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).

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.

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. The approval period will be decreased from three years to one year and the PI will be required to obtain continuing review by day 364 from the original approval date.

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 revision to the continuing review must be submitted. Upon approval, a new review category will be designated (if applicable) and a new expiration date will be calculated by the IRB based on the approval date of the continuing review.

2.3.3. For any project that qualified for any exempt category, a change in funding must be reported to the IRB.

2.4. Any correspondent student (defined as a non-local student enrolled in a UF run distance learning class or program), who submits a research protocol as a means to complete a UF program, and does not list a UF faculty member as the P.I. of the research, does not need to have UF IRB approval provided:

2.4.1. The research is minimal risk, there is no federal funding, and fits into one of the following categories:
   2.4.1.1. Retrospective chart or data review
2.4.1.2. Survey or questionnaire research
2.4.1.3. Evaluation of an existing program

2.4.2. A mentor at the student’s location site is listed on the research projects
2.4.3. A local IRB has approved the research prior to the initiation of the research
2.4.4. The appropriate College will be responsible for:
    2.4.4.1. Informing correspondence students of the requirement
    2.4.4.2. Keeping records of all said research for 3 years, which includes:
        2.4.4.3. The local IRB approval letter
        2.4.4.4. The final write-up of the completed research project

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

ADDENDUM TO DISCRETIONARY POLICY

Expedited 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.

Expedited 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).