1. INTRODUCTION:

The following policies and procedures have been developed to promote a fair, thorough and timely response to allegations of possible misconduct in science. The policies and procedures comply with the provisions of 42 CFR 50. This material must be circulated to all scientific and administrative staff of the Research Foundation for Mental Hygiene Inc. (RFMH) and to all other persons carrying out functions under grants funded through RFMH.

Some requirements for dealing with allegations relating to NSF funded research differ from those found in this policy and procedure statement. A description of the differences can be found in the attachment.

RFMH is committed to promoting the integrity of the scientific process and to maintaining the highest ethical standards in research. Researchers bear the responsibility for ensuring that their research is carefully done and accurately reported. Researchers and their staff should be adequately informed of their responsibility to maintain scientific standards and to conduct their work in an ethically sound manner.
The Director at the facility which is the recipient of the grant award has a central role in the policies and procedures described in this document. For example, if an investigator from research institute "A" is conducting research at facility "B" and the research is funded through research institute "A", the inquiry/investigation is the responsibility of the Director of research Institute "A" even if the allegation relates to work conducted at facility "B". Of course, the Director of facility "B" should be consulted and kept informed.

In situations where the Director has a real or apparent conflict of interest, the functions assigned to the Director shall be carried out by the Managing Director of RFMH or a person authorized to carry out these functions by the Managing Director of RFMH.

Questions relating to these policies and procedures should be addressed to:

Managing Director
Research Foundation for Mental Hygiene Inc.
150 Broadway Ste. 301
Menands, New York
(518) 474 5661

2. **APPLICABILITY:**

Although the Office of Scientific Integrity (OSI) reporting requirements apply only to research, research training, and related activities for which Public Health Service (PHS) funding has been provided or requested, the remaining policies and procedures in this document apply to all research, research training, and related activities which are funded through RFMH or conducted by RFMH employees in their capacity as RFMH employees or by other persons within the control of RFMH (except as specified in the attachment on NSF funded research).

Sub-contracts, under federal grants awarded to RFMH, are also covered by these policies and procedures. At the time that a sub-contract is negotiated, the sub-contracting institution must either provide a copy of its Assurance (or other documentation satisfactory to RFMH which provides evidence of its policies and procedures for complying with the provisions of 42 CFR 50) or, agree to be bound by the provisions of RFMH's policies and procedures. Institutions that agree to be bound by RFMH's policies and procedures must also agree to fully cooperate with RFMH in the event that an inquiry or an investigation becomes necessary.
3. **DEFINITIONS:**

"**Inquiry**" means information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

"**Institution**" means the public or private entity or organization (including federal, state, and other agencies) that is applying for federal assistance from the PHS, e.g., grant or cooperative agreements, including continuation awards, whether competing or noncompeting. The organization assumes legal and financial accountability for the awarded funds and for the performance of the supported activities.

"**Investigation**" means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

"**Misconduct**" or "**Misconduct in Science**" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

"**OSI**" means the Office of Scientific Integrity, a component of the Office of the Director of the National Institutes for Health (NIH), which oversees the implementation of all PHS policies and procedures related to scientific misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary.

"**OSIR**" means the Office of Scientific Integrity Review, a component of the Office of the Assistant Secretary for Health which is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where scientific misconduct has been established.
4. **POLICY:**

   It is the policy of the RFMH to maintain high ethical standards in research. Cases of alleged or apparent misconduct will be fairly, promptly and thoroughly investigated. To the maximum extent possible, the affected individual(s) shall be afforded confidential treatment. They shall be given adequate opportunity to comment on allegations and findings of the inquiry and/or the investigation. The standard of proof to be used shall be a preponderance of the evidence.

5. **PROCEDURES:**

   Allegations, or other evidence of possible misconduct, must be promptly reported to the Director of the facility. Every effort shall be made to protect the privacy of those who, in good faith, report apparent misconduct. Such persons shall be protected by the institution from retaliation and discriminatory practices to the extent possible. At the same time, every effort should be made to protect the interests of the person(s) against whom the allegation has been made.

6. **INQUIRY:**

   Upon receipt of an allegation of apparent misconduct, the Director shall appoint at least two qualified persons, who are not associated with the research, to conduct an impartial initial inquiry. The purpose of this inquiry is to provide the Director with sufficient information to determine whether a full investigation is warranted.

   The Managing Director of RFMH must be notified when an allegation of apparent misconduct is received. This notification shall include the nature and source (if known) of the allegation and the names and qualifications of the persons appointed to conduct the initial inquiry.

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

   The persons conducting the inquiry shall prepare a written report that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of the inquiry. If they
comment on that report, their comments shall be made part of the record. Records of the inquiry shall be maintained in a secure manner.

An inquiry should generally include an assessment of the following:

(a) the accuracy and reliability of the source of the information about the possible misconduct;
(b) the seriousness of the possible misconduct;
(c) the scope of the incident(s) and the context in which they became known;
(d) explanations that are provided by the subject(s) of the inquiry; and
(e) other information developed during the inquiry.

The report of the inquiry shall be presented to the facility Director who shall then determine whether an investigation should be conducted. If the Director determines that an investigation is not warranted, the reasons for the decision must be documented.

A copy of the report and the Director's determination shall be forwarded to the Managing Director of RFMH. A copy of the report must be kept by the facility, in a secure manner, for a period of at least three years after the termination of the inquiry. Upon request, a copy of any report relating to research which is funded by PHS or for which PHS funding has been sought, must be given to authorized HHS personnel.

NOTE: Persons conducting an inquiry or investigation should be aware that the subject may be employed by the State of New York. State employees, especially those represented by a union, may enjoy certain due process protections during the course of an inquiry or investigation by the state which may lead to disciplinary action. Prior to commencing either, persons conducting an investigation or inquiry should consult with either the administrative or personnel director of the facility employing the subject.

7. INVESTIGATION:

If the Director determines that the findings of the inquiry provide sufficient basis for undertaking an investigation he/she shall appoint a committee to conduct the investigation. The committee shall consist of at least three members selected to ensure the appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence and to avoid real or apparent conflicts of interest. The committee should, with the consent of the Director, utilize consultants when specialized expertise is needed.
The committee shall include at least two scientists who possess appropriate expertise to evaluate the scientific aspects of the alleged misconduct. One of these scientists must not be an employee of the facility conducting the investigation. If the alleged misconduct relates to misuse of funds at least one member of the committee shall possess the experience and qualifications necessary to adequately examine the financial records. In addition to the members appointed by the Director, one member may be appointed by the Managing Director of RFMH.

The investigation must commence within 30 days of the completion of the inquiry and should ordinarily be completed within 120 days of its initiation. If the allegation relates to research for which PHS funding has been provided or requested and the facility Director determines that it will not be able to complete the investigation within 120 days, the Director must submit a written request for an extension to OSI. The request must include an explanation for the delay, an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps.

The 120 day period includes conducting the investigation, preparing the report of findings, making that report available for comment by the subject(s) of the investigation, and submitting the report to the OSI (see section 10). If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation.

The investigation will normally include: an examination of all documentation, including, but not necessarily limited to, relevant research data and proposals, publications, correspondence, and memoranda of telephone calls, and inspection of laboratory or clinical facilities and materials. Whenever possible, interviews should be conducted with all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations. Complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

During the course of an investigation the committee may wish to have access to identifiable subject/patient information. The facility's Institutional Review Board (IRB) should be consulted to ensure that the subjects' rights and welfare are protected to the maximum extent possible. Access to identifiable subject data, and/or publication of identifiable subject data in the investigation report, may be restricted by the facility director, acting upon the advice of the IRB and legal counsel.

When the person against whom the allegation has been made is interviewed by the committee during the investigation he/she may have a person of his/her choosing present. This person may advise the accused, but will not be permitted to directly address the committee.
The investigation committee shall prepare and maintain documentation of its investigation. The report shall be made available to the person(s) against whom the allegation has been made and their (comments shall be incorporated. A final comprehensive report shall be forwarded to the facility Director and to the Managing Director of RFMH.

**NOTE:** If a subject of an investigation is a state employee, it is possible that the state might eventually institute disciplinary action as a result of the final investigation report. Because failure to afford an employee due process rights to which he or she might be entitled during an investigation may jeopardize the disciplinary process it is essential that, prior to commencing the investigation, the individuals responsible for its conduct consult with either the administrative or personnel director of the facility employing the subject.

**8. INTERIM ADMINISTRATIVE ARRANGEMENTS:**

Prior to the completion of an investigation, administrative actions may be necessary to safeguard the integrity of the project, prevent inappropriate use of funds, ensure that the purposes of any federal financial assistance are carried out, and otherwise protect the interests of the investigator, the funding agency, the human or animal research subjects, the public or the institution. Any interim action should be taken with a view toward protecting the rights of all involved parties and minimizing disruption to the project, the institution, and the activities of those involved in the project. Restrictions that have been imposed should be periodically reviewed, and modified if warranted by additional facts or findings.

**9. POST-INVESTIGATION PROCEDURES:**

If the alleged misconduct is not substantiated, diligent efforts should be made to restore the reputation of those under investigation.

If, based on the investigation report, the Director determines that the misconduct is confirmed, sanctions will be imposed on the persons found guilty of misconduct by the Director, in consultation with the Managing Director of the Research Foundation. These sanctions are in addition to any imposed by the funding agency, other employers etc. If the state decides to institute separate disciplinary action, it will do so in accordance with appropriate collective bargaining agreement or civil service law procedures.

Listed below are some possible sanctions, to the severity of the infraction.
Level I Sanctions

- Send a letter of reprimand, that clearly describes the incident, to the affected employee and place a copy of the letter in the employee’s RFMH personnel file.

- Require, for a specified period of time, that all work performed, data collected and/or reports prepared by the employee be reviewed and certified as to their compliance with policies, regulations, guidelines or special terms or conditions of an award by an institutional official other than the individual found culpable.

Level II Sanctions

- Require, for a specified period of time, that all activities or expenditures against an active award be reviewed, approved and countersigned by an institutional official other than the individual found culpable.

- Require, for a specified period of time, that all grant applications, protocols or other initiatives proposed by the affected employee be subject to an internal review by a special institutional peer review committee prior to submission to a granting agency or commencement of the project.

Level III Sanctions

- Immediately terminate or suspend all projects in which the employee has a supervisory or directory role.

- Terminate the affected employee's Foundation employment.

- Suspend or demote the affected employee for a specified period of time.

- Terminate the affected employee's Foundation privileges permanently or for a specified period of time.

- Terminate or suspend, for a specified period of time, the affected employee's status as a member of the Corporation.
10. REPORTING REQUIREMENTS FOR RESEARCH FOR WHICH PHS FUNDING HAS BEEN PROVIDED OR REQUESTED:

The Director of the Office of Scientific Integrity (OSI) must be notified when the Director determines that an investigation is warranted, or prior to the determination if any of the following conditions exist:

(i) There is an immediate health hazard involved;

(ii) There is an immediate need to protect Federal funds or equipment;

(iii) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

(iv) It is probable that the alleged incident is going to be reported publicly;

(v) There is a reasonable indication of possible criminal violation. In that instance, the Director must inform the OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

The decision to initiate an investigation must be reported, in writing, to the Director, OSI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS application or grant number(s) involved. Information provided to OSI through the notification will be held in confidence to the extent permitted by law, will not be disclosed as part of the peer review and Advisory Committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.

If a decision is made to terminate an inquiry or investigation for any reason without following all of the procedures outlined above, a report of such planned termination, including a description of the reasons for such termination shall be made to OSI, which will then decide whether further investigation should be undertaken.

If an investigation cannot be completed within 120 days the Director must submit a written request to OSI for an extension. The request must include an explanation for the delay, an
interim report on progress; to date and an estimate for the date of completion of the report and any other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the extension is granted, the Director must file periodic progress reports, as requested by OSI.

During the course of an investigation, OSI should be kept informed of any developments which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

When an investigation has been completed, the Director must submit a report to OSI which describes the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and 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 RFMH.

Upon receipt of the final report of investigation and supporting materials the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. The OSI may perform its own investigation at any time prior to, during or following the facility investigation. The Department of Health and Human Services (DHHS) may impose sanctions of its own on investigators or institutions if such action seems appropriate. OSI and DHHS may comment on RFMH's conduct of an investigation but do not have the authority to overrule sanctions imposed by RFMH.

11. **INSTITUTIONAL ASSURANCE:**

The Research Foundation for Mental Hygiene Inc. will submit an Institutional Assurance to OSI as soon as possible after November 8, 1989, but no later than January 1, 1990. Thereafter, annual updates and aggregate information on allegations, inquiries, and investigations, as prescribed by the Secretary of HHS, will be submitted on a date specified by OSI.
ATTACHMENT—NSF RESEARCH

NSF regulations, 45 CFR 689, currently differ from the PHS regulations. Until the NSF regulations are revised, the following differences in policies and procedures should be applied to allegations of misconduct relating to research for which NSF funding has been provided or requested.

**Definition of Misconduct:**

"Misconduct" means (1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from research; (2) material failure to comply with Federal requirements for protection of human subjects, or the public or for ensuring the welfare of laboratory animals; or (3) failure to meet other material legal requirements governing research.

**Sanctions Imposed by NSF:**

For those cases governed by the debarment and suspension regulations, the standards of proof contained in those regulations shall control. Otherwise, NSF will take no final action without a finding of misconduct supported by a preponderance of the relevant evidence. Interim actions may be taken by NSF to protect Federal resources or to guard against continuation of any suspected or alleged misconduct (see 45 CFR 689.2 (c)).

**Group I Action:**

(i) Send a letter of reprimand to the individual or institution.

(ii) Require as a condition of an award that for a specified period an individual, department, or institution obtain special prior approval of particular activities from NSF.

(iii) Require for a specified period that an institutional official other than those guilty of misconduct certify the accuracy of reports generated under an award or provide assurance of compliance with particular policies, regulations, guidelines, or special terms and conditions.

**Group II Actions:**

(i) Restrict for a specified period designated activities or expenditures under an active award.

(ii) Require for a specified period special reviews of all requests for funding from an affected individual, department, or institution to ensure that steps have been taken to prevent repetition of the misconduct.
Group III Actions:

(i) Immediately suspend or terminate an active award under appropriate NSF regulations.

(ii) Debar or suspend an individual, department, or institution from participation in NSF programs for a specified period after further proceedings under applicable regulations.

(iii) Prohibit participation of an individual as an NSF reviewer, advisor, or consultant for a specified period.

In deciding upon appropriate actions NSF will consider how serious the misconduct was, whether it was deliberate or merely careless, whether it was an isolated event or part of a pattern, and whether it is relevant only to certain funding requests or awards or to all requests or awards involving an institution found guilty of misconduct.

Institutional Responsibilities:

If an institution wishes NSF to defer independent inquiry or investigation, the Director must:

- immediately inform NSF if an initial inquiry supports a formal investigation,

- keep NSF informed during the investigation,

- notify NSF even before deciding to initiate an investigation or as required during an investigation; (i) if the seriousness of the apparent misconduct warrants; (ii) if immediate health hazards are involved; (iii) if NSF's resources, reputation, or other interests need protecting; (iv) if Federal action may be needed to protect the interests of a subject of the investigation or of others potentially affected; or (v) if the scientific community or the public should be informed.

If an institution wishes NSF to defer independent inquiry or investigation, it should complete any inquiry and decide whether an investigation is warranted within 90 days. It should similarly complete any investigation and reach a disposition within 180 days. If completion of an inquiry or investigation is delayed NSF may require submission of periodic status reports.