA Authorization form. Please refer to 45 CFR 164.512(i)(2) for the federal requirements regarding documentation of waiver approval.

Please keep the below information in mind when completing a Waiver/Alteration of HIPAA Authorization form for CGIRB:

PAGE 1:

To be Completed by Covered Entity or Party to Whom Disclosure is Being Made

"Protocol # and Title" box

- Please ensure that this is filled with not just the protocol number, but also the actual study title in text.

"Provide a description of the PHI for which use or access has been determined to be necessary and how it will be extracted and used."

- This section needs to be completed keeping in mind what the specific identifiers are and how they are being obtained.
- Specific PHI preferred to be written out includes (but is not limited to) name, telephone number, address, and Social Security Number.
- Regarding medical PHI, allowance for generalization is accepted. Example. "In addition to the listed PHI, potential subject's medical/surgical/medication history is reviewed in regards to the inclusion and exclusion criteria of the above-referenced study." This language acknowledges that the PHI is study-specific.

PAGE 2:

To be Completed by Covered Entity or Party to Whom Disclosure is Being Made

Check the appropriate boxes as indicated on the page.

Section (a) "An adequate plan to protect the identifiers from improper use and disclosure"

- **#1:** Indicate who exactly will have access to the PHI. Check boxes of applicable study staff and list additional titles if "Other Site Staff" is checked.
- **#2:** If the screening documentation will be kept in hard copy form, you must indicate whether the access is limited *and* document where exactly the documentation will be kept.
- **#3**: If PHI will be entered into a database, indicate if is there is password protection and specify who exactly has access to the database.
- **#4**: Specify any additional plans to protect PHI from improper use/disclosure. If there aren't any additional plans, list "none", "N/A", or leave blank.

Section (b) "An adequate plan to destroy the identifiers..."

- **#1:** If a potential subject's PHI does not become part of the source document when enrolled into the study, you must specify what happens to this PHI.
- **#2:** If Yes, please be aware that you can only the retain information listed as necessary PHI on page 1 and that the identifiers should be protected as outlined in section (a) on page 2.
- **#3:** Check all boxes that apply to destroying the identifiers for ineligible subjects who did not give their permission for the PHI to be retained.

PAGE 3:

The page must be signed and dated.

Note: An additional page may be attached if necessary to complete the waiver/alteration of HIPAA Authorization Form.