HIPAA Procedure 5039 PR.1
De-Identification and Limited Data Set Procedures
Revision Date: 10/26/2017

De-Identification and Limited Data Set Procedures

The following procedures are to be followed in accordance with the Yale Policy 5039 on Use and Disclosure of De-Identified Information and of Limited Data Sets.

Safe Harbor De-Identification Procedure:

- It is the responsibility of the holder of PHI (e.g., investigator, clinical site) to de-identify information so that all identifiers are removed in accordance with Form 5039 - De-Identification Checklist.
- Unless de-identifying material permanently for archival purposes, an unredacted version of the information should be maintained at all times. Information on paper should therefore be copied BEFORE it is redacted, and ONLY THE COPIES should be redacted. Likewise, electronic information and information in other media should not be redacted in any permanent way.
- The holder of PHI (e.g., investigator, clinical site) must confirm that each of the items in the De-Identification list (Exhibit 5039, ExA) has been removed from the de-identified data set prior to distribution.

Statistical De-Identification Procedure:

- If it is not possible or practical to meet the de-identification safe harbor, the holder of PHI (e.g., investigator, clinical site) may wish to de-identify data by using a qualified statistician.
- The holder of PHI must obtain from the statistician written documentation of the methods and results of the analysis that justify a determination that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information. The documentation should be filed with the original copies of the information in a secure location. If the information is in electronic form or consists of biological materials, the documentation should be filed in the PHI holder's files in a secure location. Guidance on de-identification is available at http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

Limited Data Set Procedure:

- It is the responsibility of the holder of PHI (e.g., investigator, clinical site) to remove identifiers from information in accordance with Form 5039 - Limited Data Set Checklist.
- Information on paper should be copied BEFORE it is redacted, and ONLY THE COPIES should be redacted. Likewise, electronic information and information in other media should not be redacted in any permanent way.
- The holder of PHI (e.g., investigator, clinical site) must confirm that each of the items in the Limited Data Set list (Exhibit 5039, Ex. B) has been removed from the limited data set prior to distribution.
- Before using or disclosing a limited data set, a Data Use Agreement must be signed by Yale, the holder of the PHI, and the recipient. Contact the appropriate Office of Sponsored Projects, which administers the negotiation and signing of Data Use Agreements.