Policy:
Effective April 1, 2012, it is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to assess a fee for all fully or partially industry supported initial IRB applications and continuing review applications submitted to the UCI IRB requiring IRB Committee review.

I. The UCI IRB will assess a charge for all fully or partially industry-supported IRB submissions requiring initial and continuing review that meet the following criteria:
   A. Designed to assess the safety, efficacy, benefits, adverse reactions, and/or other outcomes of drugs, devices, diagnostics, treatments, procedures, medical evaluations, monitoring or preventive measures; and
   B. Fully or partially supported by an industry sponsor; and
   C. Meets UCI contractual requirements for industry-supported clinical trials.

   The fee structure is as follows:
   1. Initial full committee IRB review and approval - $2200.00
   2. Initial expedited review and approval - $1000.00
   3. Continuing review – full committee - $825.00
   4. Continuing review – expedited - $500.00
   5. Continuing review 7 year de novo – full committee - $1500.00
   6. Continuing review 7 year de novo – expedited - $725.00

   D. All initial study submissions to the UCI IRB must identify the funding sources supporting the proposed research.
   E. When an IRB submission is received and is not designated as fully or partially industry-supported, but is later determined by the IRB to be industry-supported, appropriate IRB fees will be assessed.

II. IRB applications received prior to April 1, 2012 will be charged at the previous rate, according to the following prior criteria:
   A. Designed to assess the safety, efficacy, benefits, adverse reactions, and/or other outcomes of drugs, devices, diagnostics, treatments, procedures, medical evaluations, monitoring or preventive measures; and
   B. Fully supported by an industry sponsor; and
   C. Meets UCI contractual requirements for industry-supported clinical trials.

   The fee structure for applications received prior to April 1, 2012 is as follows:
   1. Initial full committee IRB review and approval - $1000.00
   2. Initial expedited review and approval - $500.00
   3. Continuing review – full committee - $500.00
   4. Continuing review – expedited - $500.00
III. The IRB will not impose a fee for review of modifications/amendments, unanticipated problems involving risks to participants or others, closing reports, data safety monitoring reports, or responses to IRB reviews.

IV. IRB applications that are dependent on State, Federal, non-profit foundations, or fully supported by non-Industry Sponsor funds will be excluded from IRB fees.

V. Under extenuating circumstances, the Associate Vice Chancellor for Research Administration may waive the assessment of IRB fees with a formal request from the Investigator and appropriate documentation to support such circumstances.

VI. It is expected that Investigators incorporate and negotiate applicable IRB fees into the research contract.

VII. IRB fees will be assessed as recharges to the account and fund number assigned to the research study. E-mail notification is provided to the investigator and the department business office regarding the amount and date of each charge.

VIII. The collected IRB fees provide benefits to the campus research enterprise in the form of enhanced educational services for researchers, IRB members and HRP staff. In addition, stipends are provided for IRB member participation.