

Pre-Study Planning to Improve Site Compliance & Reduce IRB Fees

Pre-study planning prior to submitting your research to the IRB has been shown to reduce the overall cost of IRB services. Various upfront questions and documentation of IRB activities will ensure that the study expectations are met as well as confirm the deliverables that you can expect from your IRB.

Because each study is unique in its design, it is sometimes difficult to predict many of the “additional considerations” submitted by the sites, but there are ways to minimize and reduce some of the costs of these submissions by working with the IRB to create a research review strategy for your project. You may want to consider the following areas to help lower overall IRB expenses, as well as improve site compliance.

IRB Submission Requirements: Each IRB is unique in its request for those documents required for the ethical review of research. Over the course of the research, the sites must keep the IRB apprised of activities that affect the safety of participants, including breach of confidentiality as well as protecting privacy interests of the participants. It is important to communicate to the sites which documents they are required to submit for each IRB-related activity and the timeline for which they are required to submit.

Review of Study Documentation: It is important to understand the IRB’s processes and procedures regarding the review of IRB submissions from the sites (i.e., protocol deviations and adverse event (AE) reporting). For example, if the IRB requires review of ALL protocol deviations and adverse events, you may want to find out how often the IRB conducts the review of minor incidents (immediately, quarterly or during continuing review) and how they will communicate this review back to the sites and sponsor. You may be able to request that the IRB review and acknowledge any minor deviations and/or AEs on a quarterly basis rather than on an “as submitted” basis to reduce administrative costs.

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The IRB can provide an overview (submission sheet or slides for the investigator meeting) for the sites to ensure that proper documentation is submitted and to confirm the timelines for submitting each of the documents.

There are other considerations that can be discussed with your IRB that will result in an increase in site compliance as well as reducing IRB costs. Harrison IRB works with each study manager to provide a “Research Review Strategy” to document the IRB review plan. Pre-study planning and implementation of best practices has increased site compliance and has reduced costs for multi-center trials between 15 - 20%, up to 37% savings in some instances.

Q&A: Consent to Videotape Participants

Question: If a study sponsor wants participants to sign a consent addendum to participate in the videotaping of a study-specific medical procedure, must the videotaping be added to the protocol and the consent form?

Answer: “In an informal response..., the FDA writes, “as a Phase 2 (or Phase 3) study [it] is subject to 21 CFR 312.23(a)(6)(ii) that requires in those phases ‘detailed protocols describing all aspects of the study’. Therefore, a description for the videotaping should be included in the protocol and consent document.” Please note that the purpose for the videotaping must be outlined in the consent. Any additional use of the videotape for purposes not disclosed in the consent document would require additional consent of the subject.

Harrison IRB’s Project Analysis Program

Harrison IRB is pleased to announce it is now providing an in-depth Project Analysis Report at the close out of each study to provide an overview of your research from an IRB prospective. With various metrics, graphs, and charts, Harrison IRB is helping its clients increase site reporting compliance and savings in IRB costs. To learn

more about this new service, please call us or contact us at info@harrisonirb.com.

Harrison IRB is fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc.

