Purpose: To define the expedited category of research.

Policy:

Expedited review categories of research shall comply with “Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure”. 63 FR 60364-60367, November 9, 1998.

The only other research for which an IRB may use an expedited review procedure is that which involves no more than minimal risk to the subjects and in which the only involvement of human subjects will be in one or more of the following categories. The activities should not be deemed to be of minimal risk simply because the activity is included on this list.

- Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes.
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurances methodologies.

Continuing review of research previously approved by the convened IRB as follows: (a) where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis of records that are not anonymous (i.e., contain identifiers).

The eligibility of some research for review through the expedited procedures is in no way intended to negate or modify the policies of this institution or the other requirements of 45 CFR 46.

The IRB may use the expedited review procedures to review minor changes in previously
approved research during the period for which approval is authorized. Expedited review is carried out by the IRB Chair or designee.

In reviewing the research, reviewers may exercise all of the authorities of the IRB except the reviewers may not disapprove the research. Disapproval of a research application requires the majority of the full IRB. Reviewers may recommend that a disapproved expedited review go to the full board for review.

At a convened IRB meeting, any member may request that an activity which has been approved under the expedited procedure be approved by the IRB in accordance with full board review procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue. A PI may also request that an application receive full board review.

Amendments for previously approved research may be approved under an expedited review procedure.