Revised Investigator’s Drug/Device Brochure Form

Section I: Header Information

CHRMS #: The IRB number should be placed here.
Protocol/Project Title: The title should reflect the title on the research protocol.
Investigator Information: The name of the local principal investigator should be placed here.

Section II: Check What is Being Submitted

The submission is either a revised brochure with a new version date or batched IND Safety Reports. Check whichever is appropriate.

Section III: Does the New Information...

The update needs to be reviewed by the PI to determine if the revision or the safety reports indicate a higher risk than originally estimated. If yes, an explanation is required.

Section IV: Based on the New Information...

The PI needs to review the new information and the currently approved consent document to determine if the consent document needs to be updated as a result of the new information. All revisions to the
consent document need to be reviewed and approved by the IRB prior to use.

Section V: Should Subjects Currently in the Study...

The PI needs to determine if currently enrolled subjects need to be updated with regards to this new information and if so, indicate how and how soon the new information will be conveyed to those current subjects. **Revised consents, consent addendums, or informational sheets all require review and approval by the IRB prior to use.**

Section VI: Check Below Attachments which Pertain...

This section was included for documentation purposes for the sponsors and to assist in our record keeping. If there is a revised IDB, attach a double-sided copy, check this box and provide the edition date and number if applicable. If you are submitting batched safety reports, attach a copy of the safety reports double-sided, a completed Summary Table along with the date of the table.

Section VII: Amendment

If the revision required a change to the protocol procedures or the consent document, you need to complete a “Request for Modification/Amendment to an Approved Protocol” attached the revised protocol and/or consent and submit along with this revised brochure form. Simultaneous submissions ensure that the corresponding changes have occurred appropriately.

Section VIII: Principal Investigator Signature

PI needs to sign the form prior to submission.