MASSACHUSETTS EYE AND EAR INFIRMARY
RESEARCH MISCONDUCT POLICY AND PROCEDURES

Preamble

The integrity of the research, clinical, and teaching programs of the Massachusetts Eye and Ear Infirmary (the "Infirmary" or "MEEI"), and the responsibility of the Infirmary to the scientific and academic communities, to patients, to funding and regulatory agencies, and to the public, require prompt, full and fair consideration of allegations of misconduct in research. This Policy and Procedures provides the framework within which the Infirmary will meet these obligations. Central to the letter and spirit of this Policy and Procedures and to the Infirmary's conduct in their application is the protection of the rights and reputations of all individuals, including the person who has made the allegation. This Policy and Procedures is to be construed in a manner which permits reasonable flexibility in addressing matters of varying nature and severity and involving differing institutions and agencies. It is the intent of the Infirmary that matters of alleged misconduct be resolved as promptly as circumstances permit and with fairness and objectivity and for all interested parties to have the opportunity to be heard.

Definition of Research

"Research" means a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating, or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Definition of Misconduct

"Misconduct", "research misconduct", or "misconduct in research" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted in the scientific community in proposing, performing, reviewing, or reporting research. (See definition of misconduct for Public Health Service funded activities below). "Fabrication" is making up data or results and recording or reporting them. "Falsification" is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. "Plagiarism" is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

Allegations of Misconduct

An allegation of research misconduct may come from any source. "Allegation" means a disclosure to the Infirmary of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication. Regardless of who first is made aware of an allegation of misconduct, the appropriate department Chief shall be immediately notified, as well as the President of the Infirmary and the Vice President Research Administration. Where the person against whom an allegation of research misconduct may be lodged is a Harvard faculty member or trainee, the Office of the Dean of the appointing Harvard faculty shall be notified. In consultation, these individuals shall determine whether the allegation falls within the definition of research misconduct and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If it does, the allegation will be referred to the MEEI Research Misconduct Committee and any coordinate Harvard committee. Ordinarily the Infirmary and Harvard will act jointly with respect to the application of these procedures and any related Harvard procedures. In a particular case, however, the Infirmary and Harvard may agree that one institution will take primary responsibility for conduct of an inquiry or investigation and for resolving an allegation of misconduct. In cases in which Harvard has primary responsibility, any report submitted to the Office of the Dean of the appointing Harvard faculty will also be submitted to the MEEI Research Misconduct Committee. When considering allegations involving physician members of the Infirmary's medical staff, all review bodies will be deemed to be "medical peer review committees" under relevant state law.

Research Misconduct Committee

The Research Misconduct Committee shall be comprised of a member of the full-time staff (clinical or research) appointed by the President of the Infirmary, a member of the Infirmary Board of Directors designated by the Chairman of the Board, the Vice President of Research Administration, and such other individuals who may be appointed by the President of the Infirmary following consultation with the Chiefs of Ophthalmology and Otolaryngology. The Research Misconduct Committee will be chaired by the Board of Directors' member and shall report its findings, conclusions and recommendations to the Board of Directors.

General Principles

In carrying out their responsibilities under this Policy and Procedures, the Research Misconduct Committee and all other MEEI participants in the research misconduct process will conform to the following principles:

(a) The necessity of responding to each allegation of research misconduct in a thorough, competent, objective and fair manner.

(b) The necessity of informing, at an appropriate time, appropriate officials of the Infirmary, including but not limited to legal counsel, of the existence of the allegations, and of consulting with such officials in the application of this Policy and Procedures.

(c) The responsibility of informing, consulting, cooperating and coordinating with affected institutions and agencies to the extent necessary to meet the obligations of the Infirmary, and to comply with this Policy and Procedures and with applicable laws or regulations.

(d) The responsibility to limit disclosure, to the extent possible, of the identity of persons against whom allegations have been made and those who in good faith have made allegations to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, as otherwise provided for in this Policy and Procedures, and as allowed by law.

(e) With respect to any records or evidence from which research subjects might be identified, the responsibility to maintain confidentiality, limiting disclosure to those who have a need to know to carry out a research misconduct proceeding, except as may otherwise be prescribed by applicable law.

(f) The need to undertake all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons against whom allegations have been made but against whom no finding of research misconduct is made.

(g) The need to protect the rights of the person(s) alleged to have engaged in misconduct including the right to be informed with specificity and at the appropriate time of the allegations and the procedures to be followed, as well as the right to review and comment upon draft reports as set out in this Policy and Procedures.

(h) The need to take all reasonable and practical steps to protect the positions and reputations of persons who, in good faith, raise allegations or participate in any way in a research misconduct proceeding, and protect them from potential or actual retaliation or other adverse consequences.

(i) The need to take all reasonable and practical steps to ensure the cooperation with research misconduct proceedings of those against whom allegations have been made and other members of the Infirmary community.

(j) The need to secure necessary and appropriate expertise, from inside and outside the Infirmary, to carry out a thorough and authoritative evaluation

of the relevant evidence, and the importance of using staff resources as appropriate, including legal counsel, to advise and assist in the application of this Policy and Procedures.

(k) The need to take precautions against unresolved personal, professional, or financial conflicts of interest on the part of those responsible for carrying out any part of the research misconduct proceeding with the person against whom an allegation has been made, the person who in good faith has made an allegation, or any witness.

(l) The need to broaden the scope of any research misconduct process beyond the scope of the original allegations when deemed necessary to meet the full obligations of the Infirmary, and to fully and promptly notify the person alleged to have engaged in misconduct of any material expansion of the process and the reason for it.

(m) The need to maintain adequate records for a research misconduct proceeding under this Policy and Procedures, including research records and evidence, and to maintain appropriate custody, security, and confidentiality of those records.

(n) The importance of providing for the inclusion of minority opinions in reports generated under this Policy and Procedures.

Procedures

Upon receipt of an allegation of research misconduct, the Research Misconduct Committee shall make such inquiry, investigation, findings, and recommendations as it deems necessary or appropriate. In cases in which Harvard has primary responsibility for conduct of an inquiry or investigation, the Research Misconduct Committee shall consider any report that has been submitted to it by Harvard prior to making a determination of what action to take.

The Research Misconduct Committee may appoint inquiry panel(s) of one or more individuals, who may but need not be members of the Research Misconduct Committee, to inquire into the facts and submit the result of its inquiry, which may include findings and recommendations, to the Research Misconduct Committee. Inquiry panel(s) may include members who are from other involved institutions, including Harvard, and may be established as joint inquiry panel(s) with such other institutions. The Vice President Research Administration may serve as a member of or staff to any panel.

In deciding upon the size and composition of the inquiry panel, the Research Misconduct Committee, to help insure competence and objectivity, shall take into account such factors as:

(a) the subject matter of the inquiry, including the desirability of the panel's

possessing competence in a specialized area or investigative skills;

(b) the desirability of including on the panel persons associated with institutions other than the Infirmary;

(c) the importance of selecting persons who have had no prior involvement in the subject matter of the inquiry and who have no other actual or apparent conflicts of interest.

Upon initiation of its process, the Research Misconduct Committee will notify the subject(s) of the allegation in writing of the nature and scope of the allegation, the membership of the Research Misconduct Committee and of any inquiry panel(s) and their roles, and will provide the subject(s) with a copy of this Policies and Procedures.

The draft report of any inquiry panel(s) will be provided to the subject(s) of the allegation for review and comment. Any such comments, if timely received, will be considered by the inquiry panel(s), which may modify the draft report or otherwise respond to the comments. In any event such comments will be included in full as an appendix to the final inquiry panel report. Subject to confidentiality considerations, portions of the draft report may also be provided to other individuals if, in the opinion of the inquiry panel(s), their review and comment would assist the work of the panel(s).

The Research Misconduct Committee will consider the report(s) from any inquiry panel(s) and undertake such further investigation, deliberations, and proceedings as it deems necessary or appropriate. It will then prepare a draft report containing its conclusions and, ordinarily, comments on the gravity of any offense(s), possible sanctions, and prevention of future misconduct.

The draft report of the Research Misconduct Committee will be provided to the subject(s) of the allegation for review and comment. Any such comments, if timely received, will be considered by the Committee, which may modify the draft report or otherwise respond to the comments. In any event such comments will be included in full as an appendix to the final Committee report. Subject to confidentiality considerations, portions of the draft report may also be provided to other individuals if, in the opinion of the Research Misconduct Committee, their review and comment would assist the work of the Committee.

The Research Misconduct Committee will submit its final report to the Infirmary Board of Directors. The Board may accept, reject, or modify, in whole or in part, the conclusions and recommendations of the Research Misconduct Committee and may take whatever further actions are deemed appropriate in reaching a final resolution of the matter. Where a person found to have engaged in research misconduct holds a Harvard appointment, a final resolution of the matter, including any sanctions and remedies, will be decided in consultation with the Dean of the appointing Harvard faculty. The President of the Infirmary, in concert with the Dean of the appointing Harvard faculty as appropriate, will act to take all reasonable steps to implement the final resolution of the

matter, including notification of the outcome to affected individuals, institutions, and funding sources.

Finding of Research Misconduct

A finding of research misconduct requires finding that there has been a significant departure from accepted practices of the relevant research community, that the misconduct was committed intentionally, knowingly, or recklessly, and that the allegation has been proven by a preponderance of the evidence. Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

PUBLIC HEALTH SERVICE POLICIES

When an allegation of research misconduct is in connection with research, research training, or applications or proposals for support of research or research training, or related activities for which Public Health Service ("PHS") funds have been requested or provided, or plagiarism of research records produced in the course of PHS supported research, research training, or related activities, this Policy and Procedures will be supplemented by the remaining provisions herein as well as by all other requirements of the "Public Health Service Policies on Research Misconduct", 42 CFR Part 93, as it may be amended from time to time ("PHS Policies"); provided, however, that, for this purpose, "misconduct", "research misconduct", or "misconduct in research" shall mean fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting research. A copy of the PHS Policies is available in the Office of Research Administration.

Inquiry

Upon receipt of an allegation of research misconduct, an inquiry panel(s) will be appointed as provided for in this Policy and Procedures. The inquiry panel(s) will conduct an inquiry in accordance with the requirements of the PHS Policies. The purpose of the inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Ordinarily, an inquiry will not result in a determination that misconduct has or has not occurred.

The final report of the inquiry panel will be submitted to the Research Misconduct Committee and to any coordinate Harvard committee. After such further inquiry, deliberation or proceeding as it deems appropriate, the Research Misconduct Committee will decide whether or not an investigation, or some other disposition, is warranted. An investigation is warranted if there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, and preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

An inquiry will ordinarily be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days, the inquiry record will include documentation of the reasons for exceeding 60 days.

The Vice President Research Administration will notify ORI in writing on or before the date any investigation begins. The notification will contain all information and material provided for in the PHS Policies, and MEEI will take any other actions required under the PHS Policies.

Investigation

An investigation is the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

The investigation will be conducted by the Research Misconduct Committee, and will commence within 30 days after it determines that an investigation is warranted. The investigation will be conducted in conformance with the requirements of the PHS Policies and with such additional assistance from members of the inquiry panel(s) as the Research Misconduct Committee deems necessary and appropriate.

The Research Misconduct Committee will submit its final report to the Infirmary Board of Directors. The Board may accept, reject, or modify, in whole or in part, the conclusions and recommendations of the Research Misconduct Committee and may take whatever further actions are deemed appropriate in reaching a final resolution of the matter. Where a person found to have engaged in research misconduct holds a Harvard appointment, a final resolution of the matter, including any sanctions and remedies, will be decided in consultation with the Dean of the appointing Harvard faculty. The President of the Infirmary, in concert with the Dean of the appointing Harvard faculty as appropriate, will act to take all reasonable steps to implement the final resolution of the matter, including notification of the outcome to affected individuals, institutions, and funding sources, and will submit the final report to ORI and take any other actions required under the PHS Policies.

Unless an extension has been granted by ORI, all aspects of the investigation will be completed within 120 days of its initiation.

Notification to Office of Research Integrity

MEEI will immediately notify ORI if at any time during a research misconduct proceeding it has reason to believe that any of the following conditions exist:

(a) Health or safety or the public is at risk, including an immediate need to protect human or animal subjects.

(b) Department of Health and Human Services ("HHS") resources or interests are threatened.
(c) Research activities should be suspended.
(d) There is reasonable indication of possible violations of civil or criminal law.
(e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
(f) MEEI believes the research misconduct proceeding may be made public prematurely.
(g) The research community or public should be informed.

Cooperation with Federal Agencies

MEEI will give full and continuing cooperation to ORI during its oversight review under the PHS Policies or any subsequent administrative hearings or appeals under the PHS Policies, including providing all research records and evidence under MEEI's control, custody, or possession and access to all persons within MEEI's authority necessary to develop a complete record of relevant evidence. MEEI will cooperate with HHS during any research misconduct proceeding or compliance review, and will assist in administering and enforcing any HHS administrative actions imposed on its institutional members.

Reapproved by Infirmary Board of Directors: July 26, 2005