UNIVERSITY of NORTH CAROLINA WILMINGTON

Research Integrity Office

Revised Common Rule

UNCW Impacts and Plan

Questions? Email: IRB@uncw.edu

- **Transitioning to the Revised (a.k.a. "new") Regulations**

  The new regulations go into effect on January 21, 2019. Studies approved on or after 1/21/19 are subject to the new regulations. We will ***gradually transition*** existing studies to the new regulations.

  Specifically, studies approved by expedited or full board review **prior to** 1/21/19 are subject to the "old" regulations until the date of annual renewal, at which time they will be transitioned to requirements under the new regulations. For example, if an expedited or full board study was approved on 10/1/2018, it will be subject to the "old" regulations until October 2019. At that time, changes to the consent form or other updates may be required to comply with the new regulations. Studies that were **exempted prior to** 1/21/19 will not need to transition to the new regulations.

- **Change to Annual Renewal Requirement for Studies Reviewed at the "Expedited" Level**

  A major positive change that will impact UNCW researchers is that continuing review of research (what we call annual renewals) will no longer be required **for studies approved through expedited review**. Studies that qualify for exemption have always been handled this way, but this will be new for "expedited" studies. Only **studies reviewed at the full board level will require annual renewal**. As described in the previous section, expedited studies will gradually transition to this change in status when annual review would normally occur. Annual renewal will not be required thereafter.

  Although the regulatory requirement for continuing review on expedited studies will be eliminated, we will check in with researchers twice a year by email to provide compliance reminders and ask you to submit any modification requests or closure reports so that your records are current. The IRB may determine that other forms of post-approval monitoring are needed in the future.

  Please note that the revised regulations give IRBs the authority to require continuing review on expedited studies with appropriate justification.

- **New Category for Exempt Research**

  Another change that will benefit some studies, particularly those submitted from the Psychology Department, will be a new category of activity that qualifies for exemption. The category is called "benign behavioral intervention." There are a number of conditions that must be met in order for the exemption to apply, such as the subjects must be adults, and the intervention must be brief in duration, harmless, painless, not physically invasive and not likely to offend or embarrass subjects. We expect that certain research activities that involve online games, solving puzzles, or deciding how much cash to allocate may qualify for this exemption. W*e will have the authority to classify studies under this exemption category beginning January 21, 2019*.

- **New Concept of "Limited Review" for Research that Previously Did not Qualify for Exemption**

  Certain survey/interview/focus group studies that did not qualify for exemption due to the collection of identifiable and sensitive data may now qualify for exemption provided the IRB conducts a "limited review" to ensure that "adequate provisions" are in place related to privacy and information

security. The "limited review" process requires that the review is conducted by an IRB chair or other voting IRB member.

- **Consent Changes**
  There will be a number of changes to the consent requirements that are described in detail in another guidance document, "Changes to Informed Consent" that can be found on the IRB website. Most notably is a new requirement for consent forms to begin with a "concise and focused presentation of the key information" that is most likely to assist a subject in understanding the reasons why one might or might not want to participate. We have created new templates designed to guide researchers on meeting this standard when applicable.

Other Changes

- The regulations now define "**clinical trial**" - 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. Please note that there are additional consent requirements for clinical trial studies.

- The **"commonly established educational settings"** exemption now includes wording that the activities qualify for exemption provided they are not likely to adversely impact students' opportunities to learn required educational content or the assessment of educators who provide instruction.

- The definition of human subjects now specifically includes **biospecimens**.

- The definition section now includes a definition of **"legally authorized representative**" - an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

- The definition section now includes a definition for "**public health authority**" - an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government.

- The definition of research **now excludes certain activities** that our IRB typically excluded anyway, such as oral history projects, journalism, biography, legal research, historical scholarship, public health surveillance activities, collection of information and biospecimens for criminal justice investigations, etc.

Please be aware that this is just a selection of changes that are most likely to impact how our IRB conducts reviews. It is provided as a summary only and not intended to be viewed as new policy. The IRB will update its policy and standard operating procedures as necessary to address any new requirements.

You can find additional resources about the revised regulation from the Office of Human Research Protections (OHRP) on its Revised Common Rule Educational Materials website and from the CITI Program on its Final Rule Resources website.

Questions?

Contact the IRB at irb@uncw.edu
Or visit the UNCW Human Subjects Research website at: https://uncw.edu/sparc/integrity/irb