Subject: Procedure for IRB Fees for Industry-Supported Applications

Procedure:
This procedure outlines the process for the charging and collection of IRB fees associated with industry-supported research activities reviewed by the full, convened Committee of the IRB or by expedited IRB review.

I. Investigator Responsibilities.
A. The Investigator will complete the funding information section of the "Application for Human Research", the budgetary authorization section of the "Application for Continuing Review or Study Closure", or the budgetary authorization section of the "Request for Amendment" as applicable.
B. The Investigator will promptly respond to invoice requests for payment of IRB associated fees.
C. The Investigator requesting a waiver of IRB fees may send a detailed letter to the HRPP Director describing the extenuating circumstances for which the waiver is requested.
D. The Investigator is responsible for informing the HRPP Director of any expected delays in the payment of IRB fees.

II. HRPP Administrative Assistant (AA) Responsibilities.
A. The AA will create invoices as follows:
   1. The AA will check the invoicing database weekly for new entries. With each new entry, an invoice will be generated and faxed to the Investigator with a request to complete the invoice and return to the HRPP as follows:
      a) If a VUMC department is paying the IRB fee, the VUMC-specific invoice should include the billing information and the signature of a departmental person with budgetary authority to authorize payment processing. Checks payable to the HRPP or IRB are not accepted; or
      b) If this is an IRB fee for Stallworth or any other external site that VUMC serves as the IRB of Record the invoice will include instructions to attach a check made payable to the "VUMC IRB" in accordance with the terms defined in the signed MOU.
   2. Documentation of invoice generation is automatic within the database; however, the AA will document the date each invoice was sent in the appropriate field in the electronic invoice.
B. Upon receipt of the completed invoice from the Investigator, the AA will update the database with the billing information. The invoices and checks (if applicable) will be collected upon receipt by the AA and then forwarded for processing.
C. If the fee is being paid from a VUMC departmental account, documentation will be sent to the Department of Finance for approving payment processing.
D. If the fee is being paid from a VUMC departmental account, the charges are uploaded (those charges with complete information) via the general ledger system. The database will be updated for each charge that has been processed by completing the field "Date Uploaded."
E. If an external site for which the VUMC IRB is serving as the IRB of record is paying the fee these checks are forwarded to the Department of Finance for processing. The date the check was sent to the Department of Finance is
documented in the electronic invoice.

F. In the event an invoice has not been paid as requested, upon the 90th day from the original invoice date, the HRPP will contact the Investigator to determine the reason for the delay, obtain the billing information and document the interaction. Additionally, the HRPP will send a written reminder to the Investigator. The reminded will request billing information and inform them if payment is not received within 30 days, the HRPP Director will be notified of the past due status. The HRPP has the authority to refuse future applications. If the Investigator wishes to request a waiver of fees, the Investigator will be instructed to send their request to the HRPP Director in writing.

G. In the event the billing information has not been received within 120 days, the AA will generate a letter from the HRPP Director informing the Investigator that future submissions will not be accepted until the billing information has been provided or a waiver of the fee has been granted. The IRB database will provide a view of those Investigators from whom submissions will not be processed.

H. In addition to the letter from the HRPP Director, phone contact is made with the Investigator when billing information for a submission has not been received within 120 days. A request to the Investigator is made to provide a written plan for payment with a deadline. These phone contacts will occur every 30 days thereafter until payment is received. All correspondence with the Investigator will be thoroughly documented in the database as follows:

1. The name of the person contacted;
2. The date of the phone contact;
3. A history of the telephone discussion; and
4. A record of all other modes of communication (e.g., letters, study contact phone calls, etc.).

I. The HRPP Director is notified when an invoice becomes 120-days delinquent and the Investigator has failed to submit a plan for payment. In addition, a monthly report to the is provided to the HRPP Director which includes the following: IRB number and title for each study greater than 120 days past due by Investigator, the number of days past due, the date the 90-day letter was sent, the date the 120 day letter was sent, the dates of all telephone contacts, the Investigator’s response, and any other pertinent information. The HRPP Director will use this information to make an informed decision on whether to disallow further IRB submissions by the Investigator until payment has been made.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will verify the funding source by comparing the information submitted in the "Application for Human Research" with the study proposal, grant, Investigator’s brochure, or Investigator’s or sponsor’s protocol.

1. When the RCA is unclear of the funding source based on submitted documents, he or she will contact the Investigator for clarification.
2. When the RCA determines that the Investigator did not provide adequate information and the study is industry-supported, the AA will initiate an invoice.

B. The RCA will verify that the AA has invoiced amendments requiring full convened IRB Committee review.

C. At the time of continuing review, the RCA will verify that the funding source has not changed necessitating withdrawal of charges for studies that are no longer funded by industry or initiate a charge for those studies that are now industry-supported.