UNIVERSITY of NORTH CAROLINA WILMINGTON

Research Integrity Office

Revised Common Rule Guidance

Changes in Informed Consent Requirements

Questions? Email: IRB@uncw.edu

Although the basic elements for informed consent will not change in the revised Common Rule, there are a few concepts that are entirely new. Also, other "new" requirements in the regulations will seem familiar to researchers, as UNCW's IRB has always considered them to be best practice and has encouraged researchers to incorporate them into study methods. Following is a summary of some of the changes in the Informed Consent sections of the revised Common Rule that are most likely to be of interest to UNCW researchers who plan to conduct research that requires use of the standard consent process (an informed consent form signed by the subject).

But first, it is important to note that many studies conducted at UNCW qualify for exemption and therefore can take advantage of more abbreviated consent language and an alteration of the standard process. The following requirements apply to studies reviewed at the expedited and full board level, or studies that qualify for exemption but still necessitate a standard consent process. Additionally, the IRB will continue to have the authority to consider requests to omit or alter some or all elements of informed consent provided certain requirements are met and the request is appropriately justified.

Please note that as we refer to "informed consent" throughout this document, it encompasses the assent-permission process required for studies involving minors (under age 18).

Familiar Concepts that Have Been Formally Included in the Regulations:

- The investigator must provide prospective subjects with the information that a **reasonable person would want to have** in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- Informed consent as a whole must present information in sufficient detail and must be **organized in a way that helps the subject or legally authorized representative (LAR) understand** why one might or might not want to participate, rather than just providing a list of isolated facts.
- The regulations now specifically authorize the IRB to approve a waiver of the signature requirement on informed consent **when subjects are members of a distinct community in which signing forms is not the norm**, provided the study is minimal risk and if alternative methods of documenting consent are used. (The UNCW IRB has always considered requests to waive the signature requirement for a variety of circumstances when conditions for a waiver are met and the request is properly justified.)

New Concepts:

- "Key" Information
  When a longer format is used for informed consent forms, such as our Q&A template, the revised Common Rule will require investigators to draft them so that **"key" information is presented first**. Key information might vary depending on the study and the population, but generally it is why one might or might not want to participate in the research, such as the purpose of the research, the benefits of the research, the possible risks, the subject's time-commitment, or other variables

depending on the nature of the study and the population. The key information **must be "concise and focused" and organized and presented in such a way to facilitate understanding**.

- Posting of Clinical Trial Consent Forms
  This is a new requirement **when a clinical trial is supported by federal funding**. This requires that the awardee post the IRB-approved informed consent form on a **publicly available federal website** that will be established as a repository for such informed consent forms. The form must be posted after recruitment is closed on the study and no later than 60 days after the last study visit by any subject.

- Screening, recruiting or determining eligibility
  The IRB may now approve proposals to **screen, recruit, or determine eligibility of subjects without first obtaining informed consent from the subject or the subject's legally authorized representative (LAR)** IF the information is obtained through oral or written communication with the subject or LAR, or if the investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

- "Broad" Consent
  This new option is applicable only to the storage, maintenance, and secondary research use of **identifiable private information or identifiable biospecimens**. Broad consent is different from typical informed consent in that it would allow researchers to store information and biospecimens for ***unspecified future research***. Typically, informed consent requires subjects to be informed about the nature of the research, but broad consent requires only a general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens.

  The required elements for broad consent are different from the required elements for ordinary informed consent. For example, researchers must describe the identifiable private information or identifiable biospecimens that might be used, whether they will be shared, the types of institutions or researchers who might conduct research with them, the period of time that they will be maintained, etc.

  An IRB may not approve requests to omit or alter any of the broad consent requirements. An IRB cannot waive consent if individuals were asked, and refused, to provide broad consent.

- Research Involving Identifiable Private Information or Identifiable Biospecimens
  If research involves the collection of **identifiable private information** or **identifiable biospecimens**, investigators must include one of two statements:
  - That identifiers might be removed, and that after such removal the information could be used for future research studies (or if possible, that the information might be distributed to other investigators for future research studies) without additional informed consent, or
  - That the information or biospecimens collected as part of the research will not be used or distributed for future research, even if identifiers are removed.

  For biospecimens only, when appropriate, researchers must include a statement:
  - That the subject's biospecimens may be used for commercial profit, and whether or not the subject will share in the profit
  - Whether the research will include whole genome sequencing