Subject: Procedure for Grant and Umbrella Review

This procedure provides guidance on the submission, approval, and maintenance of a Grant or Umbrella review.

I. Investigator Responsibilities.
   A. An Investigator who is awarded a grant and desires to distribute the funding among sub-studies will submit the "Request for Grant or Umbrella Review" to the IRB. The form and its instructions for completion are located on the IRB website at http://www.mc.vanderbilt.edu/irb/.
   B. The Investigator submits a copy of the grant with the Grant or Umbrella Review application. Copies of this grant should be provided to each Investigator submitting sub-studies under this grant proposal as it will be required as part of the IRB submission for each sub-study.
   C. The Investigator will indicate the titles of any known sub-studies that will be submitted for IRB review after the Grant or Umbrella is approved by the IRB. If the sub-studies are not yet identified by title, the Investigator should indicate the number of anticipated studies to be submitted at a later date. Currently approved IRB studies being incorporated under the grant are to be indicated in the Grant or Umbrella Review application by IRB number and study title.
   D. At the time of continuing review, the Investigator will provide a list of all sub-studies under the Grant or Umbrella Review by title and IRB number.

II. IRB Committee Responsibilities.
   A. The IRB may review the request for the establishment of a Grant Review through expedited procedures.
   B. Continuing review is completed at least once a year and may also be reviewed through expedited procedures.
   C. In the case of expedited review, the reviewer will complete a reviewer comment form annually to document re-assessment of the 45 CFR 46.111 criteria.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will pre-review all applications requesting the review and approval of a Grant or Umbrella request.
   B. The RCA will verify that copies of the awarded or grant proposal have been provided.
   C. The RCA will prepare the Grant Review request for review by the Chairperson or his/her designee.
   D. For Umbrella Reviews, the analyst will verify a copy of the grant proposal has been submitted along with the request and will utilize the non-research proposal approval process for review.
   E. For Grant Reviews, the analyst will prepare the Final Approval Letter and forward to the Chairperson or his/her designee for signature.
F. The RCA will complete appropriate database entries, including Committee notification of approval on the next available agenda. In addition, the RCA will enter all sub-studies included with this grant in the HRPP database.

References
HRPP III.H - Grant Review