Guidance for the Submission of Investigator's Drug Brochures (IDBs)

Version Date: January 1, 2013 August 28, 2013

In order to approve research studies under the Common Rule (45 CFR 46) or FDA regulations (21 CFR 56), an IRB must receive sufficient information about the effects of any drug under study to assess whether the risks to subjects are reasonable in relation to anticipated benefits and adequately minimized. For studies conducted under an investigational new drug (IND) application FDA guidance notes that an investigator's drug brochure (IDB) is usually required by the FDA (21 CFR 312.23(a)(5) and 312.55). In addition, FDA guidance states that even though 21 CFR 56 does not mention the investigator's brochure by name, much of the information contained in such brochures is “clearly required to be reviewed by the IRB” (FDA Information Sheets at [http://www.fda.gov/oc/ohrt/irbs/faqs.html](http://www.fda.gov/oc/ohrt/irbs/faqs.html)). The FDA provides flexibility to IRBs regarding when IDBs are required to be submitted, the format for submission, and how the IRB assesses the brochures.

When to Submit IDBs Versus Package Inserts

If a research study involves testing or evaluating a drug or drugs, an IDB should be provided to the IRB for any drugs for which an IND was issued at the time of initial review with updates to these documents provided as described below. For any drugs being tested or evaluated as part of the research that are FDA-approved, the study team should provide the IRB with package inserts rather than IDBs. Revised package inserts that contain information relevant to the research study should be provided when they are issued as New Information Reports when no changes to the IRB application or other materials are required or as Changes of Protocol when updates to the IRB application or other materials are needed. In some cases IDBs are created for drugs under study even if the drugs are FDA-approved. IDBs are required to be provided to the IRB in these cases only if the study sponsor requires the study team to do so or there is substantive information in the IDB (e.g., efficacy and safety of the drug in the subject population for the study) that is not within other documents provided to the IRB. Please see the IDB and Package Insert Decision Tree [insert hyperlink] for assistance in determining which documents should be provided to the IRB.

When to Submit Revised IDBs as a Change of Protocol

If a study team was required to submit an IDB at the time of the initial review of the research study, updated IDBs also must be submitted to the IRB. How and when study teams should submit these IDBs to the IRB depends on the whether the IDB includes revisions that:
1. affect the risk/benefit ratio of the study (i.e., will result in a change to the study documents);
2. affect alternatives to study participation for subjects; OR
3. represent new information that should be provided to subjects.

If the revised IDB contains revisions that meet any of the criteria listed above, the revised IDB AND the accompanying changes to the study documents should be submitted to the IRB via a change of protocol within 60 days of receipt by the study team.

- The change of protocol form should describe the revisions to consent documents and/or protocol as well as any documents that provide new information to subjects (e.g., letters to participants). The revised IDB should be uploaded in the IRB application, replacing the version provided to the IRB previously.
- In addition, research teams should submit any IDBs that had not been submitted previously to the IRB at that point. For example, a research team may have received updated IDBs since the study's initial approval but not submitted to the IRB yet because the revised IDBs were judged to not 1) affect the risk/benefit ratio of the study (e.g., result in a change to the protocol); (2) affect alternatives to study participation for subjects; or (3) represent new information that should be provided to subjects.

**When to Submit Revised IDBs as a New Information Report**

In the rare cases where a revised IDB will affect the risk/benefit ratio of the study, but the associated revised study documents are not yet available to the study team, the study team should alert the IRB of the revised IDB via a new information report within 14 business days of its receipt. The associated revised study documents and accompanying IDB would then be submitted, together, as a full change of protocol within 60 days of receiving the revised study documents.

**When to Submit Revised IDBs at Continuing Review**

Revised IDBs may be submitted at continuing review if:

1. The revised IDBs do NOT contain revisions that (1) affect the risk/benefit ratio of the study for local study subjects (i.e., will result in a change to study documents); (2) affect alternatives to study participation for local subjects; or (3) represent new information that should be provided to subjects; or
2. The information contained in the revised IDBs has already been assessed by the IRB (e.g., through a change of protocol)

In these cases, research teams will be required to upload an IDB log to the continuing review form in ARROW. The log should include a brief summary of the revised information in all IDBs that have been received either since the initial review or last continuing review (whichever was most recent) AND have not been submitted to the
IRB previously. As part of this form, study teams will be asked to explain why the IDBs that were assessed did not meet any of the 3 criteria noted above that would require submission prior to continuing review.