



NEW YORK MEDICAL COLLEGE GUIDELINES FOR ETHICAL PRACTICES
IN RESEARCH
AND POLICIES FOR DEALING WITH INSTANCES
OF ALLEGED VIOLATIONS OF ETHICAL STANDARDS

These guidelines apply to all individuals who may be involved with or apply for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act.

The purpose of these guidelines is to preclude the occurrences of all unethical scientific practices in research, i.e., misconduct or misconduct in science. Scientific misconduct 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.

The integrity of the entire scientific enterprise, and, in particular, of this institution requires that the College pay special attention to and expeditiously and equitably resolve any allegations of unethical scientific actions violating professional standards or regulations by investigators at the College or its affiliated hospitals. Maintenance of high ethical standards in the conduct of research and research training requires the establishment of a set of guidelines directed towards the delineation of ethical standards in research. Further, this paper cites recommendations for investigating allegations of unethical scientific practices and outlines procedures for reporting and correcting the consequences of such unethical practices, while at the same time protecting the rights and reputation of the investigators.

Guidelines for Ethical Practices in Research

(1) An investigator must not knowingly represent as empirical observations data synthesized de novo without an experimental basis or data arbitrarily altered.

(2) The primary responsibility for ensuring the authenticity of reported data rests with the principal investigator; however, all investigators identified as authors of a report assume responsibility for its authenticity.

(3) The appropriate response to a complaint of fraudulent presentation of data is the availability of the original experimental records. Written, detailed and explicit procedures for data gathering, storage, retrieval and analysis should be available in all laboratories.

(4) It is the responsibility of all investigators to maintain a record of all experimental protocols and data sufficient to allow subsequent verification. These data should be retained for a minimum of five years.

(5) It is the responsibility of the principal investigators to ensure proper supervision of aspects of the research not performed directly by them.

(6) Trainees should be supervised by experienced scientists and should be encouraged to present their studies at review sessions or seminars.

(7) Publications should give credit to all investigators and, as required by regulation or agreement, sources of grant or contract funding involved in the research and all publications should be approved by all co-authors.

The following procedures provide the framework for dealing with instances of alleged unethical scientific practices as defined above, and designates those individuals responsible for implementation of these procedures.

Procedures for Responding to Allegations of Unethical Practices in Research

(1) Allegations of unethical practices should first be reported to the immediate supervisor of the investigator(s) whose actions are in question, and simultaneously to the Department Chairperson. These allegations must be reported promptly to the Dean of the School of Medicine or the School of Basic Medical Sciences or the School of Public Health as appropriate, or to the Associate Dean of Research Administration who will notify the Dean and the Provost. In some instances the allegations may be resolved through an informal fact-finding inquiry among these three or four parties. No further action is required if the allegations are clearly frivolous, self-serving, vindictive, and without supporting documentation. Alternatively, the Dean may appoint a small ad hoc group with appropriate expertise selected from among the faculty and administration to constitute an initial Committee of Inquiry; the chairman of the Faculty Senate Research Support Services Committee will serve permanently to facilitate matters brought before the Committee of Inquiry; every effort will be made to guard against any real or apparent conflicts of interest in the selection of these individuals. Such a fact-finding inquiry should be thorough enough (including examinations of data, animals, humans or budgets in question) to withstand higher review if the matter is not dropped. When allegations are made in good faith, every effort will be made to protect the positions and reputations of those making allegations of scientific misconduct and to afford confidential treatment to the affected individuals. This initial inquiry should be completed within 60 days of the initial report alleging misconduct and a final written report prepared. The inquiry report shall include evidence reviewed, interview summaries, and conclusions of the inquiry. The inquiry report shall be given to the respondent(s) and comments by respondent(s) will be made part of the inquiry record. If at the end of the 60 day time-frame the inquiry cannot be completed, the College must notify the awarding agency, including documentation of the reasons for exceeding the 60-day period.

(2) The finding of the initial inquiry may be that there is no evidence of wrongdoing and, therefore, that no further action is indicated. Alternatively, the finding may be that a deviation from best practice or transgression of a minor nature may have occurred, but that a full investigation is not warranted. The College will undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed. Individuals against whom allegations have been made will have an opportunity to comment on the findings of the inquiry. Corrective actions, including sanctions appropriate to the situation may be instituted at this juncture and the matter concluded without the need for subsequent investigation.

(3) The Dean shall determine whether there will be an impoundment of the investigator's research records initially at the outset of the period of inquiry, but in all cases, records will be secured prior to a formal investigation. The original records will be secured by the College until such time as they can be photocopied. Tissue samples and animals may be secured as well.

(4) If it is determined that there may be evidence of significant unethical scientific practice, the Dean will form an ad hoc Committee of Investigation that will make a prompt and thorough investigation into the allegations. In the case of PHS sponsored research, the investigation must begin within 30 days if inquiry findings provide sufficient basis for doing so. This committee will consist of the Committee of Inquiry and other members of the faculty who are actively engaged in peer-reviewed research. Consideration may be given to add to the committee individuals from outside the College. This should include individuals who have expertise in the same area of science as the investigator(s) whose practices are in question. Also, one individual with expertise in the technique of gathering and evaluating evidence should be appointed. If the alleged unethical practice involves the abuse of humans or animals, the committee should have an active liaison with a representative of the Institutional Review Board or the Animal Care Committee.

(5) At this stage, the investigator(s) must be notified immediately in writing of the allegations and of the fact that a committee has been formed to investigate these allegations. Every attempt should be made to ensure that the composition of the committee is reasonably acceptable to the investigator(s). The investigator may retain a legal or other counsel and consult with such counsel during closed session of the Committee of Investigation at which the investigator has been asked to provide information but only outside the forum of the Committee's proceedings.

(6) In cases involving federally funded research, the Office of Research Integrity (ORI) will be informed that an investigation will be initiated on or before the date the investigations begins if findings from the inquiry indicate an investigation is warranted. It is the responsibility of the Dean to determine if other interested parties such as collaborators and other agencies sponsoring or funding the research in question are to be informed of the pending investigation and if there is preliminary evidence of serious question concerning the validity of the research under investigation, whether the research activities should be suspended. Nothing contained in this policy shall deprive the Dean of authority with respect to the possible suspension of a faculty member's employment.

(7) A fair and judicious investigation demands that the rights and reputations of all involved individuals are protected. All sessions of the hearings will be closed. During the inquiry and the investigation, records of the proceedings will be disclosed only in accordance with law.

(8) The subject(s) of the allegation and individual making the accusations will be interviewed by the Committee of Investigation. The committee will insure that the information collected is properly recorded.

(9) The time from the reporting an instance of possible misconduct to completion of the investigation should not exceed 6 to 9 months. Interval progress reports made by the investigation committee must be provided to the Dean and Associate Dean for Research Administration. For research involving federal funding, the College generally must take no more than 180 days to complete the investigation, prepare the report of findings, obtain the comments of the subject(s) of the investigation, and make a decision on the disposition of the case. If the College determines that it cannot complete its investigation and disposition of the case within the 180-day period, periodic status reports may be required. In the case of federal funding agencies, the investigation and report findings must be completed and a report submitted to ORI within 120 calendar days of initiation of investigation. Any extensions of this time period must be requested from the ORI; the request should include an explanation for the delay, an interim report of the progress to date, an outline of what remains to be done, and an estimated date of completion.

(10) A written summary of the findings of the investigation must be made available to the investigator(s) so that they have an opportunity for comment and rebuttal. If the summary is acceptable to the investigator(s), their signature should so stipulate.

(11) The report of the investigation will be made available to the respondent(s) for comment.

Interim Administrative Actions

At any time necessary from the initial allegation through the period of the inquiry and the investigation, the following administrative actions would be taken.

(1) ORI will be notified if there is an immediate health hazard involved, or if there is an immediate need to protect Federal funds or equipment and individuals affected by the inquiry, or if the alleged incident will probably be publicly reported. If there is reasonable indication of possible criminal violation involving PHS supported research, the ORI, will be notified within 24 hours.

(2) Appropriate administrative actions will be initiated to protect Federal funds and ensure that the purposes of Federal financial assistance are being carried out.

(3) If, in the course of an investigation, facts are disclosed that may affect current or potential PHS funding for the individual under investigation or that the PHS needs to know to ensure appropriate use of Federal funds or otherwise protect the public interest, the ORI will be notified promptly.

(4) If the College plans to terminate an inquiry for any reason without completing all relevant requirements under 42 CFR 50.103 (d), a report of such planned termination, including a description of the reasons for such termination, shall be made to ORI.

Actions to be Taken Following Completion of the Investigation

(1) If the alleged unethical scientific practices are not supported by the investigation, the Dean will take appropriate action to try to ensure that the reputation of the individual(s) under investigation is cleared of any cloud of suspicion. Other interested parties such as collaborators, supervisors and agencies sponsoring or funding the research must also be notified that the instance of alleged unethical practice was not supported by the investigation. The individual(s) should be given the option of having a written notice of clearance sent to the relevant members of the faculty from the Dean.

(2) If the investigation uncovers evidence of unethical scientific practices, a written report of the finding must be sent to the Department Chairperson, the Associate Dean, the Dean, the Provost and the President of the College.

(3) Following conclusion of the investigation, the Dean shall prepare a written report of recommendations for administrative action. These administrative actions may be directed to prevent future instances of unethical scientific practices and will include measures necessary to correct the sequelae of the practices.

(4) Any disciplinary actions resulting from the investigation will be in accordance with College procedures existing at the time. These actions require that the nature of the unethical practice (e.g., deliberate vs careless) be considered, the gravity of the violation and whether it was an isolated event or part of a pattern. Serious violations may be cause for dismissal.

(5) The formal report of the investigation and description of the corrective actions, if any, imposed against the investigator(s) must be promptly reported to the agencies sponsoring or funding the research. The final report to ORI must describe 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 include the actual text or an accurate summary of the views of any individuals(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution.

(6) The Department Chairperson and Dean will take action to have all pending abstracts and published papers associated with the unethical scientific practices of the investigator(s) withdrawn and notify editors of journals in which previous abstracts and papers appeared relating to the research in question.

(7) The Provost should, in consultation with the President, the Dean, and legal counsel, decide if there is cause for release of information about the matter. They should also determine in advance who will be the spokesperson(s) in the event of inquiries or publicity concerning the investigation at any time.

(8) If the College plans to terminate an investigation for any reason without completing all relevant requirements under 42 CFR 50.103 (d), a report of such planned termination, including a description of the reasons for such termination, shall be made to ORI.

Continuation of Investigation After Investigator's Departure

If an investigator under investigation for alleged unethical scientific practices shall resign from his or her College position or the College faculty before conclusion of the investigation, the Dean, the President or the Chancellor may direct that the investigation nonetheless proceed to a conclusion if they deem it necessary for the best interests of the College and scientific integrity. If, after consideration of relevant circumstances in such a case, the Committee of Investigation shall determine that the former College investigator is not reasonably cooperating in the continued investigation, they may consider that fact in reaching a conclusion.

Immunity from Liability

In view of the purpose of this policy to protect and promote academic and scientific integrity, each member of the College's faculty who conducts research while this policy is in effect shall be bound not to assert any claim or liability or commence any lawsuit or other proceeding against New York Medical College, College administrative officials, or any person serving as a member of the Committee of Inquiry or the Committee of Investigation hereunder in connection with or related to any of the proceedings hereunder or any oral or written statements made in connection with or arising out of such proceedings as long as such person or persons who made such statement(s) acted in good faith and without malice, and the good faith or such person or persons shall be presumed.

Records Retention

Detailed documentation of inquiries will be retained for at least three years and will, for PHS supported studies and upon request, be provided to authorized HHS personnel. Documentation to substantiate an investigation's findings will be retained for at least three years or, for PHS supported studies, for three years after PHS acceptance of the final report. This documentation is to be made available to the Director, ORI.