Expedited category 8:

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

Scenario 1

Investigational drug study was initially approved in January 2009.

4 local subjects had been enrolled (most recent, June 2011) prior to closure to further enrollment on February 1, 2012.

The current IRB approval period expires on December 1, 2012.

The study is submitted in November 2012 for CR:

Each of the four subjects has completed her year-long assigned treatment regimen per protocol

The only research-specific activity is a QOL questionnaire at f/u years 2-10.

Does this qualify for category 8(a)?

See last page for answer

Scenario 2

Investigational drug study was initially approved in January 2009.

4 local subjects had been enrolled (most recent, June 2011) prior to closure to further enrollment on February 1, 2012.

The current IRB approval period expires on December 1, 2012.

The study is submitted in November 2012 for CR:

Each of the four subjects has completed her year-long assigned treatment regimen per protocol

Each is in f/u and this includes a QOL questionnaire at years 2-10.

Each is also providing one 5tsp blood draw at Yrs2-10 for study drug antibody detection.

Does this qualify for category 8(a)?

See last page for answer

Scenario 3

Investigational drug study was initially approved in January 2009.

4 local subjects had been enrolled (most recent, June 2011) prior to closure to further enrollment on February 1, 2012.

The current IRB approval period expires on December 1, 2012.

The study is submitted in November 2012 for CR:

Each of the four subjects has completed her year-long assigned treatment regimen per protocol

Each is in f/u and this includes a QOL questionnaire at years 2-10.

Follow-up also includes a mammogram yearly, which is part of routine clinical practice

Does this qualify for category 8(a)?

See last page for answer

Expedited category 8:

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have [ever] been enrolled *[at the local institution]* and no additional risks have been identified *[from any institution engaged in the research since the local IRB's most recent prior review]*; or

(c) where the remaining research activities are limited to data analysis.

Scenario

A study is initially reviewed and approved by the convened IRB on 1/6/12.

- A new risk is identified by the investigator and reviewed by the convened IRB on 6/25/12 where the IRB approves a modification.
- The research comes up for continuing review on 12/10/12, and no subjects have been enrolled at the site.

Does this qualify for category 8(b)?

See next page for answer

Category 8(a):

Scenario 1

YES.

Although the QOL questionnaire is solely for the purpose of the research study, it is no more than minimal risk, and, the FDA and OHRP guidelines state a QOL questionnaire is an "*interaction*" (rather than an "intervention") and is considered part of "long-term follow-up".

Scenario 2

NO.

This is because of the blood draw that is being done solely for research purposes (vs a procedure/intervention that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol). However, while the CR would not be eligible for expedited review under category (8)(a), it might be eligible for expedited review under category 2(b) ["Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or, (b) from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period & collection may not occur more frequently than 2 times per week."].

Scenario 3

YES.

The mammogram is a procedure/intervention that would have been done as part of routine clinical practice to monitor the subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

Category 8(b)

Scenario

YES, the IRB could review the research at the time of continuing review under 8(b) since there are no additional risks since the last IRB review (the modification on 6/25/12), it would be considered to have "no additional risks identified" and could be reviewed via expedited procedures.