1. PURPOSE

1.1. This policy establishes the Institution’s process to implement the new 2018 Common Rule changes.

2. POLICY

2.1. The UF IRBs will apply the 2018 Common Rule changes to all UF IRB approved protocols.

2.2. All new protocols approved after January 21, 2019 will conform to the 2018 Common Rule changes.

2.3. The time-line to implement the 2018 Common Rule changes for protocols approved prior to January 21, 2019 is as follows:

2.3.1.1. All federally funded or North Florida\South Georgia VA Medical Center protocols approved under the pre-2018 rules will be required to revise their consent forms before January 21, 2019.

2.3.1.2. All protocols approved after January 21, 2019 must use the new 2018 Common Rule compliant consent form templates

3. PROCEDURE

3.1. Exempt Research and Limited IRB Review

3.1.1. When the research requires limited IRB review or HIPAA determination (waiver or alteration of authorization), the review will be conducted by the IRB Chair, Vice-Chair, or a Chair-designated IRB member by using expedited review procedures.

3.1.2. Research that falls into Exemption category 2 or 3 are eligible for limited review.

3.1.3. Exemption categories 7 and 8 related to Broad Consent will NOT be implemented.

3.2. Expedited Review

3.2.1. Expedited review of research subject to the revised Common Rule will be conducted using the following updated procedures:

3.2.1.1. The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures

3.2.1.2. Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk.

3.2.1.2.1. If the reviewer determines that the research involves more than minimal risk, it will be referred for review to the convened IRB

3.2.1.3. The limited IRB review that is required for certain exempt research (See Section 3.1) may be conducted using expedited review procedures

3.2.1.4. Continuing review of research is not required for research that qualifies for expedited review unless the IRB determines that is required and documents the rationale within the IRB record

3.3. Informed Consent

3.3.1. Under the revised Common Rule, the UF IRBs have evaluated the provisions for informed consent and new versions of the various Informed consent templates have been published on the IRB website as of October of 2018.
3.3.1.1. The IRB will not make post-2018 Common Rule changes since virtually all the information required by 45 CFR 46.116(a)(5)(i) appears in a concise and focused format.

3.3.2. For Federally Funded Clinical Trials, one IRB-approved consent form used to enroll participants will be posted publicly using the following procedures:

3.3.2.1. UF’s ClinicalTrials.gov office coordinator will be responsible for posting of an IRB approved consent to ct.gov website within the required deadline per CFR 46.116(h)(1)).
   3.3.2.1.1. The consent form must be posted on the website after the clinical trial is closed to recruitment, but no later than 60 days after the last study visit by any subject, as required by the protocol.

3.3.2.2. UF’s ClinicalTrials.gov office coordinator will work collaboratively with the appropriate offices within the Institution to identify any contractual, intellectual property or export control issues, and if necessary, will appropriately redact sensitive information from the consents.

3.3.2.3. UF’s ClinicalTrials.gov office coordinator will work collaboratively with the appropriate offices within the Institution to address a request for an exception to the requirement to post the consent document, and the process to redact confidential commercial information from the consent form.
   3.3.2.3.1. All requests will be submitted in writing to the relevant Federal Department or Agency.

3.4. Waiver of Consent and Waiver of Documentation of Consent Criteria

3.4.1. Existing requirements for waiver of consent remain unchanged for UF IRBs under the revised Common Rule.

3.4.2. Under the revised Common Rule, the IRB may approve a request for a waiver of documentation of consent for subjects for whom signing documents is not the cultural norm.

3.5. Continuing Review

3.5.1. Unless under the FDA’s or funded by the Department of Justice (DOJ), continuing review is no longer required for:

   3.5.1.1. Research approved by Expedited review

   3.5.1.2. Research has progressed to the point that it involves only one or both of the following:

       3.5.1.2.1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

       3.5.1.2.2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

3.5.1.3. All protocols approved under an Expedited category will be done so by Limited IRB review.

   3.5.1.3.1. Protocols approved after January 21, 2019 will not be required to undergo continuing review, but rather will be approved with a “Status Report” requirement (see section 3.4.2)

   3.5.1.3.2. If the IRB reviewer requires continuing review (e.g. FDA, DOJ regulated studies), the justification will be documented in the IRB records and communicated to the investigator.
3.5.2. Status Report

3.5.2.1. Every three (3) years, the PI and study staff will be notified at 45 days, 30 days, and 7 days to submit a “Status Report”

3.5.2.2. The IRB must receive a “Status Report” by the study’s expiration date, indicating if the study in question is still active or not.
   
   3.5.2.2.1. If still active, the process will be repeated every 3 years until the study is closed.
   
   3.5.2.2.2. If no longer active, the study will be automatically closed.

3.5.2.3. If a “Status Report” is not received by the IRB by the study’s expiration date, the study will be “Administratively Closed”, and the PI and study staff will be notified.

3.6. IRB Review of Grant Applications

3.6.1. The revised Common Rule removes the requirement that the IRB review the federal grant application or proposed for consistency with the protocol submitted to the IRB

3.6.2. Grant congruency review will no longer be conducted by UF IRBs

3.6.3. It is the Principal Investigator’s responsibility to ensure congruency of a grant with the protocol submitted to the IRB.

3.7. Single IRB (sIRB)

3.7.1. UF has implemented the single IRB review model for NIH funded research effective January 25 2018.

3.7.2. sIRB review mandated on January 20, 2020 per the OHRP guidance, has been implemented by UF on the effective date for already approved research that otherwise meets the criteria for sIRB review.

4. REFERENCES