1. PURPOSE

1.1. This policy establishes separate rules for the review of minimal risk protocols that are not externally funded, and thus do not fall under the Federal Wide Assurance (FWA).

1.2. This policy also establishes the process for conversion of protocols approved under this policy to the 2018 Common Rule.

2. POLICY

2.1. Protocols that are determined to be no greater than minimal risk as defined by 45 CFR 46.102, may be subject to approval under this policy.

2.1.1. Such protocols:

2.1.1.1. May be approved for up to three years

2.1.1.2. May be approved under additional categories as described in the addendum to this policy.

2.1.2. This policy will only be in effect as long as the University of Florida has chosen to limit the scope of its Federalwide Assurance (FWA) to federally funded research or until the last study approved under the policy is converted to the 2018 Common rule, whichever comes first.

2.2. The determination of whether a research project falls under the FWA or the discretionary policy will be at the discretion of the UF IRB. Mandatory Exclusions to this policy include:

2.2.1. External funding

2.2.2. Student projects for which faculty sponsor received federal funding

2.2.3. Federal sponsorship, including federal training grants

2.2.4. Studies with FDA-regulated components (any drug, device, or biologic, or food or herbal being used to treat, prevent, or ameliorate a disease).

2.2.5. Studies with contractual obligations or restrictions that preclude eligibility in this policy

2.2.6. Studies using prisoners as subjects

2.2.7. Studies using wards of the state.

2.2.8. Studies seeking or obtaining Certificates of Confidentiality

2.2.9. Studies using VA affiliations or resources

2.3. Should the funding status of a study reviewed under the discretionary policy change, it is the responsibility of the Principal Investigator to notify the IRB. Should the protocol no longer be eligible for approval under this policy, the following will occur:

2.3.1. If the PI receives federal funding less than one year into the three-year approval of a study that originally qualified under this Discretionary Policy, the PI must notify the IRB of that change via a revision request. and at the time of this revision the study will be converted to the 2018 rule.

2.3.2. If the PI receives federal funding after the first year of a three-year approval, the PI must notify the IRB and a continuing review must be submitted. At this time the study will be converted to the 2018 Common Rule. Upon Continuing Review approval, a new review category will be designated (if applicable) and the study will be reviewed based on the 2018 Rule criteria.
3. Policy expiration

3.1. Effective 1/21, no new protocols will be approved under this policy.

3.1.1. Category 10 will be retired effective 1/21/2019

3.2. Existing protocols approved under this policy will be converted to status reports (please see our Status Report Policy) and a new expedited category will be selected at the time of Continuing Review for that protocol.

4. REFERENCES

4.1. OHRP guidance on “Federalwide Assurance (FWA) for the Protection of Human Subjects”

ADDENDUM TO DISCRETIONARY POLICY

Expeditied Categories (not found under 45 CFR 46.110 and 21 CFR 56.110). This policy creates expedited categories not found in the federal regulations, for projects that do not directly conform to a specific expedited category according to 45 CFR 46. These projects will be reviewed using an approval process identical to that used for expedited research categories 1-9 under 45 CFR 46.110 and 21 CFR 56.110.

Expeditied 10: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for purposes of placing in a research tissue or data bank, for use in future unknown research (all subsequent research must be approved by the IRB).