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Handling Potential Research Misconduct

I. Introduction

A. General Policy

To maintain confidence in the integrity of the Bureau's research, Allegations of Misconduct in Research must be treated with the utmost seriousness and examined carefully and responsibly. This document outlines the procedures for responding to Allegations of Research Misconduct brought against individuals engaged in NBER Research activities. These procedures are designed to ascertain the truth and to protect the rights of accused individuals and all others who are involved in this process.

B. Scope

1. This statement of policy and procedures is intended to carry out NBER's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93, and 65 FR 76260, thereby complying with standards set by the Department of Health and Human Services, the National Science Foundation, and the Institute of Education Sciences.
2. This document applies to Allegations of Research Misconduct (Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing Research, or in reporting Research results) involving:
 - a) unfunded Research carried out using NBER data;
 - b) Research funded by an award (grant, contract, donation, etc.) made to NBER;
 - c) a person conducting Research as described in 2 a) or b) above, who, at the time of the alleged Research Misconduct, was employed by, was working on behalf of, or was affiliated by contract or agreement with NBER.
3. This policy does not apply to Allegations of Research Misconduct involving nominated, temporary, or permanent NBER affiliated researchers, such as Research Associates, Faculty Research Fellows, and Research Economists, when the research in question is funded, supported or conducted solely through an NBER-affiliated researcher's home institution, even if the research was disseminated by the NBER as a working paper or included on an NBER conference program. Under such circumstance, the NBER shall refer any Allegation to the NBER affiliated researcher's home institution, and that institution shall bear primary responsibility for handling the Allegation.

4. This policy does not apply to authorship or collaboration disputes and applies only to Allegations of Research Misconduct that occurred within six years of the date the institution or the funding agency received the Allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

II. Definitions

- A. Key terms used in this policy are defined in Appendix A; all terms used in this policy have the same meaning as given them in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93, except for those defined below.
- B. **Inquiry Panel:** Individuals appointed by the RIO or NBER President to assist the RIO in the conduct of an Inquiry.
- C. **Investigation Committee:** a group of at least three persons appointed by the RIO, in consultation with the Deciding Official, to conduct an Investigation.
- D. **Institutional Member:** A person who is employed by, is working on behalf of, or is affiliated by contract or agreement with NBER. Institutional Members may include Research Associates and Faculty Research Fellows, Research Economists, research assistants, research coordinators, postdoctoral and other fellows, Volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.
- E. **Research Integrity Officer (RIO):** the Institutional Official with primary responsibility for assessing Allegations of Research Misconduct, overseeing Inquiries and Investigations, and assuring adherence to this policy.
- F. **Deciding Official (DO):** the Institutional Official who makes final determinations on Allegations of Research Misconduct and any institutional administrative actions.

III. General Principles and Procedures

- A. **Responsibility to Report Misconduct**
All Institutional Members will report observed, suspected, or apparent Research Misconduct to the RIO or RIO designee. If an individual is unsure whether a suspected incident falls within the definition of Research Misconduct, he or she may meet with the RIO to discuss the suspected Research Misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of Research Misconduct, the RIO will refer the individual or Allegation to other offices or officials with responsibility for resolving the problem.

At any time, an Institutional Member may have confidential discussions and consultations about concerns of possible Misconduct with the RIO or

RIO designee and will be counseled about appropriate procedures for reporting Allegations.

Any Institutional Member who receives a report of suspected Research Misconduct should communicate such a report to the RIO.

B. Integrity of Procedures

Safeguarding the integrity of the policy and its procedures is critical.

1. All individuals involved in a Research Misconduct Proceeding shall act in Good Faith.
2. No one shall attempt to prejudice or coerce the judgement or decision of any individual charged with responsibility for carrying out the procedures outlined in this policy, including the RIO, President, Deciding Official, and anyone conducting the Inquiry or Investigation.
3. No one shall attempt to prejudice or coerce the testimony of any witness, the Complainant, or the Respondent.
4. No one shall engage in or threaten Retaliation.

C. Duty to Cooperate with Research Misconduct Proceedings

Institutional Members will cooperate with the RIO and other institutional officials in the review of Allegations and the conduct of Inquiries and Investigations. Institutional Members, including Respondents, have an obligation to provide evidence relevant to Research Misconduct Allegations to the RIO or other institutional officials.

D. Confidentiality

To the extent allowed by law, the NBER shall:

1. limit disclosure of the identity of Respondents and Complainants to those who need to know to carry out a thorough, competent, objective, and fair Research Misconduct Proceeding; and
2. limit the disclosure of any Records or Evidence from which research subjects might be identified to those who need to know to carry out a Research Misconduct Proceeding.

NBER officials may use written confidentiality agreements or establish other reasonable conditions to ensure the confidentiality of Allegation and Research Misconduct Proceeding information.

E. Protection of Complainants, witnesses, and others

Institutional Members may not retaliate in any way against Complainants, witnesses, or others who have participated in a Research Misconduct Proceeding or otherwise cooperated in the review of an Allegation under this policy. Institutional Members should immediately report any alleged or apparent retaliation against Complainants, witnesses, or other participating individuals to the RIO, who shall review the matter. As necessary, the RIO will make all reasonable and practical efforts to

counter any potential or actual Retaliation and protect and restore the position and reputation of any individual who has, in Good Faith, participated in a Research Misconduct Proceeding and suffered Retaliation.

F. Protection of the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in Research Misconduct, but against whom no finding of Research Misconduct is made.

During the Research Misconduct Proceeding, the RIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case. Legal counsel may only act in advisory capacity and may not represent the Respondent in Research Misconduct Proceedings.

G. Interim Protective Actions and Notifying Funding Agencies of Special Circumstances

At any time during a Research Misconduct Proceeding, NBER shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS (or other federally supported) supported Research process. Any interim protective actions will be implemented by the RIO in consultation with other institutional officials. The RIO shall, at any time during a Research Misconduct Proceeding, notify the ORI or the applicable funding agency immediately if there is reason to believe that any of the following conditions exist:

1. health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
2. HHS or other funding agency resources or interests are threatened;
3. Research activities should be suspended;
4. there is a reasonable indication of possible violations of civil or criminal law;
5. federal action is required to protect the interests of those involved in the Research Misconduct Proceeding;
6. the Research Misconduct Proceeding may be made public prematurely and HHS or other funding agency action may be necessary to safeguard evidence and protect the rights of those involved; or
7. the research community or public should be informed.

H. Maintenance and Custody of Research Records and Evidence

NBER has an obligation to ensure it maintains adequate records for a Research Misconduct Proceeding. The RIO has both the authority and responsibility to fulfill this obligation. Either before or when the respondent is notified of the Allegation, Inquiry or Investigation, the RIO shall:

1. promptly take all reasonable and practical steps to obtain custody of all Research Records and Evidence needed to conduct the Research Misconduct Proceeding;
2. inventory the Records and Evidence;
3. sequester them in a secure manner, except that 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 instruments;
4. where appropriate, give the Respondent copies of, or reasonable supervised access to the Research Records;
5. undertake all reasonable and practical efforts to take custody of additional Research Records or Evidence that is discovered, or as new Allegations arise during a Research Misconduct Proceeding, subject to exception for specific instruments in Section III.H.3 above; and
6. maintain all records of the Research Misconduct Proceeding as defined in 42 CFR 93.317(a) for seven (7) years after the completion of the Research Misconduct Proceeding, or any ORI or HHS proceeding under subparts D and E of 42 CFR Part 93, whichever is later, unless NBER has transferred custody of the records and Evidence to HHS, or ORI has advised that the records no longer be maintained.

IV. Allegations and Assessments

A. Allegation

An Allegation may be made through any means of disclosure. If in the absence of an Allegation from a Complainant, the RIO obtains information indicating potential Research Misconduct, the RIO must proceed with an Assessment.

B. Assessment

Upon receiving an Allegation of Research Misconduct, the RIO, in conjunction with the President, will immediately assess the Allegation to determine whether an Inquiry is warranted. In conducting the Assessment, the RIO need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the Allegation, except as necessary to determine whether the Allegation is sufficiently credible and specific so that potential Evidence of

Research Misconduct may be identified. The RIO may seek such advice as is necessary to evaluate whether there is any validity to the Allegation.

An Inquiry must be conducted if the Allegation meets the following criteria:

1. meets the definition of Research Misconduct;
2. involves either PHS supported Research, applications for PHS Research, Research Records specified in 42 CFR Section 93.102(b), or other federally supported research (e.g. DOE, NSF, IES); and
3. is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified.

V. Inquiry

A. Purpose and Nature

The purpose of the Inquiry is to conduct an initial review of the available Evidence to determine whether to conduct an Investigation; it serves to cull out insufficiently substantiated, erroneous or bad faith Allegations. An Inquiry does not require a full review of all the Evidence related to the Allegation.

B. Notice to Respondent

At the time of or before beginning an Inquiry, the RIO must make a Good Faith effort to notify the Respondent in writing, if the Respondent is known. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing. If applicable the RIO may also notify the Respondent's home institution.

C. Sequestration of Research Records

On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the Research Records and Evidence needed to conduct the Research Misconduct Proceeding.

D. Inquiry Panel

The RIO, with consultation from the NBER President will conduct the Inquiry, with assistance from two Program Directors. These individuals will consider whether additional expertise, either internal or external, is appropriate for proper evaluation of the relevant Evidence. If deemed required, such individuals will be appointed by the President to serve in this capacity.

E. Timing

The Inquiry will be completed within 60 calendar days of initiation of the Inquiry, including preparation of the final Inquiry report and the decision on whether an Investigation is warranted. If the RIO determines that circumstances clearly warrant a longer period, and approves an extension,

the Inquiry record must include documentation of the reasons for exceeding the 60-day period.

VI. Inquiry Report

A member of the Inquiry Panel or the RIO will prepare the written Inquiry Report.

A. Elements of the Inquiry Report

1. The name and position of the respondent;
2. a description of the Allegations of Research Misconduct;
3. the PHS or other federal agency support, including, for example, grant numbers, grant applications, contracts and publications listing the support;
4. the basis for recommending or not recommending that the Allegations warrant an Investigation; and
5. any comments on the draft report by the Respondent or Complainant.

B. Respondent Opportunity to Comment

The RIO shall notify the Respondent whether the Inquiry found an Investigation to be warranted, include a copy of the draft Inquiry report. The Respondent may return comments on the draft Inquiry report within 14 calendar days of receipt. Failure of the Respondent to return comments within 14 calendar days will constitute his/her waiver of the right to comment. Any comments that are submitted by the Respondent or Complainant will be attached to the final Inquiry report. Based on the comments, the Inquiry panel may revise the draft report as appropriate and prepare it in final form.

C. Determination Regarding Investigation and Notification

1. **Institutional Decision.** The DO will, upon examination of the final Inquiry Report, determine in writing whether an Investigation is warranted.
2. **Standard for Determination.** An Investigation is warranted if there is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct and preliminary information-gathering and fact-finding from the Inquiry indicates that the Allegation may have substance. An Allegation may have substance when there is credible Evidence to support further review of the Allegation.
3. **Notification – Internal.** The Respondent will be notified of the determination and provided with the final Inquiry report, this policy, and if the research is PHS funded, a copy of 42 CFR Part 93. As institutional officials deem appropriate the Complainant may be notified of the determination and may be provided relevant portions of the Inquiry report.

Institutional officials who need to know of the determination will be notified, as deemed appropriate by the DO.

4. **Notification – External.** Within 30 calendar days of the determination that an Investigation is warranted, NBER will provide written notification and a copy of the Inquiry report to the applicable funding agency (e.g. DOD) or regulatory oversight body, as required; in the case of PHS funded research, notification will be provided to ORI, in the case of NSF or IES funded research, notification will be provided to OIG. Upon request, NBER will provide the following information to ORI:
 - a) the institutional policies and procedures under which the Inquiry was conducted;
 - b) the Research Records and Evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
 - c) the charges to be considered in the Investigation.
 If applicable, NBER may also notify the Respondent’s home institution.

VII. Investigation

A. Initiation and Purpose

The Investigation must begin within 30 calendar days after the determination that an Investigation is warranted. The purpose of the Investigation is to develop a factual record by exploring the Allegation in detail and examining the Evidence in depth, leading to recommended findings on whether Research Misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible Research Misconduct that would justify broadening the scope beyond the initial Allegation(s).

B. Notice to Respondent, ORI, and other agencies

On or before the date on which the Investigation begins, the NBER must notify the Respondent in writing of the Allegations to be investigated. The RIO must also give the Respondent written notice of any new Allegations of Research Misconduct within a reasonable amount of time of deciding to pursue Allegations not addressed during the Inquiry or in the initial notice of the Investigation.

If the Research is PHS funded, NBER will notify the ORI Director of the decision to begin the Investigation on or before the date of its initiation. If the Research is funded by non-PHS federal agencies, NBER will notify the OIG with federal agency oversight, or the federal agency itself, as required by applicable regulations. If applicable, NBER may also provide notification to the Respondent’s home institution.

C. Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an Investigation Committee of not less than three members, including a committee chair. The Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Investigation and should include individuals with the appropriate scientific expertise to conduct the Investigation. Individuals appointed to the Investigation Committee may also have served on the Inquiry Panel or, if appropriate, may be from outside the institution.

D. Investigation Process

The Investigation will be carried out according to the Standard Procedure: Research Misconduct Investigations.

E. Timing

The Investigation is to be completed within 120 calendar days of initiation, including conducting the Investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to ORI, OIG or other funding agencies or oversight bodies as appropriate. For cases with PHS funding: if the RIO determines that the Investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

F. Standard for Determination of Research Misconduct

To conclude that Research Misconduct occurred, a majority of the Investigation committee must find:

1. a significant departure from accepted practices of the relevant research community;
2. that the Research Misconduct was committed intentionally, knowingly, or recklessly; and
3. that the Allegation was proven by a Preponderance of the Evidence.

VIII. Investigation Report

The Investigation Committee and the RIO are responsible for preparing a written draft report of the Investigation that meets the specifications outlined in the Appendix B: Standard Procedure - Research Misconduct Investigations.

A. Respondent Opportunity to Comment

NBER will give the Respondent a copy of the draft Investigation report for comment and, concurrently, a copy of, or supervised access to the Evidence on which the report is based. The Respondent will be allowed 30 calendar days from the date of receiving the report to submit

comments. Failure to submit comments within the allotted time will constitute waiver of such right. The Respondent's comments must be included and considered in the final report.

B. Confidentiality

In distributing the draft Investigation report, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality.

C. Decision by the Deciding Official

The RIO will transmit the final Investigation report to the DO, who will determine in writing:

1. whether the institution accepts the Investigation report, its findings, and the recommended institutional actions; and
2. the appropriate institutional actions in response to the accepted findings of Research Misconduct.

If this determination varies from the findings of the Investigation Committee, the DO will, as part of the written determination, explain in detail the basis for rendering a decision different from the findings of the Investigation Committee. Alternatively, the DO may return the report to the Investigation Committee with a request for further fact-finding or analysis.

D. Appeals

If the Respondent chooses to appeal the Research Misconduct determination or the sanction(s) imposed, s/he may submit a written request for subsequent review by the NBER's Executive Committee. The Executive Committee will review the investigation committee's report and the DO's decision thoroughly on their merits and make a final decision as to the correctness of the determination and the appropriateness of the sanction. The Executive Committee will complete this appeal within 120 calendar days of the Respondent's filing, unless the case is under ORI jurisdiction and ORI finds good cause for an extension based upon the institution's written request accompanied by an explanation. If a federal agency is involved, this final decision will be communicated to the agency and barring any objection from said agency after the passage of 30 days, any changes recommended in the sanction will be carried out.

E. Notification and Distribution of Final Report

1. **Respondent and Complainant.** When a final decision on the case has been reached, the RIO will normally notify both the Respondent and the Complainant in writing. The RIO will provide the Respondent with a copy of the final Investigation report.
2. **ORI.** NBER will give ORI the following:
 - a) a copy of the final Investigation reporting including any attachments;

- b) a statement on whether the institution found Research Misconduct, and if so, who committed the misconduct;
 - c) A statement on whether the institution accepts the Investigation's findings;
 - d) A description of any pending or completed institutional administrative actions.
3. **Non-PHS federal funding agencies.** For Research supported by non-PHS federal agencies, the final Investigation report will be provided to the OIG for that agency (e.g. NSF, IES), or to the funding agency itself (e.g. DOE).
 4. **Other agencies and organizations.** After informing ORI, DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent in the work, or other relevant parties including the Respondent's home institution should be notified of the outcome of the case.

IX. Other Considerations

A. Termination or Resignation of Employment of Affiliation Prior to Completion of Inquiry or Investigation

The termination of the Respondent's institutional employment, by resignation or otherwise, before or after an Allegation of possible Research Misconduct has been reported, will not preclude or terminate the Research Misconduct Proceeding or otherwise limit any of the institution's responsibilities under 42 CFR Part 93.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an Allegation, the assessment of the Allegation will proceed, as well as the Inquiry and Investigation, as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the RIO and any Inquiry or Investigation committee will use their best efforts to reach a conclusion concerning the Allegations, noting in the report the Respondent's failure to cooperate and its effect on the Evidence.

B. Completion of Cases; Reporting Premature Closures to ORI

Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO will notify ORI in advance if there are plans to close a case at the Inquiry, Investigation, or appeal stage on the basis that Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except: (1) closing of a case at the Inquiry stage on the basis that an Investigation is not warranted; or (2) a finding of no misconduct at the Investigation stage, which must be reported to ORI, as prescribed in this policy.

C. Allegations Not Made in Good Faith

If relevant, the RIO, in conjunction with the DO, will determine whether the Complainant's Allegations of Research Misconduct were made in Good Faith, or whether a witness or committee member acted in good faith. If the RIO or DO determines that there was an absence of Good Faith, the DO will determine whether any administrative action should be taken against the person who failed to act in Good Faith.

X. Other Internal or External Proceedings

A. Other Institutions' Review

Another institution may have the right to review the same Allegation (or a related Allegation) against the same Respondent. In such an event, the RIO shall consult his or her counterpart at the other institution to determine whether NBER or the other institution is best able to review the Allegation. If the RIO determines the other institution is best able to review the Allegation, the RIO shall so advise the President, who has authority to stay or terminate the NBER's review of the Allegation based on review conducted at the other institution, as set forth in Section X.D below.

B. Government Investigation

Certain federal funding sources have the option, at any stage in a Research Misconduct Proceeding, to initiate an independent Investigation of an Allegation involving Research supported by the funding source. In the event a federal funding source initiates such an Investigation, the RIO shall consult the federal funding source regarding its Investigation and will advise the President whether NBER should consider suspending its review of the Allegation, which the President has the authority to do under Section X.D below.

C. Criminal Process

In general, review of an Allegation under this policy may occur in parallel with criminal processes. If an Allegation is also the subject of a criminal proceeding and the pertinent governmental authority advises NBER that the institution's review of the Allegation under this policy may prejudice or interfere with that proceeding, the President shall have authority to stay any Research Misconduct Proceeding until the criminal proceeding is complete.

D. NBER President Authority

The President shall have the authority to:

1. stay any Research Misconduct Proceeding until the completion of the review of the same Allegation, or of a related Allegation against the same Respondent, at another institution;

2. terminate for good cause shown the review of any Allegation under this policy upon the completion of the review of the Allegation at another institution;
3. stay any Research Misconduct Proceeding until the completion of an independent Investigation by a federal funding source of an Allegation involving Research which it supported; and
4. terminate for good cause shown the review of any Allegation under these procedures upon the completion of an independent Investigation by a federal funding source of an Allegation involving Research which it supported.

Appendix A: Definitions

Allegation: a disclosure of possible Research Misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official.

Complainant: a person who in Good Faith makes an Allegation of Research Misconduct.

Evidence: any document, tangible item, or testimony offered or obtained during a Research Misconduct Proceeding that tends to prove or disprove the existence of an alleged fact.

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

Falsification: 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.

Good Faith: as applied to a Complainant or witness, having a belief in the truth of one's Allegation or testimony that a reasonable person in the Complainant's or witness's position could have based on the information known to the Complainant or witness at the time. An Allegation or cooperation with a Research Misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the Allegation or testimony. Good faith as applied to a committee member means cooperating with the Research Misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the Research Misconduct Proceeding.

Inquiry: preliminary information-gathering and preliminary fact-finding to determine whether an Allegation warrants an Investigation that meets the criteria and follows the procedures of 42 CFR Part 93.307-93.309.

Inquiry Panel: Individuals appointed by the RIO or President to assist the RIO in the conduct of an Inquiry.

Institutional Member: a person who is employed by, is working on behalf of, or is affiliated by contract or agreement with the NBER. Institutional Members may include Research Associates and Faculty Research Fellows, Research Economists, research assistants, research coordinators, postdoctoral and other fellows, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

Investigation: the formal development of a factual record and the examination of that record leading to a decision not to make a finding of Research Misconduct or to a

recommendation for a finding of Research Misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Investigation Committee: a group of at least three persons appointed by the RIO, in consultation with the NBER President, to conduct an Investigation.

Notice: a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number, or e-mail address of the addressee.

Office of Research Integrity (ORI): the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

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

Preponderance of the Evidence: proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Public Health Service (PHS): the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

Research: a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research)

Research Misconduct: Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing Research, or in reporting Research results. Research Misconduct does not include honest error or differences of opinion.

Research Misconduct Proceeding: any actions related to alleged Research Misconduct taken under this part, including but not limited to, Allegation Assessments, Inquiries, Investigations, ORI oversight reviews, hearings, and administrative appeals.

Research Record: the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, Research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the Research Misconduct Proceeding.

Respondent: the person against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding.

Retaliation: an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a Good Faith Allegation of Research Misconduct or Good Faith cooperation with a Research Misconduct Proceeding.

Appendix B: Standard Procedure - Research Misconduct Investigations

Purpose

This procedure establishes the process to conduct Investigations of potential Research Misconduct. The process begins when, after the NBER conducts an Inquiry, the President or designee has determined an Investigation is required. The process ends when the President or designee determines in writing whether s/he accepts the Investigation Committee's findings documented in the final Investigation report.

Responsibilities

- A.** The RIO, in conjunction with the President:
 1. Appoints members of the Investigation Committee based on the expertise and background needed to conduct the Investigation.
 2. Appoints a chair of the Investigation Committee.
 3. Charges the Investigation Committee with the Allegation to be investigated.
- B.** The Investigation Committee carries out these procedures within 120 days.
- C.** Investigation Committee members make their decisions based on a Preponderance of the Evidence.
- D.** Investigation Committee decisions are made by majority vote.

Procedure

A. Investigation Process Requirements

The Investigation Committee and the RIO must:

1. Examine all Research Records and Evidence relevant to reaching a decision on the merits of each Allegation relevant to reaching a decision on the merits of each Allegation;
2. Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented;
3. Interview available individuals reasonably identified as having information regarding any relevant aspects of the Investigation;
4. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;
5. Diligently pursue all significant issues and leads discovered that are determined relevant to the Investigation including any Evidence suggesting additional instances of possible Research Misconduct; and
6. Continue the Investigation to completion.

B. Notifications

1. On or before beginning the Investigation, notify the Respondent in writing of the Allegations to be investigated.
2. On or before beginning the Investigation, notify the appropriate federal agencies of the Investigation, per NBER policy.
3. If applicable, NBER may notify the Respondent's home institution of the Investigation.

C. Charge and Briefing

1. The RIO will draft a written charge to the Investigation Committee based on the Inquiry report.
2. The RIO and, if warranted, outside counsel will brief the Investigation Committee on the "Handling Potential Research Misconduct" policy and its procedures, and other relevant institutional regulations and legal or procedural issues the Investigation Committee is likely to encounter in conducting the Investigation.

D. Interviews

1. The Investigation Committee will interview the following individuals, as applicable:
 - i. Respondent(s);
 - ii. Complainant(s);
 - iii. witnesses identified by the Complainant;
 - iv. witnesses identified by the Respondent; and
 - v. any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation.
2. Record or transcribe each interview. The Investigation Committee may request a recording of all interviews and create a transcript of these interviews.
3. Provide the recording or transcript to the interviewee for correction.
4. Include the recording or transcript in the record of the Investigation.
5. Individuals being interviewed may have counsel present serving in an advisory capacity. Counsel cannot address the Investigation Committee. The Investigation Committee may exclude counsel (by a vote of the majority) when in the opinion of the Investigation Committee that person's presence is disruptive.

E. Investigation Report

1. The Investigation Committee, with assistance from the RIO, will draft a written Investigation report that includes the following elements:
 - i. A description of the nature of the Allegation of Research Misconduct
 - ii. The identification of the Respondent;

- iii. A description of the PHS or other Research funding support (e.g. the numbers of any grants that are involved, grant applications, contracts, and publications listing the support);
- iv. A description of the specific Allegations considered in the Investigation;
- v. The institutional policies and procedures under which the Investigation was conducted, if not already provided to ORI;
- vi. The identification and summary of the Research Records and Evidence reviewed
- vii. The identification of any Evidence taken into custody but not reviewed;
- viii. For each Allegation identified during the Investigation, a statement of finding of whether Research Misconduct did or did not occur.
- ix. The Investigation Committee must document each finding of Research Misconduct in the following manner:
 1. identify whether the Research Misconduct was Falsification, Fabrication, or Plagiarism, and whether it was committed intentionally, knowingly, or recklessly;
 2. summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a Preponderance of the Evidence that he or she did not engage in Research Misconduct because of honest error or a difference of opinion;
 3. identify the specific PHS or other Research support;
 4. identify whether any publications need correction or retraction;
 5. identify the person(s) responsible for the misconduct; and
 6. list any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies.

F. Investigation Conclusion

1. The Investigation Committee provides the Respondent with an opportunity to review and comment on the draft Investigation report, per NBER policy.
2. Respondent comments are incorporated in the Investigation report with any additional changes the Investigation Committee deems necessary.
3. The Investigation Committee provide the written report to the NBER President.
4. The NBER President renders his/her written determination regarding acceptance of the findings and the Investigation report.

Appendix B: References

42 CFR Part 93

NBER Policy – Handling Potential Research Misconduct