New Human Subjects Regulations

Informed Consent

09.03.2018

A template that meets the new requirements is available here:
https://www.umassmed.edu/ccts/irb/forms_templates/

The new template combines the consent and HIPAA authorization into one document (with a 6-year data retention requirement).

NEW REQUIREMENTS

- Provide the information a reasonable person would want to know, creating the opportunity to discuss that information
- Begin with a concise and focused presentation of key information most likely to aid in understanding why someone might or might not want to participate (e.g., research, voluntary, purpose, duration, procedures, risks, benefits, alternatives)
- Indicate whether clinically relevant research results - including at the individual level - will be disclosed, and if so, under what conditions
- If research involves collection of identifiable private information or identifiable biospecimens:
    - Include a statement that identifiers might be removed and material shared or used in future research without additional consent
    - or that no sharing or use in future research will occur even if identifiers are removed
- If collecting biospecimens:
    - And if a possibility: include a statement that specimens (even if identifiers are removed) may be used for commercial profit & whether subjects will share in the profits
    - indicate whether research will (if known) 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)

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CONSENT FORM SIGNATURE

- Documentation of consent in writing is expected for research that involves sharing of identifiable information or identifiable biospecimens.
- IRBs can now waive written documentation of consent if research participants are members of a distinct cultural group or community in which signing forms is not the norm, the research is minimal risk, and there is an alternative mechanism for documenting that informed consent was obtained.

ELECTRONIC CONSENT

- Electronic consent satisfies a requirement to document consent in writing.
- FDA has two guidance documents for those considering electronic consent:
    - Use of Electronic Information Consent Questions and Answers, December 2016 (https://www.fda.gov/downloads/drugs/guidances/ucm436811.pdf)
    - Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions and Answers, June 2017 (https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm563785.pdf)

SHORT FORM CHANGES

- Short forms – which may apply when obtaining consent from individuals with limited English proficiency – must state that key information was presented first before other information.
- Revised UMMS short forms are pending.
- Use the existing short forms for now
    - If research is not federally funded
    - If research is federally funded and approved before the effective date.
- Submit new short forms with your research if the research is federally funded and approved on or after the January 21, 2019, effective date.

USE AN ADDENDUM TO RECONSENT

- If you need to reconsent research participants, use a consent addendum that includes just the new information.
- A consent addendum is easier for research participants to understand, and it fits easily with the old and new regulations.

See also
ADDITIONAL REQUIREMENTS FOR FEDERALLY-FUNDED RESEARCH
Consent Language for Certificates of Confidentiality
Consent Form Posting Requirements