From: OC GCP Questions
To: [redacted]
Subject: RE: Exempt Category 8 (a)
Date: Friday, December 18, 2015 1:29:00 PM

Dear [redacted]
In general, research involving radiation exposure would not be considered minimal risk, and would not qualify for expedited review because Category 4 explicitly excludes procedures involving x-rays or microwaves (i.e., energy introducing interventions). According to the Information Sheet Guidance on Significant Risk and Nonsignificant Risk Medical Device Studies http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126418.pdf , digital mammography is considered nonsignificant risk, but not minimal risk. To the best of my ability to determine, FDA has never indicated a radiation dose or procedure that would be considered "minimal risk" or that an IRB could review studies involving radiographic procedures through the "expedited" process.

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: Thursday, December 17, 2015 9:07 AM
To: OC GCP Questions
Subject: Exempt Category 8 (a)

"Guidance for IRBs, Clinical Investigators, and Sponsors IRB Continuing Review after Clinical Investigation Approval U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research (CBER) Center for Devices and Radiological Health (CDRH) Center for Drug Evaluation and Research (CDER) Office of Good Clinical Practice (OGCP) February 2012 Procedural (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf)
…
Expedited review category (8)(a) and the meaning of "long-term follow-up" Under expedited review category (8)(a), FDA 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

§ 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.**

…

Please clarify if a study that meets the criteria in 8(a) i and ii, can undergo expedited review if the procedure or intervention that would have been done as part of routine clinical practices to monitor a subject for disease progression or recurrence involves more than minimal risk.

E.g., if a study of an experimental drug treatment for breast cancer (after the study is closed to enrollment and the experimental treatment is over) requires annual mammograms, or a chest x-ray, that would be done if the subject was not in a research study, could that have expedited review under the provisions of expedited category 8(a)?

Thanks very much,

[redacted]