

New Guidance Outlining the Responsibilities of Investigators Conducting Clinical Trials

The new guidance distributed in October of 2009, is to “help investigators better meet their responsibilities with respect to protecting human subjects and ensuring the integrity of the data from clinical investigations”. More specifically the guidance clarifies the investigator’s responsibility to “(1) supervise a clinical study in which some study tasks are delegated to employees or colleagues of the investigator or other third parties and (2) to protect the rights, safety and welfare of study subjects.”

The FDA has outlined four major areas of investigator responsibility for the supervision of the conduct of a clinical investigation:

1. The investigator must determine whether individuals who are delegated tasks are qualified to perform such tasks;
2. The investigator must ensure that the study staff receives adequate training on how to conduct the delegated tasks and are provided with an adequate understanding of the study.
3. The investigator must ensure that there is adequate supervision and involvement in the ongoing conduct of the study and;
4. The investigator must ensure that there is adequate supervision or oversight of any third parties involved in the conduct of a study so the extent such supervision or oversight is reasonably possible.

The FDA also addresses the investigator’s responsibility to protect the rights, safety and welfare of study subjects. It is the responsibility of the investigator to inform the subject’s primary physician of his/her participation in the trial. In addition, the following responsibilities must also be met.

1. The investigator ensures that reasonable medical care is provided to a subject for any adverse events related to the trial participation.

2. The investigator must be available to research participants during the conduct of the trial for medical care related to participation in the trial.
3. The investigator must seek to minimize risks to the participant and others by adhering closely to the study protocol.

In closing, it is important for the investigator to understand that his/her responsibilities exceed those listed in the FDA Form-1572 should have knowledge of the appropriate regulations that are required. To access the updated guidance, select the following link:
<http://www.fdanews.com/ext/files/UCM187772.pdf>

Draft Guidance for Continuing Review of Research

On October 20, 2009, OHRP provided draft guidance for IRBs when conducting Continuing Review of Research supported by HHS. For more information about the draft guidance, select the following link:
http://www.hhs.gov/ohrp/requests/200911guidance_rev.pdf

Notice to Sponsors and CROs

Sponsors and CROs working with Harrison IRB should note that beginning January 1, 2010, all sites must submit reports/information on Harrison IRB’s template documents to ensure we maintain compliance with AAHRPP regulations. Unless Harrison IRB has authorized the use of Sponsor, CRO or site-specific documents, Harrison IRB will be required to return the documentation that has not been submitted on Harrison IRB, AAHRPP reviewed templates. If you have any questions regarding documentation that has been previously approved by Harrison IRB, please do not hesitate to contact us at (740) 845-0814.

Thank you for your assistance in this matter!!

Happy Holidays from Harrison IRB!

