

Final Rule Revisions to Informed Consent

Overview of Major Changes

- 1) **New process requirements** for the content, organization, and presentation of information and the process to facilitate a prospective subject's decision about whether to participate in research.
- 2) **New requirements** for the basic and additional elements of consent.
- 3) **Electronic consent is allowed**, but must provide written copy.
- 4) **New broad consent** elements for the storage, maintenance, or secondary research use of identifiable private information and identifiable biospecimens.
- 5) **Changes in the waiver and alteration criteria** for consent.
- 6) **New consent provision** that allows Institutional Review Boards (IRBs) to approve a research proposal for which investigators obtain information or biospecimens without individuals' informed consent for the purpose of screening, recruiting, or determining the eligibility of prospective human subjects, provided certain conditions are met.
- 7) **New requirement to post**, to a federal website, a copy of an IRB-approved version of the consent form that was used for enrollment purposes for each clinical trial conducted or supported by a federal department or agency.



New Requirement for Informed Consent Form Language

Added at 46.116(b)(9) is a new requirement to include one of two statements about the collection of private information or identifiable biospecimens for future research:

- *Identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject.*
- *The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.*

Additional Elements of Informed Consent 46.116(c) - Three New Requirements

In 46.116(c), there are no changes to the six previous elements, but three new requirements have been added. The information that would have to be disclosed under these additional elements of consent is, according to public comment on the Notice of Proposed Rulemaking (NPRM), “often relevant to the decision of whether to participate in a research study.”

NEW

46.116(c)(7) requires a statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

NEW

46.116(c)(8) requires a statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.

NEW

46.116(c)(9) requires a statement about whether the research project might include whole genome sequencing (the sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).