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1. PURPOSE

1.1. This policy establishes the submission and review process for previously approved protocols under expedited or convened IRB requesting minor modifications.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. The IRB may review minor changes in previously approved research during the period for which approval has been given, under expedited review procedures (45 C.F.R. § 46.110 and 21 C.F.R. § 56.110). A '*minor change*' is a change in approved research that can be approved through expedited review procedures that neither materially increase risk, nor materially decrease benefit, nor materially decrease scientific merit. If the change is not considered '*minor*,' it must be reviewed by the full board IRB at a convened meeting.


3.2. Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. The IRB Chair or experienced IRB members review the amendment, after a pre-review by ORC, to ensure all criteria for review are considered, met, and documented.

3.3. If the reviewer determines that the amendment involves significant changes or new risks that warrant review by the convened IRB committee, the amendment will be referred to a full board meeting. The IRB Member(s) conducting the review of the amendment make one of the following determinations:

- (1) **Approved** as submitted.
- (2) **Modifications** are required to secure approval to implement.
- (3) **Refer** for review by full board IRB.

3.4. The IRB members may not disapprove an amendment to a research protocol under expedited review procedures.

3.5. The IRB is informed of all amendments to previously approved research protocols reviewed and approved under expedited review procedures on the next available meeting agenda and this is documented in the IRB meeting minutes in accordance with 45 C.F.R. § 46.110(c) and 21 C.F.R. § 56.110(c).

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3.6. The date of approval of an amendment does not change the original approval period or the expiration date (if applicable) by which the regularly scheduled continuing review of the research project should be done.