Compliance deadline: January 19, 2018

Preparing for this date but there could be an implementation delay.

Significant changes (this isn’t everything)

What is not research and thus does not require IRB review:

- Most scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship).
- Public health surveillance activities, that are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance. Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. [Note: Not intended to include social and behavioral studies of the causes of criminal behavior.]
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Human Subjects definition revised:

- Human Subject: A living individual about whom an investigator conducting research:
  1. obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  2. obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Exemption categories:

- The proposed changes to the Common Rule included an exemption decision tool for researchers to utilize in making their own exemption determinations. Since this tool is not part of the Final Rule, UNC Charlotte will follow Office of Human Research Protections (OHRP) guidance that Investigators should not make Exemption determinations for their own research. Therefore, Exemption determinations will continue as per current procedures. Investigators may propose exemption eligibility as part of the IRB application submission; however, the Office of Research Compliance (ORC) and IRB will make the Exemption determination.
- New Exemption categories - Exempt categories added for secondary research on identifiable private information and identifiable biospecimens collected prior to and after the time of IRB review and approval. Secondary research involves reusing identifiable information and identifiable biospecimens that were collected for a different, primary purpose.
• **New** Exemption category for studies involving benign behavioral interventions with adult subjects.
• Some Exemptions may require “Limited IRB review” (similar to the expedited review process).

**Continuing review:**

• Continuing review for Expedited level studies is no longer required unless at the time of initial Expedited review, the IRB determines that continuing review is appropriate to enhance protections of research subjects.

**Informed consent:**

• The informed consent process must now 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. The informed consent must also be “organized and presented in a way that facilitates comprehension.”
• Added requirements to the basic information that the consent needs to provide. Including one of the following statements:
  o 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
  o that the subject’s information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.
• Consent forms must include the following additional information, when appropriate:
  o biospecimens, even if identifiers are removed, may be used for commercial profit and whether the subject will share in the profit
  o whether clinically relevant research results will be disclosed to subjects
  o whether the research project might include whole genome sequencing.
• A new option for “broad consent,” may be used in lieu of study specific informed consent only with respect to the storage, maintenance and use of private information and identifiable biospecimens.
• An IRB may approve a proposal wherein an Investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects without informed consent.

**Clinical trials are now specifically defined:**

• Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
• In addition, there is an added requirement for posting clinical trial consent forms on a publicly available Federal website that will be established (this posting process has not been established, but is likely to be through clinicaltrials.gov) as a repository for consent forms no later than 60 days after the last study visit by any subject. [Funded clinical trials only.]

**Single IRB:**

• The Common Rule changes require single IRB review for cooperative/multi-site research unless more than single IRB review is required by law or if the federal sponsor determines that single IRB review is not appropriate.
• The lead IRB is determined by the sponsor or proposed by the lead institution.
• This Common Rule change aligns with the National Institutes of Health (NIH) single IRB policy. NIH sIRB policy effective January 25, 2018. Common Rule changes effective in 2020.