

DEPARTMENT: Yale University Human Investigation Committee  
POLICY NUMBER:  
SECTION: HIC Operations / Billing  
REVIEW RESPONSIBILITY: Contract Administration and HIC Leadership  
ORIGINAL CREATION DATE: August 3, 2007  
REVISION DATE(S):

## **Yale University Policy Regarding Billing Human Subject Research Project for Review by the Human Investigation Committee**

### **I. Purpose:**

The purpose of this policy is to identify when the Human Investigation Committee (HIC) will charge fees for the review of a human subject research protocol submission.

### **II. Definitions:**

**Amendment**—Any change or modification to a currently approved protocol, including supplemental documents such as, but not limited to, informed consent documents, advertisements and investigator brochures.

**Initial Application**—The first submission of the collection of documents that constitute a written human subject research protocol. Documents include, but are not limited to, the HIC Application, the Investigator or Sponsor protocol or brochure, informed consent documents, advertisements and HIPAA authorizations and requests for waivers.

**Major Amendment**—The term “major amendment” is a Yale defined term used to identify and recover costs for the review of amendments that require a fully convened HIC. Typically amendments labeled as “major” are those that change the research-related activities in such a manner that the previous assessment of the risk-benefit ratio to subjects participating in the study is affected. Major amendments are also considered to be those that substantially change the specific aim(s), scope or design of the study. Examples of a major amendment include, but are not limited to:

- Broadening the range of inclusion criteria or populations
- Narrowing the range of exclusion criteria
- Changing the dose or administration method of a drug
- Substantially expanding the duration of the intervention(s) or the duration of exposure to the test material
- Adding new risks or possible adverse events to the protocol and consent document that are new to those already known to be potential risks or events

**Minor Amendment**— The term “minor amendment” is a Yale defined term used to identify and recover costs for the review of amendments by means of expedited review. Typically a minor amendment does not materially affect the assessment of the risk-benefit ratio to subjects participating in the study, nor does the amendment substantially change the specific aim(s), scope or design of the project. Examples of a minor amendment include, but are not limited to:

- New advertisement materials or advertisement methods
- An increase or decrease in the number of subjects targeted for enrollment
- Changes in the amount of, or method of, subject payment(s)
- A change in the study title
- Administrative and clerical changes to improve the clarity of consent documents

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- Adding or deleting study sites or study personnel
- Lessening the number or volume of biological sample collections or record reviews

**Non-Billable Amendment** —A term defined by Yale to identify amendments for which the HIC will not recover the cost to review amendment requests.

**Request for Continuing Review or Renewal** — A periodic review conducted by the HIC to ensure continued IRB approval of a research project. The frequency or interval at which continuing review is required is determined by the IRB and is no less than annually.

### III. Policy

The HIC charges the sponsor for services associated with the review of initial applications, requests for renewals and major and minor amendment requests when the research project is funded, for example, by a commercial, for-profit company or other qualified entity per Grants and Contracts Administrator determination.

The HIC reserves the right to bill for protocol review services rendered to investigators who are not full-time Yale faculty members, but who wish to utilize HIC services.

### IV. Procedure

#### Billing Fees

The HIC's review of certain amendments is billable to some research sponsors. In particular, the HIC bills the sponsor for the review of amendment requests when the research project is funded by a commercial, for-profit company. The IRB fees are negotiated into the project contract by the Yale University Grants and Contracts Administrator. The company is billed according to the HIC's billing schedule in place at the time the contract is negotiated. (For current billing schedule, [see http://www.info.med.yale.edu/hic/forms/forms/FEE\\_SCHEDULE\\_FOR\\_IRB\\_REVIEW\\_OF\\_INDUSTRY\\_3-28-07.pdf](http://www.info.med.yale.edu/hic/forms/forms/FEE_SCHEDULE_FOR_IRB_REVIEW_OF_INDUSTRY_3-28-07.pdf).)

Generally speaking, the company will be billed at the major amendment rate when the amendment requires review by the fully convened HIC. The company will be billed at the minor amendment rate when the amendment request qualifies for expedited review. In some instances the company will not be billed for the review of an amendment. Such instances are considered non-billable amendments. Non-billable amendments are those initiated by a Yale investigator for operational purposes such as adding or deleting Yale research team members to the project and revising contact information on protocol documents.