



Albert Einstein College of Medicine

Research Misconduct Policy

Table of Contents

I.	Purpose.....	2
II.	Scope.....	2
III.	Policy.....	2
III.A.	Procedures for Dealing with Allegations of Research Misconduct.....	2
III.A.1.	Allegations	2
III.A.2.	Ethical Screening Committee	3
III.A.3.	Committee on Ethical Research Performance and the Investigative Committee	3
III.A.4.	Investigative Procedures.....	5
III.B.	Actions	7
III.C.	Support of Ethical Research Performance.....	7
IV.	Definitions.....	7
V.	Effective Date.....	8
VI.	Policy Management and Responsibilities.....	8
VII.	Approved (or Revised).....	8

I. Purpose

This Policy affirms the commitment of the Albert Einstein College of Medicine (“Einstein” or “College of Medicine”) to require and maintain the highest standards of ethical performance on the part of all members of the Einstein community. It establishes procedures for the prompt, thorough, and fair investigation of allegations of research misconduct in the conduct of research for which Einstein assumed legal and financial accountability for the funds and/or for the performance of the activities. This Policy defines the mechanisms for investigating all allegations of research misconduct involving research Einstein as herein defined. The procedures set up herein are to be invoked in response to any and all such allegations of research misconduct. This Policy states the mechanisms through which investigation of such allegations will be carried out and reported. It provides procedures for enforcing high standards of ethical performance within Einstein, as well as complying with governmental regulations regarding research misconduct.

II. Scope

This Policy applies to all research conducted by students, post-doctoral researchers, or faculty of Einstein and affiliated institutions. Where an allegation has been made relating to an employee of an affiliated institution involved in such research or an allegation involves an Einstein employee concerning research for which another institution is responsible, Einstein will notify the affiliated institution of the allegation. An appropriate investigation of the allegation pursuant to a P.H.S.-approved policy of this or the other institution will be undertaken as required. In all cases, however, the responsibility for any disciplinary action shall reside with the employing institution.

III. Policy

III.A. Procedures for Dealing with Allegations of Research Misconduct

All allegations of research misconduct are to be reported to the Dean. The Dean will promptly forward each such allegation to the Ethical Screening Committee (referred to in Section III.A.2). Unless such allegation is deemed by the Ethical Screening Committee to be frivolous or trivial (see Section III.A.2.a), the Ethical Screening Committee will promptly refer the allegation to the Committee on Ethical Research Performance (CERP) for non-formal inquiry into the substance of the allegation. (See section III.A.3). The CERP will determine from its inquiry whether the allegation requires a formal investigation. If such an investigation is deemed necessary by the CERP, an Investigative Committee (referred to in Section III.A.4) will carry out such formal investigation following the procedures set forth in Section III.A.4.(a). Where research supported by government funds is involved, the procedures set out in this policy are intended to conform with the requirements for investigating and reporting possible misconduct in science involving research supported with government funds that are stated in Subpart A of Part 50, Title 42, Subchapter D of the Code of Federal Regulations.

III.A.1. Allegations

It is the responsibility of all members of the Einstein community to report any perceived research misconduct to the Dean. Allegations can be made anonymously but an anonymous allegation must be sufficiently specific to provide a factual basis for investigation. A copy of the allegation (or a write-up

giving the substance of the allegation) must be given to the accused by the CERP forthwith. The CERP will take any steps that may be necessary to preserve the evidence necessary to enable it to inquire into an allegation.

III.A.2. Ethical Screening Committee

The Ethical Screening Committee shall review all allegations of research misconduct presented to the Dean to determine whether the allegation falls within the purview of this policy and is not of a frivolous or trivial nature. This preliminary examination of allegations shall be conducted promptly and ordinarily completed within 5 days.

- a. The Ethical Screening Committee shall comprise the Executive Dean (or his/her designated representative) and two additional senior faculty members appointed by the Dean for three-year terms from slate(s) of possible candidates requested by the Dean from the Senate through its Committee on Committees. The Executive Dean shall serve as chairperson of the Ethical Screening Committee.
- b. A determination that an allegation of research misconduct is frivolous or trivial and therefore does not warrant inquiry or otherwise does not fall within the purview of this policy requires a unanimous finding by the Ethical Screening Committee.
- c. If the Committee decides that the allegation of research misconduct is not frivolous or trivial, the accused must be promptly notified in writing by the Committee of the substance of the allegations. He must also be advised of his rights and obligations under the investigative procedures defined below. The accused must be advised of the right to obtain counsel, after being notified that an allegation of research misconduct has been made and that his exercise of his right to obtain counsel shall not affect his faculty or employment status or impair his right to a full hearing under the investigative procedures described herein.

III.A.3. Committee on Ethical Research Performance and the Investigative Committee

The CERP is charged with the non-formal inquiry into all allegations of research misconduct referred to it by the Dean after review by the Ethical Screening Committee, in keeping with this policy and as required by governmental regulations. The CERP is responsible for determining whether an allegation of research misconduct requires a formal investigation. The CERP shall make its determination no later than 60 calendar days from the time the allegation was first received by the Dean, unless the Dean agrees with the CERP that the circumstances of the allegation and the necessary inquiry require a longer period.

- a. The CERP shall comprise no fewer than five (5) members of the Faculty appointed by the Dean for three-year terms, with two of the five members appointed from slate(s) of possible candidates requested by the Dean from the Senate through its Committee on Committees. The CERP should include a balanced representation of the Faculty. A chairperson will be selected by the Dean. Should a member of the CERP have any conflict of interest regarding a specific allegation, that member shall not participate in any aspect of the inquiry into that allegation. Additional ad hoc members to serve in regard to a specific allegation of research misconduct may be appointed by the Dean after consultation with the CERP and the Senate Council with all due consideration given to the need to protect the confidentiality of the inquiry. The selection of ad hoc members will be made with due

consideration for the required expertise and to avoid possible conflicts of interest. Ad hoc members will serve for the duration of a specific inquiry or investigation.

The CERP's findings are to be presented in a written report to the Dean which shall set forth what evidence was reviewed, shall summarize relevant interviews and shall include the conclusions of the inquiry. The individual (s) against whom the allegation was shall be given a copy of the report of the inquiry. If the individual against whom the accusation is made comments on such report, such comments shall be appended.

At such time as the CERP determines that a formal investigation of possible research misconduct is necessary involving research supported by government funds, the President or his designated representative shall so notify the Director of the Office of Research Integrity (ORI) indicating 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 and such other information as may be pertinent. However, the President or his designated representative is responsible for notifying the ORI and the funding agency if it is ascertained at any stage of the inquiry or investigation, that any of the following conditions exist.

- i. There is a public health or safety 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 or civil law violation. In that instance, the President or his designated representative must inform ORI within 24 hours of obtaining that information;
 - vi. If research activities should be suspended;
 - vii. If the research community or public should be informed.
- b. Where the CERP has determined that an allegation of research misconduct requires a formal investigation, that investigation will be conducted by the Investigative Committee. The funding agent must be notified. The Investigative Committee shall comprise no fewer than five (5) members of the Faculty none of whom were regular members of the CERP or served as ad hoc members in the non-formal inquiry of the same or related allegation. Members of the Investigative Committee shall be selected by the CERP at a duly called meeting for that purpose.

Up to three additional ad hoc members of that Committee may be appointed by the Dean after consultation with the Senate Council with all due consideration for protecting the confidentiality of the investigation. If an accused is not a faculty member, an additional ad hoc member shall be from the peer group (e.g., student, employee) of the accused. All members will be subject to the rules stated in Section III.A.3(a) regarding conflict of interest.

- c. The College of Medicine shall provide the CERP and the Investigative Committee with such administrative and secretarial support as is required to carry out their functions and shall reimburse members of such committees for any necessary expenses incurred during the course of carrying out the investigations provided for in this policy. Counsel designated by the institution shall serve in an advisory capacity to the CERP and the Investigative Committee to assure that institutional obligations are carried out and appropriate laws and procedures are followed.

- d. The institution will defend the members of the CERP and the Investigative Committee against any legal actions brought against them that result from their good faith actions consistent with applicable laws, regulations and this policy that were within the scope of their responsibilities and in connection with pursuing inquiries or investigations of allegations referred to them by the Dean as members of the CERP or the Investigative Committee respectively and will hold them harmless and indemnify them for any liability resulting therefrom.

- e. In regard to any allegation that was found to be without substance, the CERP must also endeavor to determine whether the allegation was made in good faith. If it decides that the allegation was made in good faith but does not involve research misconduct, the CERP shall make recommendations to the Dean as how to restore the reputations of all concerned. If the CERP judges that the allegation was not made in good faith or was made with malicious intent, the CERP is to recommend to the Dean a course of action which may include referral of the actions of the accuser for disciplinary consideration.

III.A.4. Investigative Procedures

III.A.4(a) Investigation into an Allegation of Research Misconduct

Within 30 days of any determination by the CERP that an allegation of research misconduct requires formal investigation, the Investigative Committee shall undertake formal investigation into the substance of the allegation and any additional issues of possible research misconduct raised by the CERP's inquiry. This inquiry must be conducted thoroughly but expeditiously, adhering to the requirements of the PHS and its ORI in cases involving Research Misconduct in regard to research supported by government funds.

The Investigative Committee shall act to obtain whatever testimony and documentary evidence it requires to evaluate the substance of the alleged misconduct and any circumstances that materially bear on the allegation. The Investigative Committee is not bound by strict rules of evidence. The accuser, if known, will be asked to testify and present evidence, represented by counsel if he desires. Testimony and evidence may also be presented by witnesses called by the Investigative Committee. The accused must be given the opportunity to testify and may be represented by his counsel. The accused will be entitled to present witnesses on his own behalf and to know of and have an opportunity to respond to the substance of all allegations against him. The accused will have the opportunity to confront and cross examine any individual who has specifically charged the accused with research misconduct (if such individual's

identity is known) and any other witnesses. All testimony to the Investigative Committee is to be recorded verbatim with a copy made available to the accused.

All records including testimony and documentation are confidential files that will be maintained by the institution for at least three years after the completion of the investigation. The institution shall provide such records or copies thereof to competent governmental authorities as required by applicable law or regulation and to otherwise fulfill institutional responsibilities.

Efforts shall be made by the members of the Ethical Screening Committee, the CERP and the Investigative Committee to preserve the confidentiality of the proceedings and to protect the rights and reputation of all individuals who may be involved in any way in the investigation. The Investigative Committee shall also make recommendations concerning the actions it considers appropriate to assure the integrity of the research work at issue and the reputation and rights of all concerned.

III.A.4(b) Report of the Investigation

The Investigative Committee shall provide a written report of the investigation that states the original allegation, the potential research misconduct found by the CERP to require investigation and that fully describes the examined and completely summarizes the substance of the relevant interviews. The specific charges and findings arising from the investigation that are the basis for any recommendations for disciplinary action by the Investigative Committee must be fully and clearly described, together with the recommended actions. This report shall be completed no later than 65 calendar days following initiation of the inquiry by the Investigative Committee unless the Investigative Committee requests and the Dean agrees that the report cannot be then completed due to unavoidable delays. If the Investigative Committee has concluded on the basis of its investigation that research misconduct has occurred, the specific charges, evidence and findings including those that form the basis for any proposed disciplinary action must be presented to the accused in writing before such findings are reported, and before any recommendation for disciplinary action is made. The accused must be given a period of 30 days during which he may prepare a written response and present additional evidence and witnesses to the Investigative Committee that are relevant to the findings and/or recommendations of the Investigative Committee. The Investigative Committee shall reconvene within that period to receive such additional evidence suggested by the accused and any further evidence the Investigative Committee deems appropriate to its consideration of the new evidence presented at the request of the accused. The report, the appended response by the accused, and the results of additional investigation by the Investigative Committee and the Committee's recommendations will be forwarded to the Dean within 100 calendar days of the initiation of the investigation unless an extension is requested and granted by the Dean. The Dean may request further investigation by the Investigative Committee which shall be carried out as expeditiously as possible. In any event, a final report will be provided to the Dean by the Investigative Committee within 110 calendar days of the initiation of the investigation. The Dean shall send the Final Report of the Investigative Committee and copies of any supporting documentation that the Dean deemed appropriate or was requested by the President along with the Dean's comments and recommendations to the President of the University for decision by the President on behalf of the institution. If research that was supported by government funds was involved, a final report will be submitted by the institution to the ORI within 120 calendar days of the initiation of the investigation. The report 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 evidentiary basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) who submitted relevant testimony as well as the individual found to have engaged in misconduct, as well as a description of any sanctions to be taken by the institution. No recommendation for disciplinary action based on the research misconduct alleged to have occurred may be made that is not based on these formal written charges. The accused, the accuser, the CERP and the Investigative Committee shall be provided copies of all such reports. If the accused is found not to have committed misconduct, the Investigative Committee shall recommend appropriate steps designed to restore the reputation of the accused including proper notification to the ORI.

III.A.4(c) Extended Investigation

In cases of alleged misconduct that require a more extensive investigation than can be completed in this 120-day period, the Investigative Committee shall submit a report to the Dean prior to the 120 days including a request for an extension and a statement of the reasons that further investigation requiring time beyond this 120-day period is required. This report shall be provided to the Dean to enable an institutional request of the ORI for an extension of time to complete the investigation. The procedures to be followed during an extended investigation are the same as described in Section III.A.4(a) and the report thereof as in Section III.A.4(b).

III.B. Actions

A report of any investigation of research misconduct will be reviewed by the Dean, and forwarded to the President of the University, together with any additional comments or recommendations the Dean may consider appropriate. The Institution will report the investigative findings and recommendations to all appropriate governmental bodies in accordance with applicable laws or regulations. The Dean shall take administrative actions as deemed necessary to remedy the effects of any research misconduct that the investigation has revealed or to prevent its future occurrence. With respect to actions regarding research misconduct affecting a member of the faculty, the procedures described herein shall supersede the Rules and Regulations Providing for a System of Appointments, Titles and Compensation Arrangements of the Albert Einstein College of Medicine. In such instances where continuance of the individual in his duties threatens immediate harm to himself or to others or may cause irreparable damage to the College of Medicine, a person against whom written charges have been made may be suspended from his duties by the Dean pending final action on such charges. In the case of a faculty member such suspension by the Dean would be with salary pending final action upon such charges. This policy also encompasses investigation and reporting of allegations of research misconduct involving students and non-faculty employees of the College of Medicine; however, disciplinary actions resulting from such investigations may be dealt with in the disciplinary process applicable to the group involved (e.g., student disciplinary procedures or grievance and arbitration machinery of employee collective bargaining agreements).

III.C. Support of Ethical Research Performance

It shall be the responsibility of all members of the Einstein community to actively foster ethical practices in the conduct of research.

IV. Definitions

Research misconduct includes fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or reporting research results. Misconduct does not include honest error or differences of opinion.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Findings of Research Misconduct: A finding of research misconduct requires that:

- there be a significant departure from accepted practices of the relevant research community; and
- the misconduct be committed intentionally, or knowingly, or recklessly; and
- the allegation be proven by a preponderance of evidence.

V. Effective Date

Effective as of: 27 July 2018

VI. Policy Management and Responsibilities

The Responsible Office under this policy is the Office of the Dean. The Responsible Executive and the Responsible Officer under this policy are Einstein's Executive Dean.

VII. Approved (or Revised)



Responsible Executive

August 21, 2018

Date