Chart 8: May the IRB Review Be Done by Expedited Procedures?

View text version of Chart 8

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

NO

Go to Chart 9

NO

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

YES

Review by convened IRB is required.

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

Go to Chart 10

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)]

February 16, 2016

Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?


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)?
    - **NO**
    - **YES**
      - **YES**
        - Research is eligible for IRB review through expedited procedures.
      - **NO**

- **YES**
  - **YES**
    - 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**
          - **YES**
            - (b) Have no subjects been enrolled at this site? **and**
              - Have no additional risks been identified anywhere?
                - **NO**
                - **YES**
                  - Category 9
                    - Is the research conducted under an IND or IDE?
                      - **NO**
                      - **YES**
                        - **YES**
                          - Have any additional risks been identified since IRB review at a convened meeting?
                            - **YES**
                            - **NO**

- **NO**
  - **NO**
    - Go to Chart 10

Review by convened IRB is required.