Updated IRB Forms and Policy on Unanticipated Problem and Safety Reporting should streamline external reporting for investigators

Over the past few years FDA and the Office for Human Research Protection (OHRP), have finalized guidance on reporting unanticipated problems and adverse events to the IRB. The intent has been to improve the quality and efficiency of reporting by focusing on critical, meaningful, and interpretable information and minimizing uninformative reports.

The FDA’s guidance acknowledges that “the practice of local investigators reporting individual, unanalyzed events to IRBs, including external reports….received from the sponsor of a multi-center study—often with limited information and no explanation of how the event represents an unanticipated problem—has led to the submission of large numbers of reports to IRBs that are uninformative.” FDA released guidance for industry in 2015 which encouraged industry sponsors to develop safety assessment committees to review and triage safety reports.

In response to the federal guidance and in consultation with several UK researchers, the IRB has made the following policy and form changes to streamline and clarify safety reporting requirements.

The IRB Policy provides reporting timelines and updated criteria for prompt reporting of events that rise to the threshold of an Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO). Such events suggest greater risk of harm than was previously known; may change the risk-benefit ratio; or have implications for the conduct of the study (e.g., requires safety-related change in the protocol, monitoring plan, or informed consent). For additional guidance on determining which adverse events should be considered an Unanticipated Problem Involving Risks to Subjects or Others, refer to the FDA Guidance for Clinical Investigators, Sponsors, and IRBs, or the OHRP Unanticipated Problems Involving Risks and Adverse Events Guidance.

The policy also addresses timely provision of Unanticipated Adverse Device Effects (UADE) and reports from independent data and safety monitoring boards which can provide meaningful information based on aggregate, un-blinded data analysis.

**Applicable UK IRB Policy, Procedures, and Forms**

- **IRB Policy on Unanticipated Problem and Safety Reporting [D2.0000]**: This policy includes updated criteria for prompt reporting to the IRB and required timeframes for reporting.
- **Continuation Review Form**: Clarified the requirements for a written summary of safety reporting at Continuation Review.
- **The Unanticipated/ Anticipated Problem/ Adverse Event Reporting SOP [C2.0350]**
- **The Continuation Review SOP [C2.0250]**
- **UK Internal Prompt Reporting Form [F9.0000]**
- **UK External Prompt Reporting Form [F10.0000]**
- **IRB Cover Form for Non-prompt Reporting of Problems/Adverse Events [F11.0000]**

Contact Tammi Gausepohl with questions about the new forms or policy (tinewb2@uky.edu or 257-2910).
Submit IRB applications by Email

Beginning Monday, April 11th, all new protocol submissions, modifications, adverse events, violations and continuation reviews may be transmitted electronically to the general IRB email. This is an initial step in the shift from paper to electronic submission as the web-based E-IRB program is being developed.

To submit electronically, all IRB forms and study documents should be submitted as one PDF that is readable, searchable, and contains standardized bookmarks. Step-by-step instructions on how to prepare your submission are posted on the web page that corresponds to the type of application you plan to submit (e.g., for a medical protocol eligible for expedited review, go to the Medical Expedited Review Application webpage). Instructions will also be available on the main human research forms website. Email completed PDF submissions to irbsubmission@uky.edu. You will receive an automated notification of receipt by email. IRB approvals and correspondence will be sent to investigators by email as well.

Please contact Heather Gozzard (Heather.Gozzard@uky.edu or 257-9118) or Michelle Hill (Michelle.Hill@uky.edu, 257-9428) with any questions.

Clinical Trial News

Opportunities for Feedback

- NIH and FDA Request for Public Comment on Draft Clinical Trial Protocol Template for Phase 2 and 3 IND/IDE Studies
  grants.nih.gov/grants/guide/notice-files/NOT-OD-16-043.html
  The National Institutes of Health (NIH) and Food and Drug Administration (FDA) are developing a template with instructional and sample text for NIH funded investigators to use in writing protocols for phase 2 or 3 clinical trials that require Investigational New Drug application (IND) or Investigational Device Exemption (IDE) applications. The agencies are seeking feedback from investigators, investigator-sponsors, and IRB members, etc. regarding the utility and clarity of the instructions and sample text. Based on comments, NIH may consider developing an online, step-by-step protocol template tool to dynamically guide users through steps to write a clinical trial protocol.

- International Committee of Medical Journal Editors proposal to require authors to share data as a condition of consideration for publication
  https://forms.acponline.org/webform/comments-icmje’s-proposals-sharing-clinical-trial-data
  The ICMJE is seeking feedback on its proposal to require authors share data and to include a plan for data sharing as a component of clinical trial registration (e.g., Clinicaltrials.gov). Data Sharing has implications for informed consent as human subjects must be informed and provided with the opportunity to consent to share their data. Details are available in the editorial, "Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors".