1. PURPOSE

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

2. POLICY

2.1. Scope


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

2.1.3. The time-line to implement the 2018 Common Rule changes for protocols approved prior to January 21, 2019 is outlined below.

2.2. Informed Consent Changes

2.2.1. Templates

2.2.1.1. Revised versions of the various Informed consent templates will be published on the IRB website in October of 2018

2.2.1.2. For those currently brief consents, 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.

2.2.2. Timeline for conversion

2.2.2.1. 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.

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

2.2.2.3. Protocols not falling under 2.2.2.1 must update their consent forms to the new 2018 Common Rule templates at:

2.2.2.3.1. The time of continuing review

2.2.2.3.2. If a revision is submitted to revise their pre-2018 Common Rule template

2.2.3. Posting of Consents for Federally Funded Clinical Trials

2.2.3.1. 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)).

2.2.3.2. 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.

2.2.3.3. UF’s ClinicalTrials.gov office coordinator will work collaboratively with the appropriate offices within the Institution if a request for an exception from CFR 46.116(h) is needed from the Federal Department or Agency. All such requests will be submitted in writing to the relevant Federal Department or Agency.

2.3. Continuing Review
2.3.1. All protocols approved under an Expedited category will be done so by Limited IRB review.

2.3.1.1. Protocols approved after January 21, 2019 will not be required to undergo continuing review, but rather will be approved with a “Status Report” requirement.

2.3.1.2. If the IRB reviewer requires continuing review, the justification will be documented.

2.3.2. Status Report

2.3.2.1. 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”.

2.3.2.2. The IRB must receive a “Status Report” by the study’s expiration date, indicating if the study in question is still active or not.

   2.3.2.2.1. If still active, the process will be repeated every 3 years until the study is closed.
   2.3.2.2.2. If no longer active, the study will be automatically closed.

2.3.2.3. 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. REFERENCES