

Revised Common Rule Changes to Informed Consent and Waiver Requirements

New Informed Consent Elements

Required for all expedited and full Board studies governed by the new Common Rule that include a consent form. (Elements may be waived under previous consent waiver criteria)

- Consent documents require a concise summary of study activities, risks, and benefits presented to research participants in advance of the body of the consent document. The consent process should include a focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research.

Required for all studies that collect identifiable private information or identifiable biospecimens

- One of two statements about the collection of private information or identifiable biospecimens for future research (either that identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject; or, that the subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.
 - This refers to use of subjects' de-identified data/specimens for secondary or downstream research studies
 - The template language that will be included in the UNC consent documents is that investigators may share de-identified information or biospecimens for future research without additional informed consent from the subject.

Required when appropriate to the study

- A statement that the subject's 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.
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- For research that may involve genetic testing, whether the research will (or might) include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Other consent changes

- In requests for a full waiver of informed consent when using identifiable data and specimens, the IRB must now find that it would be impracticable to rather use de-identified data. (NOTE: this element already live in IRBIS).
- A waiver of documentation of informed consent (i.e. waiver of *signed* consent) is no longer required for the following screening activities:
 - information obtained through oral or written communication with the prospective subject or legally authorized representative
 - e.g. telephone survey

- identifiable private information or identifiable biospecimens obtained by accessing records or stored identifiable biospecimens
 - e.g. screening of administrative data to determine eligibility prior to potential subject contact
- There is a new condition for granting a waiver of signed consent
 - If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.