The purpose of this Standard Operating Procedure (SOP) is to describe when the IRB may review new applications, modifications, and continuing review reports by an expedited procedures, as well as requirements for the expedited review process.

This SOP applies to all Investigators, IRB members and administrative staff.

Use of expedited review by the IRB must be restricted to those IRB applications that fulfill one of the nine categories listed in the Procedures section below. This procedure may be used to review studies or to approved studies.

A review mechanism that provides allowance for one or more IRB members to conduct the review.

The following nine categories are outlined by federal regulations as follows:

- Research on drugs for which an investigational new drug application (21 CFR 312) is not required or research on medical devices for which a) an investigational device exemption application (21 CFR 812) is not required or b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: (a) from healthy, non-pregnant adults, who weigh at least 110 pounds. For these subjects, amounts drawn may not exceed 550 ml in an 8-week period and no more than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the

cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

- Continuing review of research previously approved by the convened IRB (a) where the research is permanently closed to the enrollment of new subjects, and allys) aony

employability, insurability, reputation, or be stigmatizing
- Is not classified
- Fits one (or more) of the expedited review categories

1.0 The investigator submits all applicable IRB application materials for review. For guidance, see IRB Getting Started Page – Documentation Required for Project Submission.

2.0 For qualified expedited research:

2.1 (non-biomedical) studies will be reviewed at a scheduled convened meeting (every three weeks) for review of initial and continuing reviews. The IRB Committee designated as "Educational and Behavioral Research – IRB" will conduct the reviews. The purpose of conducting these reviews at a convened meeting is to facilitate and improve IRB timelines for review and approval.

The expedited review process may be exercised via a designated IRB member for review of amendments.

2.2 studies that qualify for expedited review will be conducted by a

6.3 If the proposed new, continuing or amendment submission is not eligible for f(o)2 (r)4 (a1)4 (c)8 (o)2 ((v)7 he)13 n(e)3 (d)14.1 ((I)7 Rc)8 Beeing

6 eeoee-091 soge13 (d)6 (so)2 ( )]TJ0.002 Tc- 0.002 Tw