

Revised Template: For the Confidentiality Section of the Consent Form

CONFIDENTIALITY:

1. Provide a statement explaining how individual identifiers will be used in maintaining the research records (i.e., research record labeled with subject's name or research records labeled with a code number. A master key that links the name and code number will be maintained in a separate and secure location).
2. Insert HIPAA authorization portion in confidentiality section. (refer to HIPAA authorization language template)
3. If the study involves the use of a federal Certificate of Confidentiality, provide the information about the certificate and how it protects subject information from re-disclosure. *(Example: To further help protect your privacy, the investigators have obtained a confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). With this federal Certificate, the investigators cannot be forced (i.e., court order) to disclose information that may identify you in any federal, state or local court. However, disclosure is necessary upon the request of the DHHS (i.e., for audit or program evaluation).*
4. If information about the subject's participation in the study or the results of procedures performed in the study will be placed in the subject's medical record (as contrasted with research record), then it should be specified.
5. Specify that the individual subjects will not be identified in any presentations or publications based on the results of the research study.