Subject: Procedure for Initial Application Materials to be Reviewed by the Full IRB Committee

Procedure:
This procedure outlines the initial application materials to be reviewed by the full IRB Committee in order to make preliminary or final determinations on the approval of the proposed research activities.

I. Investigator Responsibilities.
   A. The following materials are to be provided by the Investigator in order for the IRB Committee to obtain information in sufficient detail to make the preliminary or final determinations required by the Federal regulations for research approval:
      1. A completed IRB application to include PI and department Chair, or division Chief signatures and conflict of interest statement;
      2. The full sponsor’s protocol and Investigator’s brochure, if applicable;
      3. Informed consent documents and/or scripts, as appropriate (If NIH, include NIH-approved sample informed consent document.);
      4. Supplemental information pertaining to vulnerable populations;
      5. Copies of all research instruments (e.g., surveys, questionnaires, videotapes);
      6. Copies of all letters of cooperation or IRB approval letters for each research site, if applicable;
      7. The Investigator’s study protocol if not defined in detail within the grant;
      8. Relevant scientific portions of the grant, if applicable;
      9. Relevant sections of the contract, if applicable, including subject injury language and costs to the research participants;
      10. Investigator's brochure, including compounding information if applicable;
      11. Device Manual, if appropriate; and
      12. All advertising materials intended to be seen or heard by potential participants, (e.g., email solicitations, TV/radio spots, flyers/brochures).
   B. Investigators will assist the IRB reviewers/staff in obtaining additional information as requested.
   C. The IRB may require the Investigator to:
      1. Summarize specific information contained in the grant application and cross-reference to the IRB application;
      2. Identify any IRB-approved protocols that describe the proposed research; and
      3. Either certify that the grant application or proposal is consistent with any corresponding IRB protocols or submit protocol amendments to reconcile any discrepancies.
   D. If NIH-supported research, the Investigator must:
      1. Justify in writing any deletion or substantive modification of information concerning risks or alternative procedures contained in the NIH-approved sample ICD.
      2. Provide details of the proposed involvement of humans in the research, including the characteristics of the subject population, anticipated numbers, age ranges, and health statuses. The proposed research should specify the gender and racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any sub-population.

II. IRB Committee Responsibilities.
   A. The following materials will be distributed to and reviewed by the Primary and Secondary Reviewers for presentation at the full IRB Committee meeting. These materials should be received by members sufficiently in advance of the meeting date to allow review of the material and the request of additional information, if needed;
1. A completed IRB application to include the PI and department Chair’s signature and conflict of interest statement;
2. The full sponsor’s protocol and Investigator’s brochure, if applicable;
3. Informed consent documents and/or scripts, as appropriate (if NIH, include NIH-approved sample informed consent document.);
4. Supplemental forms pertaining to vulnerable populations;
5. Appropriate reviewer comment forms to document their comments;
6. Copies of all research instruments (e.g., surveys, questionnaires, videotapes);
7. Copies of all letters of cooperation or IRB approval letters for each research site, if applicable;
8. The Investigator’s study protocol if not defined in detail within the grant;
9. Relevant scientific portions of the grant, if applicable;
10. Relevant sections of the contract, if applicable, including subject injury language and costs to the research participants;
11. Investigator’s brochure, if provided;
12. Device Manual, if applicable; and
13. All advertising materials intended to be seen or heard by potential participants, (e.g., email solicitations, TV/radio spots, flyers/brochures).

B. All Committee Members have access electronically to the same documents provided to the Primary and Secondary reviewers.
   These materials should be received by members sufficiently in advance of the meeting date to allow adequate time for review and the request of additional information, if needed.

C. If a grant exists, the Primary and Secondary Reviewer should review the grant application, if any, to ensure that the research described in the IRB application is consistent with the grant application. The grant application does not need to be reviewed by every IRB Committee member. A copy of the grant application or proposal is retained in the database and made available to any IRB members who may wish to review it.

D. If NIH-supported, the IRB Committee must receive and review a copy of the NIH-approved sample informed consent document (ICD) and the full NIH-approved Investigator’s protocol as a condition for review and approval of the local ICD. In addition, if any deletions or substantive modification of information concerning risks or alternative procedures contained in the sample ICD, they must be approved by the IRB Committee.

E. If a contract exists, the Primary and Secondary Reviewer should review the contract pages that state the subject injury language and the costs for which the research participant will be responsible. They should verify that the language in the contract is consistent with the language in the ICD. In addition, they should verify the language in the ICD is understandable to the subjects participating in the research.

III. Investigational Drug Service (IDS) Representative Responsibilities.
A. To adequately evaluate the use of investigational agents in research, the IDS representative will receive:
   1. The same review materials as the Primary and Secondary Reviewer;
   2. All drug-related adverse events or unanticipated problems to the subject or others that have occurred since the last review will be included, if applicable; and
   3. The Pharmacy reviewer comment form.

B. The IDS representative will retain all copies of the investigator’s/sponsor’s protocol and investigator’s brochure for pharmacy records, as applicable.

IV. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will verify that all of the required documents as described in the Investigator’s section of this policy have been submitted.
B. The RCA will verify that appropriate signatures have been obtained.
C. Additional requests will be sent via e-mail to the Investigator.
D. The RCA will complete the pre-review process.
E. When all requested revisions are received, the RCA assigns appropriate reviewers and assures appropriate materials are available. Reviewers are electronically notified once assigned.
F. If NIH-supported, any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample ICD must be approved by the IRB Committee and reflected in the IRB Committee minutes.