BRANDEIS UNIVERSITY
RESEARCH MISCONDUCT POLICY AND PROCEDURES
Revised effective June 2004

I. Introduction

A. General Policy

The integrity of a research university and the faculty members and scientists within it should never be in question. Thus, Brandeis University (the "University") and its academic and scientific community are committed to do everything possible to prevent research fraud, unethical treatment of human subjects and animal research or other misconduct in science and research.

It is the policy of the University to take action when scientific or research misconduct or serious deviation from regulatory and ethical standards in the conduct of research, including human subjects and animal research, undermines the integrity of the scientific process and of the research enterprise. Because of concern about the effect that possible Misconduct, as defined below, may have upon the University and its research activities, this policy was developed to prevent, detect, and address possible Misconduct in the University's research programs. This policy intends to create an environment that balances the need to deal firmly and effectively with allegations of possible Misconduct against the need for openness and creativity in the academic and scientific enterprise.

In all of its scientific and research activities, the University observes the highest standards of professional conduct. The enterprise of academic and scientific research relies upon the trust and confidence of both the scientific community and the public at large in the integrity of the academic and scientific process. Unethical behavior represents a breach of the confidence among University faculty and other research scientists that is central to the advancement of knowledge. It also undermines the confidence that the public and research subjects should have in the reliability of the University. For these reasons, the University considers Misconduct a betrayal of fundamental scientific and research principles, and shall deal with all instances of possible Misconduct promptly and firmly.

B. Scope and Application

This policy and the associated procedures apply to all research activities conducted under the auspices of the University, whether funded or unfunded. This policy applies to any individual paid by, under the control of, or affiliated with the University, such as faculty members, scientists, post-doctoral fellows, trainees, technicians and other staff members, graduate and undergraduate students, guest researchers, or collaborators at the University. In addition, this policy applies to all individuals utilizing the University's

Institutional Review Board and Privacy Board ("Research Boards") for review and monitoring of research projects, regardless of whether the individuals are employed by, under the control of, or formally affiliated with the University.

This policy and the associated procedures will normally be followed when a University official receives an allegation of possible Misconduct in science or research, or noncompliance with legal and ethical standards applicable to human subjects and animal research. Particular circumstances in an individual case may dictate variation from the normal procedures when deemed to be in the best interests of the University and/or any relevant federal agency. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation from this policy and associated procedures should be approved in advance by the Provost and Senior Vice President for Academic Affairs.

Allegations of Misconduct and/or Retaliation, as defined below, occurring more than six years prior to submission of the allegations will not be investigated. In the case of allegations of Misconduct, however, an investigation may be warranted notwithstanding the lapse of more than six years where circumstances indicate that the alleged Misconduct was not reasonably discoverable at an earlier time, or the Misconduct poses a current threat to the health and safety of employees or research subjects.

II. Definitions

A. *Allegation* means any written or oral statement or other indication of possible Misconduct made to a University official.

B. *Complainant* means the individual(s) who submits an allegation of Misconduct and/or Retaliation.

C. *Conflict of interest* means the real or apparent interference of one individual's interests with the interests of another individual or of the University, where potential bias may occur due to prior or existing personal or professional relationships.

D. *Deciding Official* means the University official who makes final determinations on allegations of Misconduct and any responsive University actions. At the University, the Deciding Official is the Provost and Senior Vice President for Academic Affairs.

E. *Good faith allegation* means an allegation made with the honest belief that Misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for, or willful ignorance of, facts that would disprove the allegation.

F. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of Misconduct warrants an Investigation.

G. *Investigation* means the formal examination and evaluation of all relevant facts to determine if Misconduct has occurred, and, if so, to determine the responsible individual and the seriousness of the Misconduct.

H. *Misconduct* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within and/or applicable to the academic and scientific communities for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data, or of regulatory and ethical standards. Misconduct includes significant departure from applicable University policies and Research Board directives on the appropriate and ethical conduct of human subjects and animal research.

I. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services ("DHHS") that is responsible for the Misconduct and research integrity activities of the U.S. Public Health Service.

J. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.

K. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific Misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

L. *PHS support* means PHS grants, contracts, or cooperative agreements or applications therefor.

M. *Research Integrity Officer* means the University official responsible for assessing allegations of Misconduct and determining when such allegations warrant Inquiries and for overseeing Inquiries and Investigations. At the University, the Research Integrity Officer is the Associate Provost for Research.

N. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding

the proposed, conducted, or reported research that constitutes the subject of an allegation of Misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

O. *Respondent* means the individual against whom an allegation of Misconduct is directed or the individual whose actions are the subject of the Inquiry or Investigation. There can be more than one Respondent in any Inquiry or Investigation.

P. *Retaliation* means any action that adversely affects the employment or other University status of an individual, that is taken by the University or an employee of the University, because the individual has made a good faith allegation of Misconduct or of inadequate University response thereto or has cooperated in good faith with an Inquiry or an Investigation of such allegation.

III. Procedures for Handling Allegations of Misconduct

A. General Rights and Responsibilities

If an individual, in good faith, suspects that an individual subject to this policy is involved in Misconduct, the individual is encouraged to meet privately with the Associate Provost for Research, who is the University's Research Integrity Officer. The purpose of this meeting is to provide a confidential forum in which an initial determination of the need for a formal allegation can be made. The potential Complainant must be informed that if the Research Integrity Officer determines that an allegation of Misconduct is warranted, the Research Integrity Officer must submit an allegation even if the Complainant chooses not to do so. The Complainant must also be informed that an allegation may be submitted by the Complainant and will be accepted by the Research Integrity Officer, regardless of the Research Integrity Officer's opinion of the merits of the allegation. An individual who is not comfortable bringing his or her concerns to the Research Integrity Officer may direct his or her concerns to the University's Director of Sponsored Programs.

Once an allegation of Misconduct has been made, the following procedures will be undertaken, as is described in more detail below: (A) submission of the allegation, assessment and initial inquiry; (B) when warranted, an investigation to collect data and

thoroughly examine the evidence; and (C) issuance of formal findings and appropriate disposition. If the circumstances described or allegations made by the individual do not meet the definition of Misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

University employees will cooperate with the Research Integrity Officer and other University officials in the review of allegations and the conduct of Inquiries and Investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other University officials on Misconduct allegations.

If at any time during an Inquiry or an Investigation, information is obtained that reasonably indicates the occurrence of possible criminal violations, the Research Integrity Officer must notify the Office of the General Counsel; the appropriate office of the sponsoring agency; ORI, if applicable; the University's Director of Public Safety; and other appropriate law enforcement officials within twenty-four (24) hours. If applicable, the Research Integrity Officer will notify ORI at any stage of the Inquiry or Investigation if: (i) there is an immediate health hazard involved; (ii) there is an immediate need to protect the interests of the Complainant(s) or the Respondent(s) or their co-investigators and associates; (iii) there is an immediate need to protect federal funds or equipment; (iv) it is probable that the alleged incident will be reported publicly: or (v) the allegation involves a public health sensitive issue. In addition, ORI must be kept promptly apprised of any developments that disclose facts that may affect current or potential DHHS funding for the individual(s) under investigation, or that PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest. Additional reports shall be made as required under the University's Federalwide Assurance (FWA), Animal Welfare Assurance, and applicable state law.

The rights and reputations of all parties involved in the allegation of Misconduct, including the individual who reported the alleged incident, must be protected throughout these procedures. The affected individual(s) should be afforded confidential treatment to the maximum extent possible. Individuals accused of Misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice, and may bring the counsel or personal adviser to interviews or meetings on the case. University faculty and staff employees are required to participate in these procedures, including attending meetings and answering questions put to them, upon reasonable notice. If any other individual subject to this policy refuses to cooperate with these procedures, the University reserves the right to take steps to disassociate itself from his or her research, revoke all University support and/or approval, and report to government authorities, as required and applicable.

B. Submission of an Allegation

After consulting with the Research Integrity Officer, a Complainant may submit an allegation in writing to him or her. If the Research Integrity Officer determines that an allegation of Misconduct is warranted, the Research Integrity Officer must treat it as a submitted allegation even if the Complainant chooses not to submit it. Upon receiving an allegation of Misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an Inquiry. Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, the Research Integrity Officer will select an *ad hoc* committee to conduct an Inquiry (the "Inquiry Committee"). Members of the committee shall not have real or apparent Conflicts of interest.

The Research Integrity Officer will prepare a charge for the Inquiry Committee that describes the allegation(s) and any related issues identified during the allegation assessment and states that the purpose of the Inquiry is to make a preliminary evaluation of the evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether there is evidence of possible Misconduct that is sufficient to warrant an Investigation. The purpose of the Inquiry is not to determine whether Misconduct definitely occurred or who was responsible. Inquiry by the committee shall begin immediately after the charge is received. The Research Integrity Officer should notify the accused individual(s) of the initiation of the Inquiry, and of the names of the individuals solicited to serve on the Inquiry Committee. The Respondent may at this time raise objections (e.g., Conflict of interest) to the membership of individuals on the Inquiry Committee, and the Research Integrity Officer shall consider these objections.

C. Inquiry

The Inquiry Committee will normally interview the Complainant, the Respondent, and key witnesses as well as examine relevant research records and materials. In order to avoid any claims of alteration of data, the Inquiry Committee will promptly attempt to locate and secure the originals of all relevant research data and/or documents if it is ascertained that such data and/or documents may be part of the case. Supervised access to the data and/or documents should be available to the Respondent. The Inquiry Committee may employ such outside resources and expertise (e.g., legal or consulting services) as it deems appropriate to assist in the Inquiry. Witness interviews shall be summarized in writing by the Committee or staff to the Committee, and witnesses given the opportunity to review and correct such summary of their own statements.

All Inquiries shall be completed within 60 days of initiation unless circumstances clearly warrant a longer period. If circumstances do so warrant, the record of the Inquiry shall include documentation of the reasons for exceeding the 60 day period. The

individuals selected to conduct the Inquiry shall make every effort to be objective, impartial, and fair. The proceedings of the Inquiry will be kept confidential and will not be disclosed except as necessary to facilitate a complete and comprehensive Investigation.

The Inquiry Committee is expected to carry its inquiry through to completion and diligently to pursue all significant issues. If, for any reason, the Inquiry Committee decides that it is appropriate or necessary to terminate the Inquiry, the approval of the Deciding Official is required. If the Deciding Official approves such termination, a report of the planned termination, including the reasons for the termination, shall be made to ORI, if applicable, which will then decide whether further investigation should be undertaken.

The Inquiry Committee will evaluate the evidence and testimony obtained during the Inquiry. Upon conclusion of the Inquiry, the Inquiry Committee shall prepare a written report that identifies the evidence reviewed, summarizes relevant interviews, and states the conclusions of the Inquiry. The report must include sufficiently detailed information documenting the Inquiry Committee's recommendation as to whether further investigation is warranted. The Respondent shall be provided with a copy of the Inquiry Committee's report and shall have ten working days to provide written comments on it. Any comments made by the Respondent may be made a part of the record.

Within 30 days of completion of the Inquiry, and after consultation with the Office of the General Counsel, the Research Integrity Officer will transmit the final report and any comments to the Deciding Official, who will make the determination of whether the findings from the Inquiry provide sufficient evidence of possible Misconduct to justify conducting an Investigation. The Deciding Official shall also determine whether any interim administrative actions are appropriate in order to protect federal funds and ensure that the purposes of the federal financial assistance are being carried out. The Inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the Inquiry Committee. Any extension of this period will be based on good cause and recorded in the Inquiry file. The Research Integrity Officer will notify the Complainant and Respondent in writing of the determination. The Research Integrity Officer will also notify all appropriate University officials of the Deciding Official's decision. The sponsoring agency and ORI, if applicable, shall also be notified. Such notification must be done in writing and must contain the name(s) of the Respondent(s), the general nature of the allegation and the PHS application or grant numbers implicated by the Inquiry.

D. Investigation

If the Deciding Official determines that further investigation is necessary, the Research Integrity Officer, in consultation with other University officials as appropriate, shall, within 30 days after the completion of the Inquiry, appoint an *ad hoc* committee (the "Investigation Committee") to hear the formal charges against the Respondent alleged in the previously described Inquiry. The Respondent will be notified within 10 days of the determination that an Investigation is planned, or as soon thereafter as is practicable. The Investigation Committee will include at least three members of the University faculty. Members of the committee shall not have real or apparent Conflicts of interest in the case, shall be unbiased, and shall have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the Investigation. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee. The Respondent will be informed by the Research Integrity Officer of the proposed composition of the Investigation Committee within 5 days of that determination, and will have the opportunity to raise objection to individual appointees. If the Respondent submits a written objection to any appointed member of the Investigation Committee, the Research Integrity Officer shall determine whether to replace the challenged member with a qualified substitute.

If applicable, the University's decision to initiate an Investigation must be reported in writing to the Director of ORI on or before the date the Investigation begins. At a minimum, the notification shall include the name of the Respondent(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of Misconduct, and if applicable, the PHS applications or grant number(s) involved.

The Research Integrity Officer will convene the first meeting of the Investigation Committee to review the charge, the Inquiry report, and the prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific Investigation plan. The Investigation Committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation. The Investigation Committee shall fully investigate the charges set forth and recommend appropriate action. The Investigation shall focus on the allegations of Misconduct, and shall examine the factual matters of the case. The Investigation Committee may employ such outside resources and expertise (e.g., legal or consulting services) as it deems appropriate to assist in the Investigation. Witness interviews shall be summarized in writing by the Committee or staff to the Committee, and witnesses given the opportunity to review and correct such summary of their own statements. The individuals selected to conduct the Investigation shall make every effort to be objective, impartial, and fair.

The Investigation Committee's charge is to generate a report that compiles all of the information considered, the Committee's conclusion as to whether there is sufficient evidence to support the allegation of Misconduct, and any recommended administrative or disciplinary actions to be taken against the Respondent in the event the allegation is substantiated. It is within the discretion of the Investigation Committee to incorporate by reference any report or portions thereof from the Inquiry Committee, to the extent that the Investigation Committee is satisfied with any aspect(s) of the Inquiry Committee report or portions thereof as constituting a comprehensive review and resolution of the issues.

All Investigations should be conducted expeditiously and completed within 120 days if possible. This includes conducting the Investigation, preparing the report of findings, making the report available for comment by the Respondent and submitting the report to ORI, if applicable. If the 120-day deadline cannot be met, the Investigation Committee shall request an extension from the Research Integrity Officer. If applicable, the Research Integrity Officer shall submit to ORI a written request for an extension and an explanation for the delay. This request to ORI shall include an interim report on the progress to date, an outline of what remains to be done, an estimate for the date of completion of the report, and any other necessary steps. If this request is granted, periodic progress reports may also be requested by ORI. The Investigation Committee shall also determine whether any interim administrative actions are appropriate in order to protect federal funds and ensure that the purposes of the federal financial assistance are being carried out.

The Investigation Committee is expected to carry its investigation through to completion and diligently to pursue all significant issues. If, for any reason, the Investigation Committee decides that it is appropriate or necessary to terminate the Investigation, the approval of the Deciding Official is required. If the Deciding Official approves such termination, a report of the planned termination, including the reasons for the termination, shall be made to ORI, if applicable, which may then decide to undertake its own investigation.

When the Investigation Committee reaches a conclusion regarding the allegation of Misconduct, it shall submit a preliminary report reviewing all information and its conclusion to the Respondent. The preliminary report shall adequately detail the evidence that supports or refutes each allegation included in the Investigation. Respondent will have ten working days to prepare a written response to the preliminary report, which shall be considered by the Investigation Committee before the investigation report is finalized.

After receiving the Respondent's written comments on the preliminary report, if any, the Investigation Committee shall prepare and maintain a final report that lists and adequately substantiates the basis for its findings, describes the policies and procedures under which the Investigation was conducted, and describes how and from whom

information was obtained relevant to the Investigation. The final report of the Investigation Committee shall be made available to the Respondent, who will be provided a full and fair opportunity to respond in writing to the Investigation Committee within seven working days of receipt of the final report. Such comments, if any, may be made a part of the record of the Investigation.

The final report, including the Respondent's comments, if any, and the Investigation Committee's recommended administrative or disciplinary actions, if any, shall be provided to the Deciding Official. He or she will determine whether to accept the final report, its findings, and any recommended administrative or disciplinary actions. If the Deciding Official's determination varies from that of the Investigation Committee's final report, the Deciding Official will explain in detail the basis for rendering a decision different from that of the Investigation Committee. The Deciding Official's determination, together with the Investigation Committee's final report, constitutes the final investigation report for purposes of ORI review. ORI and/or other government authorities, if applicable, (e.g., the federal Office of Human Research Protections and/or state agencies) shall be provided with the final report, along with the actual text or an accurate summary of the views of any individual(s) found to have engaged in Misconduct, as well as a description of any sanctions taken by the University. The Complainant(s) shall be provided with those portions of the final report that address his, her or their role and opinions in the Investigation.

IV. Consequences of Investigation

A. Administrative and/or Disciplinary Actions

If the Deciding Official determines that the alleged Misconduct is substantiated by the findings, he or she will decide on the appropriate administrative or disciplinary actions to be taken, if any, after consultation with the Research Integrity Officer and taking into consideration the recommendations of the Investigation Committee. The actions may include one or more of the following:

i. withdrawal or correction of all pending or published abstracts and papers emanating from the research in which Misconduct was found;
ii. removal of the responsible individual from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible discipline or termination of employment under the applicable University policies;
iii. notification to other universities, institutions and sponsoring agencies with which the individual has been or is affiliated, if there is reason to believe that previous research may be characterized by Misconduct; and/or
iv. restitution of funds as appropriate to granting agencies, the University and/or research subjects.

The Research Integrity Officer shall notify the Respondent in writing of any appropriate administrative or disciplinary actions to be taken and shall also meet with the Respondent to discuss the findings and the implementation of any such administrative or disciplinary actions. Any disciplinary action relating to faculty or staff privileges and or Research Boards review shall be coordinated with the applicable academic Dean and/or the Research Boards, as appropriate. If indicated, faculty or staff discipline will be pursued through established University disciplinary policies, but the procedures in this policy are distinct from, and may be taken without recourse to, faculty and staff disciplinary procedures.

B. Restoration of the Respondent's Reputation

If the finding is that no Misconduct occurred, and if the Inquiry or Investigation has resulted in any damage to the Respondent's reputation, the Respondent shall meet with the Research Integrity Officer to discuss how the Respondent's record shall be cleared and what reasonable efforts will be taken to restore the Respondent's reputation. Any University actions to restore the Respondent's reputation must first be approved by the Deciding Official. The implementation of such approved actions will be the responsibility of the Research Integrity Officer. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the Inquiry and/or the Investigation of the final outcome, publicizing the final outcome in forums in which the allegation of Misconduct was previously publicized, or expunging all reference to the Misconduct allegation from the Respondent's personnel file.

V. Appeal

The Respondent and/or other individual(s) affected by the decision of the Deciding Official shall be given an opportunity to appeal, but may appeal a decision of Misconduct only on the basis that procedural errors were committed. Within ten working days after the decision is received, the individual(s) shall serve upon the Deciding Official a petition, in writing, informing the Deciding Official of his, her or their intent to appeal. The Deciding Official shall have the power to affirm, reverse, or modify the decision. The Deciding Official may base his or her decision on appeal upon the written appeal and the record of the Investigation and the Deciding Official's previous decision. Alternatively, the Deciding Official in his or her discretion may require the Research Integrity Officer to appoint a new Investigation Committee to reevaluate the record and submit supplemental recommendations to him or her. The Deciding Official's decision on appeal will be final. No additional evidence may be introduced into the record on appeal as a matter of course. However, if new evidence is brought to the attention of the Deciding Official at any time during the process, he or she will determine in his or her discretion whether the matter should be referred back to the original Investigating

Committee or to a new Investigation Committee appointed to reopen the case. If applicable, ORI will be notified of the appeal and of its disposition.

VI. Other Considerations

A. Termination of University Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's University employment or affiliation, by resignation or otherwise, before or after an allegation of possible Misconduct has been reported, will not preclude or terminate the Misconduct procedures. If the Respondent, without admitting to the Misconduct, elects to resign his or her position or affiliation prior to the initiation of an Inquiry, but after an allegation has been reported, or during an Inquiry or Investigation, the Inquiry or Investigation will proceed. If the Respondent refuses to participate in the process after resignation, the Inquiry Committee and the Investigation Committee, if any, will use their best efforts to reach a conclusion concerning the allegations, noting in their reports the Respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Protection of the Complainant and Others

It is the University's policy that no one shall suffer Retaliation for making a good faith allegation of Misconduct, or for providing testimony regarding the facts and circumstances surrounding the alleged Misconduct during an Inquiry or Investigation. Regardless of whether the University or ORI determines that Misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect the positions and reputations of Complainants who have made an allegation of Misconduct in good faith and others who cooperate in good faith with Inquiries and Investigations of such allegations. Upon completion of an Investigation, the Deciding Official will determine, after consulting with the Complainant, what steps, if any, are needed to restore the position or reputation of the Complainant. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves.

C. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the Complainant's allegations of Misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative or employment action or discipline should be recommended against the Complainant.

VII. Records Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any Inquiry or Investigation and copies of all documents and other materials furnished to the Research Integrity Officer or the committees. The Research Integrity Officer will keep the file in a secure manner for six (6) years after completion of the case to permit later assessment of the case. ORI or other authorized government personnel will be given access to the records upon request.