Overview of Changes to Informed Consent under the Revised Common Rule

Additional Required Elements of Informed Consent

Required for All Research: Informed consent documents must now include a statement regarding the future use of data, where the investigator must explain that either data may be de-identified and retained for additional or subsequent research or, if not applicable, that the data collected will not be distributed for future research, even with the identifiers removed.

Required for Biomedical/Clinical Research: If your study is biomedical in nature, rather than being a social, behavioral or educational research study, and involves a clinical trial your informed consent document will need to include informed consent document. These include: identifying and describing experimental procedures and statements related to the commercial use of biospecimens, the disclosure to subjects of clinically relevant research results, and whether the research might or will include whole genome sequencing.

Waiver of Informed Consent Criteria

1. A new criterion for the waiver of or alteration to informed consent has been added.

- The research could not practicably be carried out without the waiver
- The research involves no more than minimal risk to the subjects
- The waiver will not adversely affect the rights and welfare of the subjects
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- **NEW:** If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

2. An additional category for waiver of documented informed consent has been added.

- The consent document would provide the only link to the subject and the principal risk of the research would be a breach of confidentiality
- The risk to the subjects is minimal and consent would not be required outside the research context
- **NEW:** The subjects or LARs (Legally Authorized Representatives) are members of a distinct cultural group or community in which signing forms is not the norm,

the research presents no more than minimal risk of harm to subjects, *and there is an appropriate alternative mechanism for documenting that informed consent was obtained.*

Presentation of Key Information and Other Important Information

1. Informed consent forms must begin with a concise and 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. Please see Elements of Informed Consent Document for an overview.

2.E-signatures are permissible

- This does not mean one's name has been typed on the form. The electronic system must include a method to ensure that the person electronically signing the informed consent is the subject or LAR him/herself.

- If verification of signature is not possible, you must request a waiver of documented informed consent.

3. The subject must be provided with a physical copy of the informed consent form

Obtaining a physical copy could include the participant printing out the informed consent. The ability to print the consent would need to be verified by the investigator.