

Sample: Guidelines for Using HIPAA Authorization Text As an Addendum to Informed Consent Forms

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The Confidentiality and Right to Withdraw sections for an informed consent form have been modified to include the new information regarding authorization of use of health information required by HIPAA (Health Insurance Portability and Accountability Act of 1996) as provided in 45 CFR Parts 160 and 164. The modified text can be found in the document *Sample: Confidentiality and Use and Disclosure of Health Information for Research Purposes*. If needed, this text may be provided as an “addendum” to a sponsor supplied informed consent form template.

The following summarizes the HIPAA requirements regarding the information that must (or is recommended to) be included when obtaining the patient’s “authorization of the use and disclosure of personal health information” (referred to below as “the Authorization”).

1. The authorization language found in the document *Confidentiality and Use and Disclosure of Health Information for Research Purposes* is intended to replace the Confidentiality and Right to Withdraw sections of an informed consent form. If a stand-alone authorization for research is required, please use the document entitled *Sample: Authorization for Use and Disclosure of Health Information for Research Purposes*.
2. The title of the combined informed consent form and authorization document should be changed to **"Informed Consent and Authorization for Use and Disclosure of Health Information for Research Purposes."**
3. ***A copy of the signed Authorization must be provided to the research participant.***
4. Obtaining the Authorization is the responsibility of the **covered entity**, i.e., the health care provider (principle investigator and investigator site), pursuant to the requirements of the final HIPAA privacy regulation. The Authorization is required to be obtained from a research participant enrolled in a research study or “re-consented” after April 14, 2003, unless an IRB or internal privacy board issues a waiver of authorization.

Sponsors and CROs are not covered entities or business associates under HIPAA; therefore an investigator site, which may also be a covered entity, should not expect CRO or the sponsor to sign a Business Associate Agreement. On the other hand, if a covered entity fails to obtain a valid authorization for research from the study subject, that entity may refuse to disclose the information to the CRO or sponsor. CRO monitors will be confirming that there is a signed authorization (separate or combined with the informed consent form) and that CRO and the Sponsor are included as authorized “Receivers” of the health information.

5. The Authorization should be in “plain” language (e.g. 8th grade reading level). Note that the document should always say "health information about you" and not "your health information" to avoid setting up an idea of ownership in the information.
6. The Authorization should list the names of the entities or classes of persons receiving the health information; for example, name of sponsor of the research, name of the clinical research organization and the classes of the work force such as the study monitor, auditor, project manager, central laboratory, and regulatory and other legal authorities.

7. The Authorization should describe in detail the health information to be used and disclosed. This should include details about laboratory tests that will be used, text should be specific but profiled to a reasonable extent (to keep it simple for the patient). For example, “blood tests” could be used instead of listing “hematology, CBC, WBC, etc.”. ***Any genetic related testing should be listed.***
8. The Authorization should list the specific research purposes for use and disclosure; i.e., that the health information that identifies the research participant will be used for medical, statistical, and regulatory purposes related to the research.
9. The Authorization should include an expiration date. The phrases “no expiration date” (**recommended**), or “end of study” can be used.
10. The Authorization can be revoked by the patient at any time, but the revocation must be received in writing. The Authorization should include the name of the responsible individual at the site (the “privacy officer” if one exists) to whom the patient should address his/her revocation, and the mailing address. The site’s email address can be included, but as a patient may not have email access, the mailing address should always be listed.
11. HIPAA requirements apply only to “covered entities”, so a statement that once the covered entity discloses a patient’s health information, “the information may no longer be covered by the federal or state privacy regulations”, is included. Note, however, in most Clinical Trial Agreements and Informed Consents, there are provisions for protection of confidential information (including the research participants’ health information) by the Researchers and CRO / Sponsor.
12. The signature information at the end of this document is not intended to be included in the Confidentiality and Withdraw sections of the informed consent form– it should be used to replace whatever existing signature information appears on the informed consent form.

Note: This signature block is a minimum requirement. Sites may be required to add signatures for their respective institutions. The additions of those signatures is appropriate.

Note: The term “personal” representative encompasses “legal” representatives.