I. Policy Statement

It is a well understood premise that research is fluid and elements of a research project can change once a principle investigator (PI) starts conducting their research. These changes can be minor or they can be major. The primary purpose of this policy is to address how these changes are to be handled both by the researcher and the IRB. The overall goal, however, is to still protect the rights and welfare are human research participants.

II. Operational Definitions

Modification: Any change made to a research protocol after it has been approved by the IRB. These changes can be to the research methodology, participant recruitment, instruments used, editorial changes, etc.

Major Modification: Any change to an approved protocol where the risk/benefit assessment changes, participant rights are altered, health/welfare benefits and protections are altered, etc. These changes reflect a significant alteration to the approved research. Major modifications include, but are not limited to:

- Changes in personnel, including PI
- Changes to the research methodology
- Any change that alters the risk level up or down
- Addition/change to participant rights, protections and/or welfare
- Adding/removing deception use in research
- Adding/revising questions to the survey or interview documents
- Addition of a new participant pool not originally presented in the protocol (ex. protocol was approved for adults with diabetes now you want to add normal/healthy adults)
- Addition or removal of a protected population pool (ex. minors, prisoners, etc.)
- Changing the research’s identification status (ex. use of identifiable information to de-identifiable information)
- Changing the use of data/information protected by another regulation or law (Ex. HIPAA and FERPA)
- Increasing needed participants by 20% or more from the originally approved number for protocols requiring full board review.
- Adding or changing participant compensation or incentive.

Minor Modification: Any change to an approved protocol where the risk/benefit assessment does not change, participant rights are not altered, health/welfare benefits and protections are not altered, etc. These changes reflect a non-substantial alteration to the approved research. Minor modifications include, but are not limited to:
Correction of typos
Minor wording clarifications (in informed consent forms, surveys, etc.) that do not change/alter any rights, protections, etc.
Participant increases that involve minimal risk protocols (Exempt and Expedited).
Adding an additional (previously approved) recruitment notification round (ex. approved for 2 e-mail notices going out and then adding 1 more)
Addition of a participant pool similar to the one(s) already approved (ex. protocol was approved for people with diabetes in town A and now you want to add the same type of group from town B.)
Adding/changing dates of X (ex. we stated X would be in Aug., but we had to move it to Oct.)
Adding/changing room locations, testing sites, addresses, etc. unless there is a privacy/security issue or requires a letter of support
Removal of survey/interview questions

III. Procedures

A. Principle Investigator (PI)
   i. PI’s are not required to submit minor modifications for IRB review, unless they are also part of a modification request involving major modifications.
   ii. It the PI’s responsibility to submit any major modification for review by the IRB. Major modifications must be submitted for review and approved before the PI can act on the proposed modifications. Some major modifications may be handled by administrative review (see III. C. below)
   iii. Minor modifications must be submitted with the next continuing review submission (for Expedited and Full Board reviews) so that there is a complete and current record of the PI’s proposed research. Ex. minor editorial changes were made to the informed consent form, so this would need to be included with the continuing review.
   iv. Minor modifications for Exempt protocols only need to be submitted if the PI is also submitting a major modification for review.

B. IRB and ORI
   i. The IRB will review any proposed major modifications at the next available committee meeting (for Expedited and Full Board reviews).
   ii. The ORI will review any major modification request to determine if the risk and/or review level have changed sufficiently to alter the review level. If the modification is sufficient to alter the review level, the ORI will assign it to the appropriate committee for review.

C. ORI Administrative Review
   i. The IRB has determined that some modifications are more administrative in nature and not ones that impact risk, health/welfare, rights, and so forth. As such the IRB has authorized the ORI to review these modifications, make applicable determinations and approve, disapprove, or send the modification(s) for further review by the IRB.
   ii. The list of items that fall into the administrative review category can change over time, reflect changes in regulations, and so forth. Items that fall into the administrative review category include, but are not limited to:
      1. Change of PI
      2. Personnel changes
      3. Closures
      4. Addition of research site(s) where a letter of support is needed

D. Exceptions
   i. These procedures do not apply when
1. Any administrative or regulatory body that has direct jurisdiction over the IRB process specifically requires that all modifications be reviewed and approved by the applicable IRB committee
2. Specifically required as part of the initial IRB review and made part of the formal approval
3. Modification(s) impacts and/or involves some other regulation, statute or applicable law
4. Multi-site studies involving multiple IRBs. These will be handled on a case-by-case basis