UNC School of Medicine Clinical Research Support Office

CRSO: IN THE KNOW

Updated FDA Guidance

October 2021

On September 30, 2021, the U.S. Food and Drug Administration (FDA) issued new draft guidance, *Investigator Responsibilities—Safety Reporting for Investigational Drugs and Devices*. This draft guidance addresses how investigators must assess and report adverse events to ensure participant safety in drug and device studies. Are you in the know?

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The new FDA guidance for investigator responsibilities combines and updates concepts from previous guidelines, *Safety Reporting Requirements for INDs and BA/BE Studies* (December 2012) and *Adverse Event Reporting to IRBs—Improving Human Subject Protection* (January 2009).

The new draft guidance focuses on investigator's safety reporting requirements in investigational new drug (IND) studies, bioavailability and bioequivalence studies that are exempt from the IND requirements, and clinical trials involving an investigational device exemption (IDE). In addition, the guidance provides further clarification regarding the investigator's responsibilities in assessing adverse events and promptly reporting to the IRB all unanticipated problems involving risk to subjects or others (UPIRSO).

Sponsor recommendations for safety reporting were also parsed out from the referenced 2009 and 2012 guidelines and issued in a separate FDA guidance in June of 2021, *Sponsor Responsibilities—Safety Reporting Requirements and Safety Assessment for IND and BA/BE Studies*. When the sponsor and investigator responsibilities guidances are finalized, they will replace the 2009 and 2012 guidances.

The UNC Office of Human Research Ethics has released an update to SOP 1401, *Promptly Reportable Information* (previously titled *Reporting New Safety Information),* that aligns with this guidance on reporting adverse events and IND safety reports to the IRB. SOP 1401 was revised to increase readability by revising the formatting, reorganizing promptly reportable information tables, and updating definitions. Parallel updates to the IRBIS Promptly Reportable Information submission form (formerly NSI submission form) are forthcoming.

More Information Available

To learn more about IND safety reporting and this guidance, please watch FDA's Small Business and Industry Assistance (SBIA) webinar, Investigator Responsibilities — Safety Reporting for Investigational Drugs and Device.

If you have questions regarding the IRB's Prompt Reporting requirements of adverse events and IND safety reports, please contact the IRB at irb_questions@unc.edu or 919-966-3113.

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