



In January 2009, the FDA published “Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs – Improving Human Subject Protection” to assist the research community in interpreting requirements for submitting reports of unanticipated problems to an IRB. The guidance was generated as a response from IRBs regarding concerns with large volumes of individual adverse event reports, often lacking in context and detail, and it is believed this inhibits rather than enhances human subject protection. Without the proper context and detail, the large number of reports act more as background noise and a significant event may then be missed by the IRB.

In response to the guidance, Goodwyn IRB has altered the reporting requirements and report forms to “walk” an investigator through the process of what should be reported and what no longer needs to be reported to the IRB.

In general, an adverse event only needs to be reported to an IRB if it is serious, unanticipated and related or possibly related to the test material. Keep in mind that this change in no way affects reporting requirements to the sponsor.

Along with these changes, Goodwyn IRB modified the Protocol Deviation Report Form. The new form only requires reporting of major deviations. Major deviations have the potential to result in increased risk to subjects or others, affect the rights, safety or welfare of subjects or affect the integrity of the study. The revised form “walks” an investigator through the process of determining what qualifies as a major deviation.

In addition, Goodwyn IRB has produced a new form for reporting any other Unanticipated Problems that are not categorized as adverse events or deviations. A list of potential unanticipated events is included on the form.

Further information can be found in the guidance document at [www.FDA.gov](http://www.FDA.gov) , at [www.GoodwynIRB.com](http://www.GoodwynIRB.com) or by calling Goodwyn IRB at 513-793-8900.