From: OC GCP Questions
To: [redacted]
Subject: RE: when a clinical investigation transitions into collecting follow-up clinical data and/or analyses of identifiable data
Date: Tuesday, December 26, 2017 11:51:00 AM
Attachments: [redacted]

Dear [redacted],
Expedited category (8), which applies only to continuing review, provides that continuing review of research previously approved by the convened IRB (e.g., not originally subject to expedited review) may be eligible for expedited review:

(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

FDA's current Guidance on IRB Continuing Review after Clinical Investigation Approval (February 2012) interprets "long-term follow-up" to include:

- Research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); **and** *(emphasis added)*
- Collection of follow-up data from procedures or interventions 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.

According to the guidance, both conditions must be true for a study to be eligible to receive expedited review under category 8(a) - all research interactions must meet the definition of minimal risk **and** the collection of follow-up data from procedures done for clinical reasons for follow-up, where the results are collected and shared for the research. If testing conducted as part of the subject follow-up would not be considered minimal risk, the study follow-up would not be eligible for expedited review. The continuing review guidance may be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-gen/documents/document/ucm294558.pdf

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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From: [redacted]
Sent: Wednesday, December 20, 2017 2:36 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: when a clinical investigation transitions into collecting follow-up clinical data and/or analyses of identifiable data

Hello,

When a clinical investigation was originally reviewed/approved at an IRB full-board meeting (which requires an annual IRB continuing review) later transitions into a minimal risk research reviewed and approved at a continuing review for Expedited Category research (in which the clinical research interventions and research subject accrual is complete, and the only procedures left are collection of follow-up clinical data and/or analyses of identifiable data), would an annual continuing IRB review be required at this stage of the clinical investigation (when the clinical investigation becomes a minimal risk study because the clinical research interventions/accrual is complete, and the clinical investigation is only collecting follow-up clinical data and/or analyzing identifiable data)?

Thank you for your guidance.

Best regards,

[redacted]