

Procedures for Dealing with Issues of Research Misconduct

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I. Introduction

The School of Medicine is an institution dedicated to truth in pursuit of knowledge through biomedical research, to the transmission of knowledge through teaching, and to the application of medical knowledge to patient care. A spirit of mutual respect and a broad trust that all faculty members, students, and staff share this dedication to scientific integrity are essential values of the School. When from time to time some member of the community disregards the accepted norms of scientific inquiry, the entire community is diminished.

Misconduct in research endangers public trust and the pursuit of scientific truth, and the School has an obligation to deal promptly with allegations or evidence of research misconduct. The procedures outlined here were developed to provide a fair and orderly means of handling allegations or suspicions of research misconduct. These procedures were designed to comply with applicable federal regulations for research institutions¹ and will be applied with respect to all allegations of research misconduct regardless of sponsor. This policy applies to all faculty, trainees, and staff of The Johns Hopkins University School of Medicine insofar as they are engaged in any manner of scientific inquiry.

Definitions and Standards

1. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
 - a) Fabrication is making up data or results and recording or reporting them.
 - b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in research records or reports.

- c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
 - d) Research misconduct does not include honest error or honest differences of opinion.
 - e) Research misconduct includes the destruction of, absence of, or accused person's failure to provide research records accurately documenting the questioned research.
2. Each of the following must be met to support a finding of research misconduct:
 - a) there has been a significant departure from the accepted practices of the scientific community;
 - b) the misconduct was committed intentionally, knowingly, or recklessly; and
 - c) the allegation has been proven by a preponderance of the evidence.
 3. The review process for determining whether research misconduct has occurred and providing corrective actions consists of three phases: inquiry, investigation, and adjudication. The goal of these procedures is to ensure fair treatment for each person alleged to have committed an act of research misconduct. The following procedures recognize that it may be difficult to determine whether misconduct has occurred, and that the process of inquiry or investigation must be sufficiently flexible to permit early termination of the proceedings when it becomes clear that charges are unjustified or that the issue can be resolved appropriately by other expeditious means (e.g., an allegation of misconduct might arise due to disorganized research records, which would be dealt with by means other than those just described).
 4. Every inquiry and subsequent investigation will be based on a presumption of innocence until proven otherwise. It is not intended that the proceedings be adversarial. Rather, all phases of the procedure should be conducted in the spirit of peer review.
 5. The School believes that duly constituted boards and committees of the faculty should be free to meet directly with a member of the academic community on the business of the School, without counsel present. No accused person and no accuser may appear before these internal review panels with legal counsel.
 6. Since a charge of misconduct, especially if unjustified, may seriously damage an individual's career, any allegation of misconduct should be handled as confidentially as possible. As few people should be involved at any stage of the procedure.

The Division of Research Integrity within the Office of Policy Coordination (OPC), part of the Office of the Dean, is charged with overseeing investigations into any allegations of misconduct and staffing all committees involved in the process. The Division of Research Integrity is available to answer questions concerning the procedures described below from all involved in the process.

¹ The applicable federal policies, statutes, and regulations (new regulations became effective June 16, 2005) may be found on the Office of Research Integrity (ORI) of the U.S. Department of Health and Human Services' [website](#).

II. Reporting Allegations of Research Misconduct

1. Any faculty member, trainee, or staff employee of the School of Medicine who suspects that research misconduct has occurred has an obligation to report that suspicion to the director of the department or division affected, or to the Dean of the School of Medicine.
2. The School considers those who bring allegations in good faith as fulfilling their obligations under this policy to report suspicions of misconduct, and there must be no recriminations for a person bringing an allegation in good faith. Persons who raise allegations will be protected from retaliation even if, in the judgment of the Inquiry or Investigation Committees, the allegations, however incorrect or unsupportable, appear to have been made in good faith. The School will adhere to federal rules and guidelines regarding the protection of whistleblowers, as applicable ².
3. If the report is made to the director of a department, the department or director must report the allegation to the Dean or the Dean's designee in a timely fashion, regardless of the department director's assessment concerning whether the activity in question constitutes possible misconduct. The department director may make a recommendation to the Dean or the Dean's designee. If the report is made to the director of a division, the division director must report the allegation to the department director.
4. If the allegation arises in another division of the University, the relevant Deans and/or Deans' designees will meet to collaboratively decide how to proceed.
5. The School may receive allegations of misconduct from other sources (e.g., journal editors, National Institutes of Health, and other granting agencies). In all cases, once a report is received, the Dean will take appropriate action in accordance with these procedures and federal regulations.

² The institution is required to establish policies and procedures that provide for "undertaking diligent efforts to protect the positions and reputations of those who, in good faith, make allegations." 42 C.F.R. Part 50.103(d)(13).

III. Inquiry

1. At the time of or before beginning an inquiry, the Dean or the Dean's designee will notify the accused person(s) in writing.
2. The School will take all reasonable and practical steps to obtain custody of all the research records and the evidence needed to conduct the inquiry, to inventory the records and evidence, and to sequester them in the office of the Dean or another designated location. The accused person is obligated to cooperate with all requests of the University to obtain this information. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the information on the instruments.
3. The purpose of the inquiry is to conduct an initial review of the evidence to determine whether to proceed with an investigation by identifying meritorious accusations and to put quickly to rest frivolous, unjustified, or mistaken allegations. The question is: Do the initial allegations or suspicions warrant investigation?
4. The Dean may designate the reporting department or division director to conduct the inquiry. Alternatively, the Dean may designate another member of the faculty of the School or other academic division of the University to conduct the inquiry. Attention is given to assuring that the individuals conducting the inquiry do not have a conflict of interest in the matter, and that they have the necessary and appropriate expertise to evaluate the available evidence.
5. Every effort will be made to complete the inquiry within 60 calendar days of its initiation. If the inquiry requires longer than 60 days to complete, the record of the inquiry will document the reasons for exceeding 60 days.
6. When the inquiry is completed, a draft report will be prepared by the Inquiry Committee. The written report will state what evidence was reviewed, summarize relevant interviews (if interviews were conducted), and include sufficient details to support the conclusions of the inquiry. The person(s) accused of research misconduct will be provided a copy of the draft inquiry report and given an opportunity to comment on the report. Comments from the accused person must be received by the Dean's Office within 14 days of receipt of the draft inquiry report. The final written report of the matter along with any comments received by the person(s) accused of research misconduct will be submitted to the Dean.

7. At the conclusion of the inquiry, the Dean or the Dean's designee, at his discretion, may advise the person who made the allegation about how the matter was decided.
8. If the inquiry determines that an investigation is not warranted, sufficiently detailed documentation of the inquiry must be maintained to permit a later assessment of the reasons. Efforts to restore the reputation of the accused person(s) will be made as deemed appropriate by the Dean. The records of the inquiry will be kept secure by the Dean's Office for seven years. Records will be available to authorized federal personnel upon request, if the allegations concern federally supported research.
9. If the inquiry concludes that there appear to be grounds for a charge or research misconduct and that an investigation is warranted, the Dean will initiate a formal investigation into the matter and notify the Provost of the pending investigation. If the accused person has joint or secondary appointment(s) in other School of Medicine departments, those department directors will be notified. If the matter involves federally supported research or an application for federal support, the ORI will also be notified, as required by federal regulations.

IV. Investigation

1. The purpose of the investigation is to collect all evidence relevant to the allegation of research misconduct, from documentation, interviews with those involved, and interviews with those knowledgeable about the activities under investigation. This collection of evidence is to be objective, independent, unbiased, and thorough.

The investigation will be conducted by an Investigation Committee appointed by the Dean and consisting of two or more faculty members from The Johns Hopkins University or other academic institutions as may be needed to provide the necessary expertise. The Investigation Committee will initiate the investigation within 30 days of the completion of the inquiry and make a good-faith effort to complete the investigation within 120 days of its initiation. If the Investigation Committee is unable to complete its investigation within 120 days and federal funds are involved, a request for an extension will be made to the ORI.

2. The Investigation Committee will conduct a careful review of the allegation and afford a fair opportunity to all individuals concerned to present their knowledge and information. The Investigation Committee may consider it necessary to review all research with which the accused person is involved, or the Dean may direct the Investigation Committee to do so. Other areas of professional misconduct (e.g., clinical practice, personnel supervision, human or animal subjects research, or personal interaction) may be investigated as well, if the Investigation Committee has reason to believe, or uncovers evidence to indicate, that a broader range of misconduct has occurred. If, in the course of the investigation, the

Investigation Committee finds reasonable grounds to believe there should be an inquiry into actions of individuals other than the accused, it must notify the Dean promptly.

3. At the initiation of the investigation, the Dean or the Dean's designee must inform the person accused of misconduct in writing of all the charges against him or her, the source of the accusation, and the fact that an investigation is taking place. The accused person must be informed promptly and in writing of any amendment to the original charges.
4. The accused person will be notified of the names of the members of the Investigation Committee appointed by the Dean to conduct the investigation. The accused person may request that the Dean replace a member of the Investigation Committee on a reasonable showing of potential bias or conflict of interest.
5. The Investigation Committee will give the accused person written notification of the place, time, and date of any meeting at which her/his appearance is requested. Every effort will be made to schedule such meetings at a mutually convenient time. Unless waived by the accused person, no initial meeting with the Investigation Committee will take place less than seven days after he or she receives the Investigation Committee's request to appear. The accused person may request a rescheduling of the meeting(s) with the Investigation Committee for good cause. The accused person's failure or refusal to meet with the Investigation Committee will not deter the progress of the investigation. If the accused person is no longer a member of the Johns Hopkins academic community, the requirements of written notice and an opportunity to answer to the charge of misconduct will be observed as far as is practical, but the failure of the accused to respond or to make himself or herself available to those with investigatory responsibilities will not deter the inquiry and investigation.
6. All relevant materials and documents sequestered during either an inquiry or an investigation must continue to be secured in the office of the Dean or another designated location throughout the course of the investigation.
7. At the beginning of the investigation, the accused person will be afforded the opportunity to consult with an uninvolved senior faculty member, who will serve as "advisor" to the accused person throughout the proceedings. The role of the advisor will be to offer advice and guidance regarding the procedural aspects of the process. This individual will be chosen by the accused person, subject to approval by the Dean, or appointed by the Dean, subject to approval by the accused person, and may, upon request by the accused person, accompany her or him to meetings with inquiry, investigating, or adjudicating committees. No current member of the SCD may serve as an advisor. If the accused person does not wish to consult with an advisor, he or she must so notify the Dean in writing.

8. All testimony to the Investigation Committee by the accused or other persons will be transcribed by a qualified court reporter. Copies of the recordings or the court reporter's transcription will be furnished to the accused person. The accused person may submit corrections in spelling on errata sheets provided with the transcripts but may not otherwise edit the transcript.
9. The accused person will be allowed to present a written statement at the start of the investigation. He or she may request that the Investigation Committee interview certain individuals with relevant information, and may suggest to the Investigation Committee any avenues of inquiry that he or she believes are likely to produce relevant evidence. The accused person may request an opportunity to question his or her accuser at a Committee meeting before the Committee completes its final report. If in the Dean's judgment, this would impose undue hardship on individuals involved, the face-to-face meeting may be prohibited.
10. At the conclusion of the investigation, a report will be prepared by the Investigation Committee. This report will include the names of the persons interviewed; a summary of the interviews; a description of the documents, data, and other evidence examined; and the Investigation Committee's conclusion regarding each of the allegations. The accused person will be given a copy of the Investigation Committee's draft report and a copy of, or supervised access to, the evidence on which the report is based. The accused person may submit comments to the draft report within 30 days of receipt. The Dean will be given the final report and the accused person's comments, if any; a copy will also be provided to ORI in cases where it has jurisdiction.
11. Any granting agency that is supporting, considering support, or has supported the research in question must be informed that an investigation is taking place. For Public Health Service (PHS)-sponsored research, the report must be submitted to ORI, which may then inform relevant federal sponsors in accordance with ORI policies and procedures. This may be done, consistent with the applicable sponsor rules, without identifying the individuals accused. The funding agency (if other than a PHS agency) and ORI must be kept informed of progress throughout the investigation, in accordance with regulatory requirements.
12. If at any stage of the inquiry or investigation of cases involving PHS-sponsored research it is determined that any of the following conditions exist, the Dean will immediately notify ORI:
 - a) health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
 - b) 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) the Dean or his designee believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved; or
 - g) the research community or public should be informed.
13. At any stage of the investigation, the Dean, after consultation with the Investigation Committee, may take steps to notify other parties who, in the Dean's judgment, should be informed of the ongoing investigation. The Dean will also take interim administrative action as necessary to protect any sponsored project funding and assure that intended purposes of the sponsored research in question are being carried out.
 14. The likelihood that a criminal act may have occurred must be reported immediately to the Office of the General Counsel for the University, which will assume responsibility for prompt notification of the appropriate federal, state, and local authorities.
 15. If the investigation concludes that research misconduct has not occurred, and if the Dean concurs with these findings, the matter will be closed, with appropriate action for restoration of the reputation of those under investigation and continued protection of the accuser(s) from retaliation. The Dean will retain the records of the investigation, including the findings of the Investigation Committee, in a confidential, sequestered file for a period of seven years. A copy of the Investigation Committee's findings of no misconduct will be sent by the Dean, to the accused person, the department director and to the ORI (if applicable). If, in the judgment of the Investigation Committee, the allegations, however incorrect or unsupported, were made in good faith, no retaliatory or disciplinary action will be taken against the accuser(s) and appropriate measures will be taken to protect the accuser(s) from retaliation.
 16. If, with due regard to whistleblower protections, the Investigation Committee finds the allegations of research misconduct have been maliciously motivated, or based on fraudulent evidence, the Dean may take appropriate disciplinary action against those responsible. If, in the judgment of the Investigation Committee, the allegations, however incorrect or unsupported, were made in good faith, no retaliatory or disciplinary action will be taken against the accuser(s) and appropriate measures will be taken to protect the accuser(s) from retaliation.

17. If the Investigation Committee concludes that research misconduct has occurred, it will report its findings as follows: The Investigation Committee's written report will include its findings and the significance assigned by the Investigation Committee to such findings, and will not include recommendations as to disciplinary action.

a) If the accused person is a faculty member, the report will be sent to the accused person, his or her department director and division chief, the Dean and the Standing Committee on Discipline (SCD) for further action as provided in this procedure and in accordance with SCD's procedures.

b) If the accused person is a trainee (e.g., medical student, graduate student, member of the house staff, postdoctoral fellow), the report will be sent to the accused person, the supervisor of the accused person, and the appropriate Associate Dean. The Dean or his designee will review the report, and may ask questions of the Investigation Committee and the accused person. The Dean or his designee will accept or reject the investigation report in whole or in part. Upon acceptance of the report, the Dean will forward it to the appropriate Associate Dean for action in accordance with applicable procedures.

c) If the accused person is a staff employee, the report will be sent to the accused person, the supervisor of the accused person, the divisional human resources office, the Dean, or the Dean's designee. The Dean or his designee will review the investigation report, and may ask questions of the Investigation Committee and the accused person. The Dean or his designee will accept or reject the investigation report in whole or in part. Upon acceptance of the report, the Dean will send it to the divisional human resources office for disciplinary action, as deemed appropriate.

V. Adjudication by the Standing Committee on Discipline

1. The role of the SCD is to review the investigation report in the context of any mitigating or aggravating circumstances, while considering any rebuttals submitted by those found to have engaged in research and/or professional misconduct, and to then make a recommendation to the Advisory Board of the Medical Faculty (ABMF) for corrective and/or disciplinary action, if indicated.
2. If the accused person's department or functional unit director is a member of the SCD, he or she is recused from deliberations, except for the department director's testimony before the SCD described in Point 3 of this section. Other SCD members with conflicts of interest, either real or perceived, will disclose those conflicts to the Chair of the SCD. The Chair will make a determination concerning recusal.
3. The accused person will be given an opportunity to appear before, and submit written comments to the SCD. The accused person may state his or her views on why the

findings of the Dean and the Inquiry or Investigation Committee should be accepted or rejected in whole or in part. Comments on the Inquiry or Investigation Committee's report by the accused person should be received by the SCD within ten days of receipt of the report.

4. Before making a final decision regarding sanctions and remedial actions, if any, the SCD will meet with the accused individual's department director (or, at the discretion of the department director, both the department and division directors) so the director(s) can provide the SCD with information bearing on the impact of the proposed disciplinary action and/or remediation measures on the department. If the department director disagrees with the SCD recommendations, the SCD will note the difference of opinion, but its final recommendation will be made independently. The SCD will document the reasons for any differences of opinion between the department director and the committee and it will include this documentation in its report. If there are differences of opinion, the department director will submit in writing his or her discussion of the differences to the ABMF via the Agenda Committee of the Advisory Board.
5. The SCD may accept or reject the report of the Investigation Committee in whole or in part, and recommend to the ABMF those sanctions and remedial actions, if any, that the SCD considers appropriate; or the SCD can return the matter to the Investigation Committee for additional investigation or modification of its report.
6. The SCD's recommendations to the ABMF may include one or more of the following corrective or disciplinary actions:
 - a) withdrawal or correction of papers and abstracts;
 - b) notification of journal editors where fraudulent or suspect research has been published or is under review;
 - c) notification of sponsoring agencies;
 - d) termination or alteration of employment status, including periods of supervised probation;
 - e) postponement or denial of promotion or advancement;
 - f) release of information about the incident to the public, particularly when public funds were used to support the fraudulent or suspect research; or
 - g) any other action deemed appropriate to the circumstances.

VI. Advisory Board of the Medical Faculty

1. The SCD will forward its report and recommendations to the full ABMF, which will, in executive session, consider the case and decide what if any disciplinary action to take. Interested parties may ask to appear before the Board or to submit a written statement or materials relevant to the disposition of the case, and such requests may be granted at the discretion of the Agenda Committee of the ABMF.
2. Interested parties (the accused individual and/or others) who wish to address the ABMF must direct their requests in writing, at least seven days in advance of the Agenda Committee meeting, to the Dean of the Medical Faculty. The Dean will forward the request to the Agenda Committee as an addendum to the SCD materials. The Agenda Committee will consider the case and all relevant materials and decide whether it will permit or deny a personal presentation by the interested party at the ABMF meeting. Any material to be presented to the ABMF by or on behalf of the accused individual, whether or not in person, will be provided to the Chair of the SCD and the Dean at least seven days in advance of the ABMF meeting and earlier, if possible. Details of presentation procedures to the ABMF are available from the Dean's Office upon request.
3. The ABMF will report its decision to the Dean and to the accused person. All records of the proceedings will be maintained in confidence by the Dean.

VII. Appeals

The accused person may take an appeal of the ABMF's decision to the Dean within fourteen days of receiving the decision. In the event the Dean upholds the ABMF's decision, the accused person may appeal that decision to the Provost of the University within 14 days of the Dean's decision. The appeal review by the Dean and Provost will be limited to the adequacy of the procedures followed and the appropriateness of the disciplinary action taken.

VIII. Office of the General Counsel

1. The responsibilities of the Office of the General Counsel include:
 - a) ensuring compliance with all applicable laws and regulations;
 - b) monitoring the progress of the resolution of each allegation of research or professional misconduct to ensure adherence to the established School and University procedures; and
 - c) notification to appropriate authorities of suspected criminal acts.

2. The Office of the General Counsel will not act as the prosecutor or defender of the accused person, but will act as an impartial legal advisor to the Administration of the School and University.
3. The Office of the General Counsel is available to render advice to department or division directors, the Dean or the Dean's designee, the SCD, Investigation Committees, and the ABMF at any step in the proceedings. Individuals serving in any of these capacities are encouraged to seek legal guidance regarding any procedural question, particularly in connection with the preparation of written reports of actions taken, or before any action is taken with respect to any person believed to have made an accusation of misconduct in bad faith. Any contact or inquiry to the University or School of Medicine from a lawyer outside the University, including contacts and inquiries emanating from legal representatives of any federal, state, or local agency, must be referred to the Office of the General Counsel.

IX. Exclusivity of Procedure

This procedure for the determination of misconduct is the exclusive mechanism within the School for adjudication of questions of this nature. A person disciplined under this procedure may not invoke the School's grievance procedure in an effort to gain a readjudication of the charge.