DETERMINING WHICH STUDIES NEED VERIFICATION FROM SOURCES OTHER THAN THE INVESTIGATOR

7/15/2021

Investigators are expected to provide the IRB with all relevant information regarding the conduct of the research. In order to ensure that the research is conducted in compliance with all federal and state regulations for the protection of human subjects, the IRB may require verification of information from sources other than the investigator. Such independent verification may be considered in the following situations:

- studies being conducted by persons who have previously failed to comply with all regulations or IRB requirements, including investigator non- responsiveness to requests for information;
- studies for which the investigator's conduct was questionable as detected at the time of continuing review or audit;
- Duke investigator-initiated studies for which substantial segments are conducted off site, either by the Duke investigator or by a collaborator;
- complaints from research participants that appear not to be adequately addressed by the investigator;
- studies for which the IRB wants to verify that no material changes have occurred since the previous IRB review;
- studies for which the investigator also serves as sponsor;
- studies with an unexpected frequency (high or low) or severity of reported serious adverse events;
- studies with a high participant dropout rate;
- studies where the IRB discovers previously undisclosed information regarding the investigator and/or a co-investigator after the IRB has approved the investigator and without an acceptable explanation by the investigator;
- complicated studies involving an unusual level or types of risk to subjects;
- studies requiring compliance with Duke Hospital policies: including medication use, device use, and safe medication practices (e.g., Pharmacy and Therapeutics Committee policy on restricted drug use, certification/education standards for prescribers);
- studies requiring auditing of medication use, storage and procedures as conducted by Duke Hospital's Investigational Drug Service;
- studies requiring compliance with complex Duke Hospital Nursing policies when Patient Care Nurses are involved in the conduct of the

research;
- studies for which unanswered questions exist about the conduct of the research.

In addition, when following FDA requirements, the IRB must determine which clinical investigations need verification from sources other than the clinical investigator that no material changes in the research have occurred since the previous IRB review. The IRB will consider:

- the vulnerability of the subjects;
- the experience of the clinical investigator conducting clinical research;
- the projected rate of enrollment;
- whether the study involves novel therapies.

Independent verification of information may be requested by the IRB at a convened meeting, or by the IRB Chair/Executive Director/designee in the course of performing a review using the expedited procedure. Such verification may include:

- an audit by DUHS staff
- review of communications between the FDA and the sponsor/IND holder
- NIH communications and reviews
- DSMB/DMC reports
- back translation of consent form or other material to be used by research subjects
- letters of review or approval from other collaborating IRBs or a Central IRB
- a site monitor report
- a sponsor/CRO audit
- correspondence with the sponsor/CRO.

When the IRB finds the need for independently verified information, it will notify the investigator in writing of any outstanding issues or requests. This will usually occur in the context of a Modifications request to the investigator. The IRB will not give final approval to the study until it has received and reviewed the independently verified information and found it to be satisfactory.

Previous Version Date(s): 3/13/2007, 3/2/2016