

<b>SOP: RI 801</b> <b>Version No: 1</b> <b>Effective Date: 11/01/02</b>	<b>IRB-REQUIRED INVESTIGATOR</b> <b>ACTIONS</b>	<b>Policy Revised:</b> <b>07/06</b>
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## 1. POLICY

Between IRB initial approval of a protocol and the time of continuing review of a study, it is the Investigator's responsibility to keep the IRB informed of unexpected non-serious and serious adverse events and other unexpected findings that could affect the risk/benefit ratio of the research. An Investigator is responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events. Investigators are also responsible for informing government and other Sponsors of any unanticipated or serious adverse events, as appropriate.

### Specific Policies

#### 1.1 IRB Review of Research

All human subjects research that is conducted by or under the direction of any employee, faculty, staff, student or agent of Hackensack University Medical Center in connection with his or her institutional responsibilities must be reviewed by the IRB.

#### 1.2 Informed Consent

The Investigator must obtain informed consent from subjects prior to their enrollment into the research. The Investigator must use the informed consent document approved by the IRB. Approval and expiration dates are indicated on the first page of the consent document. Consent documents are valid only during the dates indicated on the form; and the Investigator may use the forms only during the period for which they are valid. Investigators must follow Hackensack University Medical Center's guidelines for obtaining informed consent.

#### 1.3 Adverse Event Reporting

The IRB must be informed of any serious, unexpected or alarming adverse events that occur during the approval period involving a Hackensack University Medical Center Subject within seven days of occurrence. Serious adverse events are defined as an event that causes death, prolonged hospitalization, permanent disability or congenital anomaly. Any deaths of HUMC patients require immediate (within 24 hours) reporting. An IRB form for reporting adverse outcomes is provided to the Investigator at the IRB Website [www.humed.com/irb](http://www.humed.com/irb).

Investigators or Sponsors must also submit Sponsor-generated reports of adverse events occurring at other investigative sites within fourteen days of receipt (if study is open or closed following patients) **if** the event

is definitely related or possibly related to the research protocol as deemed by the sponsor, lead investigator and/ or the DSMB.

#### **1.4 Changes in Approved Research**

Changes in approved research, during the period for which approval has already been given, may not be initiated without IRB review (or expedited review, where appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects. Investigators or Sponsors must submit requests for changes to the IRB in writing. If the change represents more than a minimal risk to subjects, it must be reviewed and approved by the IRB. Minor changes involving no more than minimal risk to the subject will be reviewed by the expedited review process if requested.

Examples of changes may include:

- \* Revised CVs/licensures for staff listed on the 1572 (if applicable)
- \* IND Safety Reports (initial and follow-up reports)
- \* Investigator Brochure (IB), updated IBs, and IB Addendum(s)
- \* Quarterly Safety Summary Reports
- \* SAE Reports (initial and follow-up) for study subjects consented at your site
- \* Protocol deviations/violations/exemptions for study subjects consented at your site
- \* Revised 1572s

#### **1.5 Periodic Reports**

The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Investigators are responsible for requesting renewal in anticipation of the expiration of the approval period. Investigators or their designees and/or Sponsors are required to provide a periodic report regarding their investigation prior to the end of the approval period, or upon completion of the study.

An IRB Continuing Review Report/Renewal Request Form will be available to the Investigator for this purpose.

#### **1.6 Student-Conducted Research**

As stipulated in Statement of Authority and Purpose (2.A), all activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree must be reviewed by the IRB. For example, activities that must be reviewed and approved by the IRB include: (i) All master's theses and doctoral dissertations that involve human subjects; and (ii) All projects that involve human subjects and for which findings may be published or

otherwise disseminated. All students/fellows applying for IRB review must obtain the signature of their faculty advisor on the IRB Application form.

### **1.7 Conflict of Interest**

The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. Therefore, the IRB should consider conflict of interest issues in its deliberations of applications.

All Investigators must reveal on their application to the Department of Research whether they or any other person responsible for the design, conduct, or reporting of the research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research. It is the Investigator's obligation to also report such conflicts to the Conflict of Interest Standing Committee.

## **2. SCOPE**

These policies and procedures apply to all researchers at the Hackensack University Medical Center.

## **3. RESPONSIBILITY**

IRB Manager, and IRB Regulatory Auditor are responsible for tracking Investigator compliance with IRB requirements stipulated during the IRB's review of the Investigator's research.

IRB Chairperson (or designee) is responsible for facilitating Investigator compliance with IRB requirements through his/her management of IRB deliberations, and providing Investigators clear guidelines pertaining to that compliance through IRB communications to the Investigator.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 56.109, 56.111

21 CFR 54

45 CFR 46.109, 46.111

OHRP COI Policy Draft

## **5. REFERENCES TO OTHER APPLICABLE SOPs**

This SOP affects all other SOPs.

## 6. ATTACHMENTS

RI 801-A Investigator Responsibilities – IRB Requirements  
RI 801-B Essential Documents

## 7. PROCESS OVERVIEW

Describe what the IRB requires of Investigators in the conduct of research.

Provide detailed instructions regarding prompt reporting to the IRB of changes in research activity.

Ensure that changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

## 8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Manager</i>	Provide Investigators with complete information package on preparing IRB submissions, securing initial and ongoing approval of research, and providing all required reports.	Investigator Responsibilities – IRB Requirements
	Contact Investigators as often as needed to assist in the development of submission materials and to secure all necessary information for ongoing IRB review and approval.	
<i>IRB Chairperson</i> <i>IRB Manager</i> <i>Department of Research</i>	Provide Investigators with appropriate training in preparing IRB submissions and in conducting the informed consent process and other subject protection activities	
	Identify Investigator non-compliance as soon as possible and initiate IRB sanctions.	
<i>IRB Secretary</i>	Distribute communications to and from Investigators to appropriate IRB staff and members in a timely manner.	