HIPAA Procedure 5039 PR.1
De-Identification and Limited Data Set Procedures
Revision Date: 1/30/03

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) 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) must check each of the boxes on the De-Identification Checklist, sign the statement at the bottom, and file the signed checklist with the original copies of the information in a secure location. The holder of PHI must sign the Checklist himself or herself; proxy signatures are not allowed. If the information is in electronic form or consists of biological materials, the signed De-Identification Checklist should be filed in the PHI holder's files in a secure location.

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) may wish to de-identify data by using a qualified statistician. For the name and contact information of a qualified statistician, please contact Yale Privacy Officer or designee.
- 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.

Limited Data Set Procedure:

- It is the responsibility of the holder of PHI (e.g., investigator) 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) must check each of the boxes on the Limited Data Set Checklist, sign the statement at the bottom, and file the signed checklist with the original copies of the information in a secure location. The holder of PHI must sign the Checklist himself or herself; proxy signatures are not allowed. If the information is in electronic form or consists of biological materials, the signed Form 5039 - Limited Data Set Checklist should be filed in the PHI holder's files in a secure location.
- 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 Grant and Contract Administration, which administers the negotiation and signing of Data Use Agreements.