Final Rule Revisions: Understanding Broad Consent

Overview

Broad consent may be obtained in lieu of informed consent obtained in accordance with the basic and additional elements of consent, but only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. This is not a waiver, but an alternative.

Under the Final Rule, broad consent is permissible only for storage, maintenance, and secondary research. Institutional Review Boards (IRBs) are not permitted to omit or alter any of the required broad consent elements because each element is considered essential.

The Final Rule allows broad consent for either a specific type of specified future research (for example, prostate cancer research) or a broader scope of research (for example, any biomedical research).

The Final Rule did not contain any templates for broad consent forms. Institutions and investigators may develop their own to satisfy the required conditions.

The usefulness and ethics of broad consent remains to be further explained in guidance.

Subjects' Refusal Means No

Broad consent will provide subjects with a choice to say no to storage, maintenance, and secondary research.

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the use of identifiable private information or identifiable biospecimens.

It is not clear yet if investigators are allowed to ask subjects again if they refused to consent.

Broad Consent and Health Insurance Portability and Accountability Act (HIPAA)

In January 2013, the Office for Civil Rights modified its prior interpretation that HIPAA authorizations for research needed to be study-specific, and therefore, that such authorizations could not permit certain future unspecified research.

Under the new interpretation, an authorization now may be obtained from an individual for uses and disclosures of protected health information for future research purposes, so long as the HIPAA authorization adequately describes the future research such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for the future research purposes.

Broad Consent & Exempt Research

Category 7 (46.104[d][7])

For storage or maintenance for secondary research for which broad consent is obtained per exempt category 7, the Final Rule requires that:

- Limited IRB review must make determinations required by 46.111(a)(8), which are:
  - Broad consent is obtained.
  - Broad consent is documented.
  - If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy and maintain confidentiality.

Category 8 (46.104[d][8])

For secondary research for which broad consent is obtained per exempt category 8, several criteria must be met. Limited IRB review must make determinations by 46.111(a)(7), which are:

- Broad consent must be obtained and documented.
- Limited IRB review must determine that the research is within the scope of the broad consent.
- Investigator does not include returning individual research results to subjects as part of the study plan.

Broad Consent & Non-Exempt Research

For non-exempt research, the IRB must determine if:

- Description of research in the consent form meets the reasonable person standard to explain the secondary research.
- Elements of broad consent are included per 46.116(d).

Are Investigators Required to Use Broad Consent?

Investigators are never required to obtain informed consent through a broad consent process; it is an available optional procedure.

Instead of obtaining broad consent, an investigator may choose the following:

1) Conducting the research on non-identifiable information and non-identifiable biospecimens, and request that the IRB waive the requirement for additional prospective informed consent; or

2) Obtaining consent for a specific study.

Even if the investigator wanted to use the biospecimens with identifiers attached, the option still exists of asking an IRB to waive the requirement to obtain additional prospective informed consent instead of using broad consent.

Highlights of 46.116(d) Broad Consent

46.116(d)(1)	Requires some basic elements, namely: • *Risks* • *Benefits* • *Confidentiality* • *Voluntary statement* • *Commercial profit (when appropriate)* • *Whole genome sequencing (when appropriate)*
46.116(d)(2)	Requires a general description of the types of research that may be conducted. The IRB must assess whether the description of the research included in the broad consent form is adequate to permit a reasonable person to provide consent for the currently proposed secondary research study.
46.116(d)(3)	Requires a description of the information or biospecimens that might be used in future research; whether sharing might occur; and the types of institutions or researchers that might conduct research.
46.116(d)(4)	Requires a description of the length of time that the information or biospecimens may be stored, maintained, and used.
46.116(d)(5)	Requires a statement whether subjects will or will not be informed of the details of any subsequent research.
46.116(d)(6)	Requires a statement that research results either will or will not be disclosed to subjects.
46.116(d)(7)	Requires contact information to be provided in the broad consent.