**Investigator's Brochure (IB)**

January 2017

**Background:**

Per FDA regulations [21 CFR 312.23 (a)(5)] and [21 CFR 312.55], before investigators engage in a sponsored study to conduct a clinical investigation involving an IND, the sponsor shall give each participating clinical investigator an investigator brochure. The Investigator's Brochure (IB) must contain the following information:

1. A brief description of the drug substance and the formulation, including the structural formula, if known.
2. A summary of the pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans.
3. A summary of the pharmacokinetics and biological disposition of the drug in animals and, if known, in humans.
4. A summary of information relating to safety and effectiveness in humans obtained from prior clinical studies. (Reprints of published articles on such studies may be appended when useful)
5. A description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and or precautions or special monitoring to be done as part of the investigational use of the drug.

**Q: Does the Investigator need to submit the Investigator’s Brochure (IB) to the IRB?**

Yes, the most current version of the IB must be included with submission of the study to the IRB.

**Q: What if the sponsor revises the IB, does the revised IB need to be submitted to the IRB?**

Yes, IB’s are frequently updated during the course of the study, and sponsors require that these updated IB’s get submitted to the IRB for review and approval.

**Q. How are IB’s submitted to the IRB?**

The IB will be submitted as a revision within myIRB if the changes require updates to the protocol and consent(s). The Investigator should provide a summary of the changes. The revised protocol and consent(s) can be included with this revision.

If the IB is revised for administrative reasons only (information that does not fall in to one of the 5 categories above), the IB can be submitted as a “Miscellaneous” item within myIRB. A summary of the changes from the investigator is still required.