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Eight Questions for an IRB to Ask About Post-Study Risks

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Study participants might encounter adverse effects related to the study drug after completing a study. For example, unexpected post-study effects have been observed for antibiotics (bone marrow degradation), antidepressants (suicide), birth control pills (blood clots), acne medications (inflammatory bowel disease), cholesterol medications (rhabdomyolysis), anticoagulants (heart disease), gastrointestinal drugs (tardive dyskinesia), and drugs taken during pregnancy (fetal birth defects).

Study participants might also encounter adverse events related to an implanted medical device, due, for example, to corroded leads or physical impact.

IRBs should be concerned about any chance of a post-study serious adverse event. To assess and minimize such risks, IRBs can ask the following questions:

A. Is there a material, post-study risk of a serious adverse event?
   1) Do similar drugs or medical devices have a history of serious adverse events that arise after the length of time a participant will be in the study?
   2) Does the mechanism of action or other product characteristic suggest that study participants might incur a risk from the study drug or medical device after the study has closed?
   3) Are there any other reasons to expect that study participants might incur a risk from the study drug or medical device after the study has closed?

B. If a post-study risk exists and is material:
   4) How will the investigator maintain contact with study participants after the study?
   5) Will study participants and their physicians understand that serious adverse effects might appear to be totally unrelated to the study drug or device?
   6) What laboratory tests or studies will be performed to monitor the status of study participants after the study?
   7) What will the informed consent form say about such risks?
   8) Should any patient populations be excluded from the study based on the above considerations?

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