Subject: Procedure for IRB Review of Human Subjects Research – Full Committee

Procedure:
This procedure provides guidance for the review of human research activities that qualify for Full IRB Committee review under the federal regulations.

I. Investigator Responsibilities.
   A. The Request for “Application for Human Research” is completed in its entirety and submitted for processing. The application and instructions for completion are located on the IRB Website: http://www.mc.vanderbilt.edu/irb/.
   B. A separate protocol is required for all studies submitted for IRB review regardless of the type of review. The sponsor’s protocol may be used if it is in sufficient detail to include all of the required elements (See the Health Sciences Sample Protocol and the Behavioral/Social Sciences Sample Protocol under the IRB Forms Section of the HRPP Website at http://www.mc.vanderbilt.edu/irb/).
   C. The Consent form(s) may be written using the template informed consent document. Instructions for writing informed consent documents are located on the HRPP Website under the Forms Section.
   D. Studies that include vulnerable populations are submitted with supplemental information demonstrating added protections and a rationale as to why these populations are to be included in the proposed research. The populations include:
      1. Prisoners;
      2. Pregnant women, human fetuses, neonates and fetal material;
      3. Children; and
      4. Cognitively impaired.
   E. The Investigator replies to all requests for revisions and/or clarifications requested by the pre-reviewers or reviewers, when applicable. If the Investigator does not make the recommended changes, he/she needs to provide the rationale in writing to the IRB.
   F. Any proposed changes to IRB approved documents are submitted to the IRB using the “Amendment Request”. The Investigator receives written IRB approval before implementing any changes to the research study (See HRPP Policy III.J).
   G. All serious adverse events and unanticipated problems to participants or others are submitted to the IRB using the “Report of Unanticipated Problems Involving Risk to Participants or Others”.

II. IRB Committee Responsibilities.
   A. The assigned IRB Committee receives a copy of the research application prior to the scheduled meeting to allow adequate time for review and the request of additional information, if needed (e.g. supporting documentation from the Investigator, literature search, etc.).
   B. IRB members and consultants with a conflict of interest state so at the beginning of the meeting and should absent themselves from the meeting room during the discussion and vote on the research in which they have a conflicting interest. In order to avoid conflicts of interest, (i) no participating IRB Committee member or consultant may hold a significant equity interest (e.g., partnership, stock, or profit-sharing) in the organization requesting IRB Committee review; (ii) no participating IRB Committee member or consultant may be paid more than reasonable compensation or receive more
than reasonable benefits for IRB-related activities; and (iii) no IRB Committee member or consultant may receive compensation or benefits under arrangements that could impede or discourage objective decision-making on behalf of human subjects (See HRPP Policy VII.C).

C. Each study is assigned a Primary and Secondary Reviewer. The reviewers assigned will have expertise in the area of the research adequate to the scope and complexity of the research. The Reviewers conduct an in-depth review of all pertinent documentation.

1. The Primary Reviewer is to present the study in summary form to the full IRB Committee highlighting any controverted issues and recommending modification, if applicable.
2. The Secondary Reviewer is prepared to provide any additional information not presented by the Primary Reviewer highlighting any controverted issues and recommending modifications, if applicable.
3. If the Committee does not have a member available with expertise adequate to the scope and complexity of the research, a consultant with expertise in the area of research will be asked to review the study and provide written recommendations or may be asked to attend the Committee meeting.

The consultant may not count toward the quorum or vote.

4. The Reviewers will assess the protocol for both scientific and scholarly merit in relationship to the level of risk.
5. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, the IRB Committee determines if additional safeguards need to be included in the study to protect the rights and welfare of these subjects (See HRPP Policies under Section IX of the Table of Contents).

6. All Committee members are given the opportunity to review, ask questions of the reviewers, and request modifications in the proposal.

7. The Committee reviews the proposed research, consents, and applicable documents to determine whether the study meets criteria 45 CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111 if applicable, for approval. In order to provide written documentation of these criteria, the Primary Reviewer completes the "Reviewer's Comment" form detailing how each of these criteria is met.

8. The Committee determines the review interval appropriate to the degree of risk, but not less than once per year.

9. It is typically, although not required, the Primary Reviewer who makes the motion regarding the status of the study in accordance with applicable HRPP policies and procedures (See HRPP Policy III.B).

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA conducts a pre-review for studies submitted requesting full Committee review. If the RCA determines that the study meets criteria for exempt or expedited review, the Investigator is contacted and the appropriate forms submitted. The RCA requests any additional documents needed for the review, as well as any pre-review changes.

B. E-mails requesting pre-review changes are sent by the RCA to the Investigator.

C. Once the pre-review changes are received from the Investigator, the RCA places the new study on the next available Committee agenda, assigns reviewers and assures appropriate materials are available. Reviewers are electronically notified once assigned.

D. The RCA assigns reviewers with expertise in the area of the research adequate to the scope and complexity of the research. If the Committee does not have at least one member available with expertise adequate to the scope and complexity of the research, the RCA assists in arranging review by a consultant with the required expertise. The RCA may be asked to arrange for the consultant to attend the Committee meeting. The consultant may not count toward the quorum or vote.

E. The RCA disseminates the following documents for all Committee Members to review:

1. The cover letter submitted, if applicable;
2. The IRB application;
3. Consent documents;
4. All attached documents; and
5. Any pertinent information (e.g., questionnaires, advertisements, communications with the Investigator or study personnel).

Additionally, the primary and secondary reviews receive:
6. The protocol;
7. The Investigator’s brochure, if applicable; and
8. The Grant, if applicable.

F. The RCA captures the quorum status, discussion of controverted issues, recommendations, determinations, motions, and votes for each study reviewed during the Committee meeting in accordance with applicable HRPP policies and procedures. The minutes of the IRB Committee meeting clearly reflect the determinations regarding risk and approval period (review interval). If a member has a conflict of interest, it is noted in the minutes that a conflict exists and the Committee member was absent during the discussion and vote for that specific research study.

G. Letters requesting revisions from reviewers, and final approval letters are drafted using the appropriate template and forwarded to the IRB Chairperson or his/her Designee for signature.

H. Amendments, adverse events, and continuing reviews are completed per corresponding policies and procedures.

I. Appropriate database entries are completed.