Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at http://www.hhs.gov/ohrp/policy/index.html#expedited for further information on expedited review.

From Chart 2, 3, 4, 5, 6, or 7

Has the research been previously reviewed and approved by the IRB?

NO

Does the research present no more than minimal risk to human subjects? and

does the research involve only procedures included in categories 1 through 7 on the list of categories of research that may be reviewed through an expedited review procedure? [45 CFR 46.110(b)(1)]

YES

Is the research classified? [Paragraph (D) of Categories of Research That May Be Reviewed By an IRB through an Expedited Review Procedure.]

NO

COULD IDENTIFICATION OF SUBJECTS PUT THEM AT RISK OF CRIMINAL OR CIVIL LIABILITY, OR BE SOCIALY OR ECONOMICALLY DAMAGING [Paragraph (C) of Categories.]

YES

Review by convened IRB is required.

ARE MEASURES IN PLACE TO MAKE RISKS NO MORE THAN MINIMAL?

YES

NO

GO TO CHART 10

GO TO CHART 9

NO

IS THE REVIEW A CONTINUING REVIEW? [45 CFR 46.109(d)]

NO

DOES THE REVIEW INVOLVE A MINOR CHANGE IN APPROVED RESEARCH DURING THE (ONE YEAR OR LESS) PERIOD OF APPROVAL? [45 CFR 46.110(b)(2)]

YES

NO

Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution’s or IRB’s use of the expedited review procedure. [45 CFR 46.110(d)]