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

From Chart 2, or 7

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

YES

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

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

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)]

NO

Review by convened IRB is required.

YES

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

NO

Go to Chart 9

YES

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

NO

Go to Chart 10

YES

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)]

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