CHICKEN SOUP FOR THE BUSY COORDINATOR

June 2019

WHAT CONSTITUTE A MINOR OR MAJOR PROTOCOL AMENDMENT ACCORDING TO NHG DSRB

Scenario A

Dr Amenda (PI) was reviewing her study protocol ABC and wanted to include an additional blood draw of 10mls of blood via venepuncture for an immunoassay test. She then informed the study coordinator Mr. Action; whom just took over the study to assist with the amendment.

Mr. Action did not understand the difference between a minor and major protocol amendment and proceeded to consult Ms knor, a senior study coordinator on this. She proceeded to share on the different review categories for Study Amendments according to the NHG DSRB.

Category A Major Amendment	Amendments that significantly affect the risk-benefit ratio of the study will be reviewed by a Full Board review. Some examples include (but not limited to): a. Changes to the inclusion/ exclusion criteria that significantly alter the risk benefit ration b. Major changes to the consent document or process that increases the overall risk to the subjects involved in the study c. Addition of any study procedures that are greater than minimal risk d. Increase in study subjects for a study previously reviewed by a Full Board Review e. Alterations to the drug dose of delivery f. Any other type of amendment to the study that in the opinion of the Chairperson or Reviewer should be reviewed at a Full Board Meeting
Category B Minor amendment	Changes to the protocol that pose risk which are ^not more than minimal, or new procedures added that fit within the categories eligible for expedited review will fall into this category. *(^not more than minimal is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.)*
Category C Administrative Amendment	Administrative changes such as change in addresses or contacts of study team members, and correction of typographical and grammatical errors fall under this category.

Ms Knor explained that the additional blood draw might significantly affect the risk-benefit ratio of study participants. Mr Action proceeded to assist Dr Amenda with drafting the study amendment for submission under Category A.

The NHG DSRB will review the submitted amendment to determine the category of review for the changes that have been made to the approved proposal. For the scenario above, the amendment may be reviewed under Category A as it included an addition of study procedure.

REMINDER

No deviation from, or changes to the approved study should be implemented without documented approval from the DSRB, except where necessary to eliminate apparent immediate hazard(s) to the study subjects. Any deviation from, or a change of, the approved study to eliminate an immediate hazard should be documented and promptly reported to the DSRB via the ROAM Non-Compliance/ Study Deviation Form. (For more information, refer to NHG IM 3rd Edition and Addendum Chapter 4.8 Non-Compliances/ Study Deviations.)

References:
- ICH GCP Section 4.5 – Compliance to Protocol
- NHG Investigator's Manual 3rd Edition Chapter 4.5 Study Amendments

Additional Readings:
- NHG Investigator's Manual 3rd Edition, Chapter 3.3: Responsibilities of a PI and Chapter 3.4: Change of PI and/ or Study Team Members
- NHG Proper Conduct of Research SOP 501-A02: Responsibilities of the Research Team
- NHG Proper Conduct of Research SOP 501-B04: Interactions with Domain Specific Review Board

Article Contributed By: Ms. Poh Sock Cheng, Senior Clinical Research Coordinator, NUHCS
Edited By: NHG-RDO

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(researchcoord@nhg.com.sg)