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

FROM CHART 2, 3, 4, 5, 6, or 7

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

YES

GO TO CHART 10

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 than may be reviewed through an expedited review procedure? [45 CFR 46.110(b)(1)]

YES

Review by convened IRB is required

NO

Is the research classified? [Paragraph (D) of Categories of Research That May Be Reviewed by an Institutional Review Board through an Expedited Review Procedure]

YES

GO TO CHART 9

NO

Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging? [Paragraph (C) of Categories]

YES

Are measures in place to make risks no more than minimal?

YES

Research is eligible for institutional review board 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)]

NO

Is the review a continuing review? [45 CFR 46.109(e)]

YES

GO TO CHART 9

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

GO TO CHART 10

NO

*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.

Adapted from http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c8