Investigator's Brochure (IB) and Package Inserts

For investigational and FDA-approved drugs/biologics, you may need to submit IBs and package inserts to provide the IRB with sufficient information to assess regulatory criteria for approval. Note that you should review OHSRP Policy 801 – Reporting Research Events as some IBs and package inserts may require a Reportable New Information (RNI) submission in addition to a Modification to the protocol.

- **Initial review requirements**
  - If a research study involves testing or evaluating drug(s)/biologic(s) and their use in the research is covered under an IND, an IB should be provided to the IRB, if available. 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 IBs if no IB is available.
- **Modifications**
  - Updates to the IBs and/or package inserts must be submitted as a modification (MOD) to the IRB within the time frame outlined in Policy 500 - Research Involving Drugs, Biological, and Nutritional Products when the revisions will:
    - update the potential risks of the study (i.e., will result in a change to the study documents);
    - affect alternatives to study participation for subjects; OR
    - represent new information that should be provided to subjects.

- **Continuing review requirements**
  - Revised IBs/package inserts may be submitted at continuing review via a MOD/CR in PROTECT if:
    - The revised IBs/Package Inserts do NOT contain revisions that would require a change as described above. Or
    - The study is permanently closed to enrollment, no subjects are on treatment, and the revised IB and/or package insert contains no new information that would affect past subjects (e.g., new latent risks).
  - In these cases, you must provide a summary of changes with the MOD/CR.
    - The summary of changes should include the revised information in the document (either IB or package insert) as compared to the most recent version of the document the IRB has on file as well as an explanation why the document did not meet any of the criteria noted above that would require submission prior to continuing review.