

ACKNOWLEDGEMENT

RESEARCH FRAUD AND PROFESSIONAL MISCONDUCT POLICY

I _____ (Print Name) have received a copy of and will promptly read and familiarize myself with and comply with the CSHL policies on scientific misconduct.

Signature Date

Print Name

POLICIES AND PROCEDURES
RELATED TO
RESEARCH FRAUD AND PROFESSIONAL MISCONDUCT

Cold Spring Harbor Laboratory has the primary responsibility for preventing, detecting, investigating, reporting and resolving allegations of professional misconduct. The Department of Health & Human Services (DHHS), however, retains the ultimate responsibility and authority for monitoring such investigations.

The intent of this Policy is first, to update and codify the procedures to be followed in cases where evidence exists or allegations have been made regarding research fraud or professional misconduct and second, to describe the practices now in place to respond to such evidence or allegations. Open discussion and suggestions concerning these critical issues are encouraged from all members of the staff.

"Misconduct" means (1) fabrication, falsification, plagiarism, or other research fraud or deviation from accepted practices in proposing, carrying out or reporting results from research; (2) material failure to comply with federal or institutional requirements for protection of researchers, human subjects, or the public or for ensuring the welfare of laboratory animals; or (3) failure to meet other material legal requirements. "Misconduct" does not include covert error or honest differences in interpretations or judgments of data.

Examples of professional misconduct include, but are not limited to, falsification of research results, deliberate distortion of research data, plagiarism in scholarly publications and misappropriation of the intellectual property of others. Violations of human subject protocols, or animal research protocols, as well as recklessness and gross negligence in the conduct or direction of scientific research that do not amount to fraud may also constitute professional misconduct. The procedures described here will be used in all such cases.

Professional misconduct represents a major breach of contract between the scientist and the Laboratory and may result in the termination of employment and other sanctions as outlined in this Policy. This Policy applies to all scientific personnel of the Laboratory, and is particularly pertinent to those individuals who may be involved with a research project supported by the Public Health Service or who have submitted an application for such support.

1. Individuals who believe an act of professional misconduct has occurred at Cold Spring Harbor Laboratory should inform the Laboratory President accordingly. If the individual believes that the Laboratory President may be involved in the wrongdoing, he or she should inform the Chairman of the Board of Trustees who will then take on the responsibility otherwise assigned to the President under this policy. To the extent that it is practicable, allegations from parties outside the Laboratory will be dealt with by the President under this Policy. The individuals to whom such

reports should be directed currently and the ways to contact them are displayed in the Appendix.

2. The President will respond immediately to each allegation of scientific misconduct by implementing a preliminary inquiry to determine the merits of the allegation. This will generally involve meeting individually with the people involved, including the person making the allegation, the scientist whose conduct is in question and any others believed to have relevant knowledge. The President will endeavor to complete the preliminary inquiry within thirty (30) days but in any event the preliminary inquiry shall be completed within sixty (60) days. A completed inquiry includes the preparation of a written Inquiry Report which indicates the evidence that was reviewed, summarizes relevant interviews and states the conclusions of the inquiry. If an inquiry takes longer than sixty (60) days, the record must include documentation explaining the reasons for the delay. The President may designate a senior member of the Laboratory's scientific staff to carry out the preliminary inquiry and report back to him. The President will always ensure that the inquiry will be conducted by individuals with the necessary and appropriate expertise to evaluate the case thoroughly and authoritatively. The preliminary inquiry shall consist of gathering information to determine whether a more complete Investigation is warranted. Upon initiation of the preliminary inquiry, the President shall inform the involved individual of the charges and discuss their nature, affording this individual the opportunity to comment on these allegations. To the extent possible, confidentiality shall be maintained throughout the preliminary inquiry to protect the professional reputations of the individuals who are involved, as well as the source of the allegation.

3. If the result of the preliminary inquiry reveals that there is no basis for the allegation(s) of professional misconduct, this finding shall be reported in writing by the President to the individual(s) against whom the charges were levied as well as the individual who made the accusations. To the extent appropriate in the particular case, others may be informed. While it is hoped that the misconduct charges were kept confidential during the inquiry, the Laboratory will make diligent efforts to protect the positions and reputations of both the persons alleged to have engaged in misconduct and the persons who, in good faith, made the allegations when the inquiry determined such allegations to be unfounded.

The President will maintain sufficiently detailed documentation of the inquiry to permit a later assessment of the reasons for determining why an Investigation was or was not warranted. Such records shall be securely maintained for a period of at least three (3) years from the termination of the inquiry and be provided to authorized DHHS personnel upon request.

4. In cases where the preliminary inquiry leads the President to conclude that a more complete Investigation is warranted, the President shall report that finding in writing to the Chairman of the Board of Trustees who will refer the matter to the *Committee on Scientific and Professional Integrity*, whose sole responsibility is to assist the President and the Chairman of the Board of Trustees in determining the validity of the allegation(s). The accused individual(s) will be given a copy of the Inquiry Report and the individual(s) making the accusations

shall be notified of this referral by the President. If the accused individuals comment on the Report, their comments may be made part of the record.

If findings from the preliminary inquiry indicate that an Investigation is warranted, the President shall notify the Office of Research Integrity of the Office of the President of the National Institutes of Health (ORI) that an Investigation will be initiated on or before the date that the Investigation begins. In addition, the President will keep the agency informed of developments during the Investigation, and notify the agency of the final outcome. During both the Inquiry and a subsequent Investigation the President shall take appropriate interim administrative action to protect Federal funds and ensure that the purposes of the Federal financial assistance are being carried out. Scientific collaborators of individuals against whom charges are levied shall be notified of the charges as appropriate.

5. The Office of Research Integrity shall be notified within 24 hours of the Laboratory's obtaining any reasonable indication at any stage of the Inquiry or Investigation of possible criminal violations.

6. The President and/or the Committee shall notify the ORI at any stage of the Inquiry or Investigation that any of the following conditions exist:

- 1) There is an immediate health hazard involved;
- 2) There is an immediate need to protect Federal funds or equipment;
- 3) 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;
- 4) It is probable that the alleged incident is going to be reported publicly.

7. The Committee on Scientific and Professional Integrity (the Committee) shall be appointed by the Executive Committee of the Board of Trustees and shall be composed of impartial individuals from within the Laboratory as well as impartial individuals from outside the Laboratory at least one of which has some expertise in evaluating evidentiary questions. Individuals possessing the necessary and appropriate expertise will be selected for this Committee to enable a thorough and authoritative evaluation of the relevant evidence. No member of the Committee shall have a conflict-of-interest in an Inquiry or Investigation.

8. The Investigation by the Committee shall be initiated within 30 days of the initial report on the preliminary inquiry. Every effort shall be made to conclude the proceedings in 60 days and not later than 120 days. If the Investigation cannot be completed in 120 days, a request for an extension will be submitted to the ORI which explains the delay, reports on the progress to date, outlines what remains to be done and an estimated date of completion. The Chairman of the Committee will also provide this information to the Chairman of the Board of Trustees. The Committee's Investigation shall consist of a thorough examination and evaluation of relevant facts to determine whether professional misconduct has occurred. This

Investigation shall be performed with deliberate speed. The ORI shall be promptly advised of any developments during the course of the Investigation which disclose facts that may affect the current or potential DHHS funding for individual(s) under Investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest. If an Inquiry or Investigation is terminated without completing all the steps called for under this Policy, a report, including the reasons for such termination, will be made to the ORI.

To the extent that it is possible, confidentiality shall be maintained throughout the Committee's Investigation to protect the professional reputations of the individuals involved, including the source of the allegation when appropriate.

During the course of the Investigation, any party may obtain the assistance of counsel. Normally, the accused will have the right to confront his or her accuser. It will remain the obligation of all involved individuals to appear personally and to participate directly in the Investigation. Throughout the Investigation, the individual and any collaborator or supervisor whose role in the alleged misconduct is being questioned, shall be advised of the progress of the Investigation and afforded the opportunity to respond and to provide additional information. The Chairman of the Committee shall keep the President and the Chairman of the Board of Trustees informed of the progress of the Investigation.

9. Upon completion of the Investigation, the Committee shall promptly submit to the President a written report of its findings and conclusions. This report will describe: (1) the policies and procedures under which the Investigation was conducted, (2) how and from whom information relevant to the Investigation was obtained, (3) the findings and the basis thereof, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution. The President shall provide the Chairman of the Board of Trustees with the results of the Committee's Investigation, including the Committee report. This report is confidential to the President and the Chairman of the Board of Trustees, who have the sole authority to release its contents to any other party. However, this report must be made available to the respondent(s) for comment. The Investigation and report shall be sufficiently complete to allow the President and the Chairman of the Board of Trustees to determine whether or not a formal charge of professional misconduct is warranted. A final report must be provided to the ORI for its review and acceptance of the findings within 120 calendar days of initiation of the Investigation. This report will describe the policies and procedures under which the Investigation was conducted, how and from whom information relevant to the Investigation was obtained, the findings and the basis thereof, and includes the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution. The report shall be securely maintained for a period of at least three (3) years after ORI, PHS acceptance of the findings.

10. If the results of the complete Investigation substantiate the charges of professional misconduct, the following actions are recommended:

- In cases involving sponsored research funding, the awarding agency shall be notified in accordance with the requirements of statutes, regulations, and the policies and procedures of that agency.

- All pending abstracts and papers emanating from the fraudulent research shall be withdrawn and editors of journals in which previous abstracts and papers appeared shall be notified.

- Institutions and sponsoring agencies with which the individual has been affiliated shall be notified of the Committees findings.

- Appropriate action shall be taken to alter or terminate the employment status of individuals whose misconduct is substantiated. A range of sanctions are available to the Committee including:

- removal from the particular research project
- formal letter of reprimand on file
- probationary period of employment
- suspension
- termination of employment
- termination of employment with restitution
- termination of employment with referral to civil authorities

11. At the conclusion of the Investigation, a statement describing the findings, conclusions and disposition of the case, including a listing of any publications that require correction or retraction, will be made available to the public. If, however, during the Investigation, the Chairman of the Board of Trustees, in consultation with members of the scientific staff and legal counsel, is persuaded that the need for disclosure is so urgent that it should not be deferred, he may disclose such information as he deems necessary without awaiting a final determination.

12. If the alleged professional misconduct is not substantiated by a thorough Investigation, formal efforts should be undertaken to restore fully the reputation of the researcher and others under Investigation. All involved individuals should be encouraged to make every effort to resolve their differences. So long as the allegations were found to be in good faith, the individual making the allegations should be protected from any future discrimination. On the other hand, appropriate action should be taken against any parties whose involvement in leveling unfounded charges was demonstrated to have been malicious or intentionally dishonest.

13. Violations of human subjects protocols or animal research protocols also constitutes professional misconduct. Alleged violations of such protocols will also be referred to the Laboratory President or the Chairman of the Board of Trustees for Investigation and action in accordance with the proceedings described in this memorandum and as required by Public Health Service regulations for human subjects and by PHS and U.S. Department of Agriculture regulations for laboratory animals.

Appendix

Scientific Misconduct Contacts

Cold Spring Harbor Laboratory

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