Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

From Chart 8

Has the research been previously reviewed and approved by the IRB using expedited procedures?

NO

Have conditions changed to make the research eligible for expedited review under the applicability criteria and categories 1 through 7 on the list of categories that may be reviewed by expedited procedures (e.g., research is within those categories and experience confirms research to be of no greater than minimal risk)? [45 CFR 46.110(a)]

NO

Category 8

(a) For this site:
Is the research permanently closed to enrollment of new subjects?

and

Have all subjects completed all research-related interventions?

and

Does the research at this site remain active only for long-term follow-up of subjects?

NO

(b) Have no subjects been enrolled at this site?

and

Have no additional risks been identified anywhere?

NO

YES

(c) Are the remaining research activities at this site limited to data analysis?

NO

Research is eligible for IRB review through expedited procedures.

Review by convened IRB is required.

Have any additional risks been identified since IRB review at a convened meeting?

YES

Has the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk?

NO

Is the research conducted under an IND or IDE?

February 16, 2016