**Policy Number: 47:**
**Title: Billing of Research Participants**
**Date of Last Revision: 05/01/2006, 08/05/2010, 05/03/2021, 09/16/2022**

## Policy

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to ensure that research participants or their insurers are not billed for research-related costs unless specifically approved by the FDA.

I. The IRB has authority to evaluate, on a study-by-study basis as part of the initial review process, whether research-related costs may be billed to subjects who participate in studies where the experimental intervention is thought to be the most appropriate course of treatment for the subjects/patients and where no other funding (e.g., sponsor support) is available to cover such costs.
   A. Participants or insurers should not be charged for research-related costs associated with participation in:
      1. Phase I studies, except trials in which the experimental intervention(s) is/are considered the most appropriate treatment option;
      2. Phase II, III or IV studies, except trials where the experimental intervention(s) is/are considered the most appropriate treatment option and/or routine and customary care;
      3. Placebo-controlled studies; or
      4. IND or IDE studies, unless charging of subjects is approved by the FDA (*see below for a summary of FDA regulations on IND and IDE standards for subject billing*).

II. Participants or their insurance carrier (including MediCare/MediCal) should not be billed for an investigational/experimental procedure (i.e., not routine and customary) conducted as a part of a research study that is initiated and sponsored by a private, for-profit entity.

III. **FDA Regulations on IND and IDE Standards for Subject Billing**

   A. Charging for Investigational Medical Devices and Radiological Health Products – The IDE regulations allow sponsors to charge for an investigational device, however, the charge should not exceed the amount necessary to recover the costs of manufacture, research, development, and handling of the investigational device.
      1. The FDA generally allows sponsors to charge researchers for investigational devices, and this cost is usually passed on to the subjects.
      2. If charging for the product is permitted, researchers also may charge for related treatment or for services associated with the use of the product.
   B. Charging for Investigational Drugs and Biologics – Under the IND regulations, the FDA permits a sponsor to charge researchers for an investigational drug or biologic under certain circumstances.
      1. The charge should not exceed an amount that is necessary to recover

the costs associated with the manufacture, research, development, and handling of the investigational drug or biologic.

2. The FDA may withdraw authorization to charge if the Agency finds that the conditions underlying the authorization are no longer satisfied.
3. The FDA does not prohibit charging for marketed products that are used in clinical investigations.
4. If charging for the product is permitted, researchers also may charge for related treatment or for services associated with the use of the product.

C. Clinical Trials Under an IND

Participants/Insurers should not be charged for an investigational drug or biologic in a clinical trial under an IND without the FDA's prior written approval. In requesting FDA approval, the sponsor must explain why a charge is necessary, i.e., why providing the product without charge should not be considered part of the normal cost of conducting a clinical trial [21 CFR 312.7(d)(1)].

D. Treatment Protocol or Treatment IND

Participants/Insurers may be charged for an investigational drug or biologic for a treatment use under a treatment protocol or treatment IND, as outlined in 21 CFR 312.34 and 312.35, provided:

1. There is adequate enrollment in the ongoing clinical investigations under the authorized IND;
2. Charging does not constitute commercial marketing of a new drug for which a marketing application has not been approved;
3. The drug or biologic is not being commercially promoted or advertised; and
4. The sponsor is actively pursuing marketing approval with due diligence.
5. FDA must be notified in writing prior to commencing any such charges. Authorization for charging goes into effect automatically 30 days after receipt of the information by FDA, unless FDA notifies the sponsor to the contrary [21 CFR 312.7(d)(2)].

**References:**

21 CFR 312.7(d)
21 CFR 812.7(b)
FDA Information Sheets – Guidance for Institutional Review Boards and Clinical Investigators Charging for Investigational Products 1998 Update

**Procedure Number: 47.A**
**Title: Procedure when Requesting Billing of Participants for Research-Related Costs**

**Procedure:**
This procedure outlines the process for review and approval for billing participants or their insurance for research-related costs.

I. **Lead Researcher (LR) Responsibilities**

A. The Lead Researcher will provide all information regarding the billing of research participants or their insurance in the initial IRB Application (including attachments). This will include:
   1. Description and estimates all anticipated costs.
   2. Justification for billing participants and/or their insurer.

B. The Lead Researcher will develop a consent form that describes and estimates all anticipated costs for which participants, or their insurers would be responsible.

C. The Lead Researcher provides documentation that the FDA approved the charging of research participants.

D. Evidence of cost analysis review must be available in the research record prior to the initiation of the research. The IRB may require cost analysis review prior to IRB review, on a case-by-case basis.

II. **IRB Committee Responsibilities**

In evaluating whether billing of subjects/insurers for research-related costs may be appropriate, the IRB uses the following guidelines:

A. Participants or insurers should not be charged for research-related costs associated with participation in:
   1. Phase I studies, except trials in which the experimental intervention(s) is/are considered the most appropriate treatment option;
   2. Phase II, III or IV studies, except trials where the experimental intervention(s) is/are considered the most appropriate treatment option and/or routine and customary care;
   3. Placebo-controlled studies; or
   4. IND or IDE studies, unless charging of subjects is approved by the FDA (*see below for a summary of FDA regulations on IND and IDE standards for subject billing*).

B. Under no circumstances should a participant or his/her insurance carrier (including MediCare/MediCal) be billed for an investigational/experimental procedure (i.e., not routine and customary) conducted as a part of a research study that is initiated and sponsored by a private, for-profit entity.

C. The IRB may review, on a case-by-case basis, the appropriateness of billing participants/insurers for research-related costs generated by studies that are partially-supported by private sources but which are designed and initiated by University faculty.
   1. For purposes of this guidance, “initiated by” means that the design of the experiment originated with the faculty member and was not devised, suggested, proposed or instigated by an outside entity.

D. For all studies not specifically precluded from billing subjects, the IRB will carefully consider whether requiring participant/insurer billing is

reasonable, ethical, appropriate, fair, and is fully justified in the IRB Protocol.

E. The consent form must describe and estimate all anticipated costs for which participants/insurers would be responsible.

F. A participant/insurer should not be billed for treatment of adverse effects, complications, illnesses or injuries suffered as a result of the subject's participation in a research study, unless all three of the following conditions apply:
   1. The study is <u>not</u> initiated and sponsored by a private, for-profit entity;
   2. The experimental treatment(s) under study is/are considered the most appropriate treatment option or routine/customary care; and
   3. Billing the subject/insurer for the experimental procedure(s) that likely caused the illness/injury was determined by the IRB to be permissible.

I. **IRB Administrator Responsibilities**

A. The Administrator or designee will pre-review the IRB Application and applicable documents and request any necessary revisions.

B. The Administrator will assist reviewers in obtaining additional information that may be requested regarding the proposed billing practices from the LR.

C. The Administrator will document the Committee's rationale for the approved billing practices in the minutes.