Policy

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: V.B
Section: Records, Documentation, and Fees
Review Responsibility: HRPP Policy and Procedure Committee
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Revision Dates: March 19, 2004; December 20, 2006; July 1, 2015

Subject: IRB Fees for Industry-Supported Applications

Definitions:
Industry-Supported: When a commercial entity contributes to the design or conduct of the study (as evidenced by a sponsor’s protocol, sponsor’s identification number and/or Investigator’s brochure); coordinates the study as a multi-center trial; reimburses VU, VUMC or a VU or VUMC Investigator for costs associated with conducting the trial; or will have access to, or publish or present the data gained from conducting the trial.

Policy:
It is the policy of the Human Research Protections Program to assess a fee for all industry–supported initial IRB applications, continuing review applications, and amendments submitted to the IRB requiring full, convened IRB Committee review or expedited IRB review.

I. The HRPP will assess a charge for all industry-supported research submissions requiring full, convened IRB Committee review or expedited IRB review, with the exception of serious and unexpected adverse events and unanticipated problems involving risks to participants or others, protocol deviations, data and safety monitoring reports that do not require major amendments, administrative changes, and responses to IRB reviews.
   A. All initial study submissions to the IRB must identify the funding sources supporting the proposed research.
   B. When an IRB submission is received and is not designated as industry-supported, but is later determined by the IRB to be industry-supported, appropriate IRB fees will be assessed.
   C. Billing information must be received within 120 days of submission to the IRB or the IRB has the authority to refuse to process additional applications from the Investigator.

II. IRB applications that are solely dependent on state, federal, non-profit foundations, or internal funds will be excluded from IRB fees.

III. Under extenuating circumstances, the HRPP Director may waive the assessment of IRB fees with a formal request from the Investigator and appropriate documentation to support such circumstances.

IV. It is expected that Investigators incorporate and negotiate applicable IRB fees into the research contract. Fees are expected in a timely manner.