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Achucarro

BASQUE CENTER FOR NEUROSCIENCE

RESEARCH MISCONDUCT POLICY AND PROCEDURES

Approved by the Steering Board
February 18, 2021

Reflecting U.S. Department of Health and Human Services Public Health Service Policies on Research Misconduct – Final Rule, Code of Federal Regulations, Vol. 42, Part 93 (Federal Register, Vol. 70, p. 28370 (May 17, 2005))

Index

Achucarro Basque Center for Neuroscience
RESEARCH MISCONDUCT POLICY AND PROCEDURES

1. Introduction

a) General Policy

Achucarro Basque Center for Neuroscience (hereinafter, ACHUCARRO) observes the highest standards of professional conduct. Scientific research relies upon the trust and confidence of both the scientific community and the public at large in the integrity of the academic and scientific process. Unethical behavior in research represents a breach of the confidence among faculty and other research scientists that is central to the advancement of knowledge. It also undermines the confidence that the public and research subjects should have in the reliability of research institutions. For these reasons, ACHUCARRO considers Research Misconduct, as defined below, a betrayal of fundamental scientific and research principles, and shall deal promptly with all instances of possible Research Misconduct.

b) Scope and Application

1. This policy and the associated procedures ("Policy") apply to all research activities conducted under the auspices of ACHUCARRO, whether or not they are externally funded. This Policy applies to any individual paid by, holding an appointment from, or affiliated with ACHUCARRO, such as faculty members, post-doctoral and predoctoral researchers, trainees, technicians and other staff members, guest researchers, graduate students, and undergraduate students (the latter subject to Section 1/b/2). Such persons are subject to this Policy regardless of whether their research is conducted on the ACHUCARRO headquarters in Leioa (Spain) or elsewhere.

2. While this Policy applies to Research Misconduct by students, in cases involving allegations against undergraduates the usual conduct procedures administered by the Scientific Director of ACHUCARRO shall be followed in lieu of this Policy. To the extent that additional procedures are necessary for undergraduates, either to comply with legal requirements or because of the involvement of undergraduates in cases involving other persons subject to this Policy, the Steering Board may determine such procedures on an *ad hoc* basis.

3. In addition to cases involving Research Misconduct, this Policy may, in the discretion of the Scientific Director, be used to review allegations of possible noncompliance with legal and ethical standards applicable to human subjects and animal research.

4. Particular circumstances in individual cases may dictate variation from the usual procedures when deemed to be in the best interests of ACHUCARRO and/or required by relevant regulations or funding agency procedures. Any significant variation from this Policy and associated procedures must be approved in advance by the Steering Board.

5. Allegations of Research Misconduct occurring more than 6 years prior to submission of the allegations shall not be reviewed under this Policy unless (a) applicable regulations require review of such allegations, or (b) the alleged Research Misconduct was not reasonably discoverable at an earlier time, or (c) the Research Misconduct poses a current threat to the health and safety of employees.

2. Definitions

- Complainant means the individual(s) who submits an allegation of Research Misconduct.

- Scientific Director means the Scientific Directorate of ACHUCARRO.

- Good Faith, as applied to a Complainant or witness, means having a belief in the truth of one's allegations 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 testimony 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 an Inquiry or Investigation 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 or her acts on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest.

- HHS means the U.S. Department of Health and Human Services, the parent agency of the Public Health Service and the National Institutes of Health.

- Inquiry means preliminary information-gathering and preliminary fact-finding to determine whether an allegation or apparent instance of Research Misconduct has substance and if an Investigation is warranted.

- Investigation means the formal development of a factual record and the examination of that record leading to a finding with respect to Research Misconduct.

- NSF means the National Science Foundation.

- Office of Research Integrity or ORI means the office to which the Secretary of Health and Human Services has delegated responsibility for addressing research integrity and misconduct issues related to Public Health Service activities.

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

- Steering Board means the ACHUCARRO internal committee composed by Principal Investigators, representatives of Postdoctoral and Predoctoral researchers and the General Manager.

- Research Misconduct, as defined by the US government[1], means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion. A finding of Research Misconduct requires that the misconduct be committed intentionally, knowingly, or recklessly. A finding of Research Misconduct also requires that there be a significant departure from accepted practices of the relevant research community.

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 the Research Record.

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

- Research Record or Record means any data, document, computer file, storage media content, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of Misconduct. A Research Record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; research equipment output files; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

- Respondent means the person against whom an allegation of Research Misconduct is directed or who is the subject of a Research Misconduct proceeding.

- Retaliation means 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.

1 In December 2000, the federal Office of Science and Technology Policy ("OSTP") promulgated a revised definition of research misconduct for adoption by each of the federal agencies that conduct and support research. Educational institutions are required to apply this definition with respect to federally-supported research. See Federal Register, Vol. 65, p. 76260 (Dec. 6, 2000).

3. General Procedures and Principles

a) Responsibility to Report Misconduct

Individuals subject to this Policy who become aware of a possible incident of Research Misconduct shall immediately report the information in the manner described in Section 5/a/1.

b) Protecting the Complainant

Persons subject to this Policy who receive or learn of an allegation of Research Misconduct shall treat the Complainant who has made a Good Faith allegation with fairness and respect and shall take reasonable steps to protect the position and reputation of the Complainant and other individuals who cooperate with the Inquiry or Investigation against Retaliation. Any alleged or apparent Retaliation should be reported to the Scientific Directorate. In addition, regulations require that institutional policies "*protect [...], to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.*" [2] Accordingly, if a complainant requests anonymity, ACHUCARRO will make an effort to honor the request during the preliminary assessment or Inquiry to the extent permitted by law. If the matter is referred to an Investigation Committee and the complainant's testimony is required, however, anonymity may no longer be guaranteed.

c) Protecting the Respondent

Persons subject to this Policy who receive or learn of an allegation of Research Misconduct shall treat the Respondent with fairness and respect and shall take reasonable steps to ensure that these procedures are followed. When a Respondent has been exonerated, ACHUCARRO shall make substantial, sustained efforts to restore his or her reputation. This may be accomplished through communication with members of the scientific community who are aware of the matter, publicizing the final outcome in forums in which the allegation of Research Misconduct was previously publicized, expunging references to the allegations from Respondent's personnel file, or through other steps worked out in coordination with the Respondent.

d) Confidentiality

Allegations of Research Misconduct, and proceedings conducted under this Policy, may be damaging to the professional reputations of persons involved. Accordingly, persons subject to this Policy who make, receive, or learn of an allegation of Research Misconduct shall protect, to the maximum extent possible, the confidentiality of information regarding the Complainant, the Respondent, and other affected individuals. The Scientific Directorate may establish reasonable conditions to ensure the confidentiality of such information.

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2 Code of Federal Regulations, Volume 42, Sec. 50.103(d)(2).

e) Responding to Allegations

In responding to allegations of Research Misconduct, the Scientific Directorate or the Steering Board, or any other group or body with an assigned responsibility for handling such allegations shall make diligent efforts to ensure that the following functions are performed:

1) Any assessment, Inquiry, or Investigation is conducted in a timely, objective, thorough, and competent manner.
2) Reasonable precautions are taken to avoid bias and real or apparent conflicts of interest on the part of those involved in conducting the Inquiry or Investigation. Specifically, reasonable steps shall be taken to ensure that the Steering Board, members of Inquiry Panels and Investigation Committees, and experts have no bias and no personal, professional, or financial conflict of interest with the Respondent, Complainant, or the case in question. In making this determination, consideration shall be given to whether the individual (or any members of his or her immediate family) has any of the following involvements with the Respondent or Complainant: financial involvement; coauthor on a publication; collaborator or co-investigator; party to a scientific controversy; supervisory or mentor relationship; other special relationship such as a close personal friendship, kinship, or a physician/patient relationship. Consideration shall also be given to whether there is any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations. The Complainant and the Respondent shall have the right to comment on whether the Steering Board and members of Inquiry Panels and Investigation Committees meet the above criteria. If the Complainant or the Respondent makes a prompt, reasonable, objection to the Steering Board concerning a member of an Inquiry Panel or Investigation Committee, the challenged person shall be replaced with another person who meets the stated criteria. If the Complainant or the Respondent makes a prompt, reasonable objection to the President concerning the Steering Board, the Steering Board’s responsibilities under this Policy shall be performed by another person who meets the stated criteria. The decision of the Steering Board or the President, as the case may be, regarding such a challenge shall be final.
3) Immediate notification is provided to ORI and/or other national, European or international research sponsors supporting the research in question (to the extent required by those sponsors’ regulations) if:
   - there is an immediate health hazard involved;
   - there is an immediate need to protect funds or equipment;
   - there is an immediate need to protect the interests of the Complainant or Respondent as well as his/her co-investigators and associates, if any;
   - it is probable that the alleged incident is going to be reported publicly;
   - the allegation involves an issue that could be publicly sensitive, *e.g.*, a clinical trial; or
   - there is a reasonable indication of a possible criminal violation. In this instance, if PHS funding is involved, ACHUCARRO should inform ORI within 24 hours of obtaining that information.

4) Interim administrative actions are taken, as appropriate, to protect funds and the public health, and to ensure that the purposes of the financial assistance are carried out.

f) Cooperation by Persons Subject to Policy

Persons subject to this Policy, as defined in Section 1/b/1, are expected to cooperate with the Scientific Directorate or the Steering Board and any other investigator, in the review of allegations and the conduct of Inquiries and Investigations. Appointed staff have an obligation to provide evidence to the Steering Board or other officials on Research Misconduct allegations. Further, officials shall cooperate with research sponsors in their conduct of Inquiries and Investigations, their oversight of Inquiries and Investigations, and any follow up actions.

g) Access to Attorneys and Advisers

Respondents may consult with their own legal counsel or non-lawyer personal adviser (who is not a participant or witness in the case) to seek advice, but such counsel or adviser shall not participate in meetings with the Inquiry Panel or Investigation Committee without the prior approval of the chair of the Panel or Committee.

h) Evidentiary Standards

In accordance with regulations[3], the following standards and burdens of proof apply to findings of Research Misconduct under this Policy:

1. *Burden of Proof* - (a) ACHUCARRO has the burden of proof for making a finding of Research Misconduct.

   (b) The Respondent has the burden of proving any affirmative defenses, including honest error or differences of opinion, and of proving any mitigating factors that the Respondent wants the Inquiry Panel or Investigation Committee to consider. Regardless of whether the Respondent carries its burden of proving honest error or difference of opinion, evidence submitted by the Respondent on that issue shall be considered in determining whether a finding of Research Misconduct has been established.

2. *Standard of Proof* -- A finding of Research Misconduct must be established by a Preponderance of the Evidence.

3. *Absence of Records* – The destruction, absence of, or Respondent's failure to provide Research Records adequately documenting the questioned research is evidence of Research Misconduct where it is established by a preponderance of the evidence that the Respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner, and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

[3] See U.S. Department of Health and Human Services Public Health Service Policies on Research Misconduct – Final Rule, Code of Federal Regulations, Vol. 42, Part 93 (Federal Register, Vol. 70, p. 28370 (May 17, 2005)).

i) Recourse to Board of Trustees

Any participant in a case under this Policy who has a concern about the procedures being followed shall have the right to raise this concern with the President of the Board of Trustees, who shall look into the matter and make such recommendations, based on his/her experience and in the advice of other members of the Board (due to the broad experience in research and academic conducts), if any, as are appropriate to address the participant's concerns.

j) Allegations Not Made in Good Faith

If at any time an Inquiry Panel or Investigation Committee determines that an allegation of Research Misconduct was not made in Good Faith, it shall report its determination to the Scientific Directorate. If the Scientific Directorate, independently or on the basis of a report from an Inquiry Panel or Investigation Committee, determines that an allegation of Research Misconduct was not made in Good Faith, he or she shall determine whether any employment or disciplinary action should be recommended against the Complainant.

k) Early Termination of Proceedings

If the matter involves research support and ACHUCARRO plans to terminate an Inquiry or Investigation prior to completion of all the steps required by this policy, the ACHUCARRO shall notify responsible authorities of the planned termination and the reasons, therefore.

l) Referral of Non-Research Misconduct Issues

When the review of the allegation identifies non-research misconduct issues, the Scientific Directorate should refer these matters to the Board of Trustees or governmental authority for action.

m) Requirements for Reporting to Authorities

Certain research sponsors, such as HHS/PHS and NSF, require the reporting of significant actions in research misconduct matters, such as the institution's decision to initiate an Investigation, the institution's determination that it will not be able to complete an Inquiry or Investigation in the time specified under regulations, or the closing of a case on the basis that the Respondent has admitted guilt. The Scientific Directorate, in consultation with the Steering Board, shall comply with such reporting requirements.

n) Record Retention

Records of Research Misconduct proceedings (including records of assessments and Inquiries that do not lead to Investigation) shall be retained for seven years after completion of proceedings, or such longer time period as may be required by the responsible agency.

4. Submission of Allegations; Preliminary Assessment

a) Submission of Allegations

1. Any individual who in Good Faith suspects that a person subject to this policy is

committing or has committed Research Misconduct shall immediately report the information to (1) the Scientific Directorate or (2) to any member of the Steering Board, who shall immediately report the information to the Scientific Directorate, with the due confidentiality. The member of the Steering Board shall notify the Scientific Directorate in cases involving sponsored research.

2. Allegations involving the Steering Board should be submitted to the Scientific Director. In any case involving one Steering Board member, the Scientific Director or his/her designee(s) shall carry out the responsibilities assigned to the Steering Board under this Policy.

3. Allegations involving the Scientific Director should be submitted to the President of the Board of Trustees, or informed to the General Manager, so the Steering Board shall appoint an individual to carry out the responsibilities assigned to the Scientific Director under this Policy.

b) Preliminary Assessment of Allegations to Determine if Inquiry is Warranted

1. Upon receiving an allegation of Research Misconduct, the Scientific Director or the Steering Board shall, within 15 working days and without notice to any of the parties involved, consult with one another, and determine whether an Inquiry is warranted. If they are unable to agree on whether an Inquiry is warranted, the Steering Board shall appoint a tenured faculty member to participate in the assessment, and these three individuals shall determine by majority vote whether an Inquiry is warranted.

2. An Inquiry is warranted if the allegation --

a. Falls within the definition of Research Misconduct under this Policy; and
b. Is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified.

3. If it is determined that an Inquiry is warranted, the Steering Board shall promptly:

a. appoint a panel of three faculty members to conduct the Inquiry and charge the Inquiry Panel (see Section 5/b/1);
b. secure the relevant Research Records (see Section 5/a);
c. notify the Complainant, the Respondent, the Scientific Directorate (see Section 5/c); and
d. provide the Respondent with a copy of the allegations and this Policy.

4. There is not always sufficient information to permit Inquiry of an allegation. For example, an allegation that a researcher's work should be subjected to general examination for possible misconduct is not sufficiently substantial or specific to initiate an Inquiry. In the case of such a vague allegation, an effort should be made to obtain more information before initiating an Inquiry. This information may be sought from any reasonable source, including the Complainant if known. However, if further information is to be requested from the Respondent or other persons involved in the alleged misconduct, the Steering Board should secure the relevant Research Records before making such a request.

5. Anonymous allegations of Research Misconduct will be considered only if sufficient evidence, in the judgment of the Steering Board and Scientific Director, is provided to permit Inquiry of the allegations.

6. If it is determined that an Inquiry is not warranted, the Steering Board shall so inform the Complainant in writing. The Complainant may request reconsideration of this decision by addressing a request for reconsideration to the Steering Board within 15 working days of the date of the Steering Board's notice. If the Complainant does not request reconsideration, or the Steering Board upon reconsideration reaffirms his or her determination that an Inquiry is not warranted, the Steering Board shall also inform the Respondent of the allegations and the action thereon.

5. Inquiry

If it is determined that an Inquiry is warranted, the following procedures shall apply:

a) Sequestration of Research Records

1. *Immediate Sequestration* -- If the relevant Research Records have not been secured at the assessment stage, the Steering Board shall immediately locate, collect, inventory, and secure them to prevent the loss, alteration, or fraudulent creation of records. In addition to securing records under the control of the Respondent (see below), the Steering Board may need to sequester records from other individuals, such as coauthors, collaborators, or Complainants.

2. *Sequestration of Records from Respondent* -- The Steering Board should notify the Respondent that an Inquiry is being initiated simultaneously with, and in any event no earlier than, the sequestration to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the Respondent of tampering with or fabricating data or materials after the notification. The Steering Board should obtain the assistance of the Respondent's supervisor and the General Counsel in this process, as necessary. If the Respondent is not available, sequestration may begin in the Respondent's absence.

3. *Inventory of the Records* -- A dated receipt should be signed by the sequestering official and the person from whom Research Records are collected, and a copy of the receipt should be given to the person from whom such records are taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the Research Records were collected. As soon as practicable, a copy of each sequestered Record should be provided to the individual from whom the Record is taken, if requested. Where the Research Records constitute scientific instruments or other materials shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, or copies of the other materials, so long as those copies are substantially equivalent to the originals.

4. *Security and Chain of Custody* -- The Steering Board shall keep original Research Records in a secure place. Upon request, and to the extent feasible, the persons from whom Records are collected may be given access to their own original Records under the direct and continuous supervision of an official. Questions about maintaining the chain of custody of records should be addressed to the General Counsel.

5. *Data Retention Policy* -- Persons subject to this Policy are reminded of ACHUCARRO's Data Retention Policy which requires, among other things, that

research data generated while individuals are pursuing research studies as faculty, staff, or students at ACHUCARRO, and data generated by visiting scholars utilizing the facilities of ACHUCARRO, are to be retained by the institution for a period of three (3) years after submission of the final report on the research project for which the data were collected, unless a longer period is specified by the sponsor. See http://wiki.achucarro.org/index.php?title=Data_Retention_policy

b) Designation of Inquiry Panel; Use of Outside Experts

1. Within 15 working days of the determination that an Inquiry is warranted, the Steering Board shall appoint the Inquiry Panel and designate one of its members to serve as chair. The Inquiry Panel shall consist of no more than three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the Inquiry. Ordinarily, the members of the Inquiry Panel will be drawn from within ACHUCARRO. However, the Steering Board may designate Panel members from outside ACHUCARRO if necessary, to obtain the relevant expertise and/or avoid conflicts of interest.

2. The Inquiry Panel shall determine whether additional experts other than those appointed to the Panel need to be consulted during the Inquiry to provide special expertise regarding the analysis of evidence. If consulted, such experts shall provide a strictly advisory function to the Panel and shall not vote. At the request of the chair, they may interview witnesses and participate in Panel deliberations. The experts chosen may be from inside or outside of ACHUCARRO.

c) Notification of Complainant and Respondent

The Steering Board shall notify the Complainant and Respondent in writing of the opening of the Inquiry. The notification to the Complainant and the Respondent should: identify the research project in question and the specific allegations; provide a copy of this Policy; refer to the definition of Research Misconduct; identify any external funding involved; list the names of the members of the Inquiry Panel (if appointed) and experts (if any); explain the opportunity to challenge the appointment of a member of the Inquiry Panel or expert for bias or conflict of interest; describe ACHUCARRO’s policy on protecting the Complainant against retaliation; and describe the need to maintain confidentiality during the Inquiry and any subsequent proceedings. The notification to the Respondent should, in addition: provide a copy of the allegation(s) and invite the Respondent to respond; explain the Respondent's opportunity to be interviewed, to present evidence to the Panel, and to comment on the draft Inquiry report; and address the Respondent's obligation to cooperate in the Inquiry and any subsequent proceedings.

d) Purpose of Inquiry; Criteria Warranting Investigation

1. The purpose of an Inquiry is to conduct an initial review of the evidence to determine whether to conduct an Investigation. Therefore, an Inquiry does not require a full review of all the evidence related to the allegations.

2. An Investigation is warranted if there is:

   a. a reasonable basis for concluding that the allegations fall within the definition of Research Misconduct under this Policy; and
   b. preliminary information-gathering and preliminary fact-finding from the Inquiry indicates that the allegations may have substance.

e) Inquiry Process

The Inquiry Panel shall interview the Complainant, the Respondent, and key witnesses and examine relevant Research Records and materials. Supervised access to the data and/or documents should be available to the Respondent and the Complainant, and to other witnesses as appropriate. Witness interviews shall be summarized in writing by the Panel or staff to the Panel, and witnesses given the opportunity to review and correct such summaries of their own statements.

f) Time for Completion of Inquiry

The Inquiry must be completed within 60 calendar days of the appointment of the Panel unless circumstances clearly warrant a longer period, and the Steering Board approves an extension. If the Inquiry takes longer than 60 days to complete, the Inquiry Report must include documentation of the reasons for exceeding the 60-day period.

g) Inquiry Report

1. The Inquiry Panel must prepare a written report that includes the following elements:

- The name and position of the Respondent;
- A description of the allegations of Research Misconduct;
- A description of any external support for the research giving rise to the allegations, including, for example, grant and contract numbers and references to grant applications;
- References for any publications involving the research in question;
- Any comments on the report by the Respondent, the Complainant, or a witness;
- A recommendation to the Steering Board as to whether an Investigation is warranted, and a statement of the basis for this recommendation.

2. The Respondent shall be provided with a draft of the Inquiry Panel report and shall have 10 days to provide written comments on it. The Inquiry Panel may also make relevant portions of the report available to the Complainant and/or witnesses (but not give them a copy), for comment. In preparing its final report, the Panel shall consider and attach any comments made by the Respondent (and by the Complainant and/or witnesses, if applicable) on the draft Inquiry Panel report.

h) Steering Board's Decision on Inquiry Panel's Recommendation

The chair of the Inquiry Panel shall transmit the final Inquiry Report to the Steering Board, who shall decide whether the findings from the Inquiry warrant conducting an Investigation, under the standards set forth above. The Inquiry is completed when the Steering Board makes this determination.

i) Notice of Results of Inquiry; Report to Authorities.

The Steering Board shall notify the Respondent, the Complainant, and appropriate officials in writing of his or her decision whether to proceed to an Investigation. The notice to the Respondent must include a copy of the Inquiry Report. To the extent required by the regulations, the Steering Board shall provide notice to authorities concerning the Inquiry and the decision whether an Investigation is warranted. For example, for PHS-funded research, regulations require that institutions provide ORI with the written finding of the Steering Board and a copy of the Inquiry Report (Code of Federal Regulations, Vol. 42, Sec. 93.309).

j) Restoration of Respondent's Reputation Where Investigation Is Not Warranted

In cases where it is determined that Investigation is not warranted, the Respondent may meet with the Steering Board to determine whether it is necessary for ACHUCARRO to take any steps to restore the Respondent's reputation. See Section 3/c.

6. Investigation

a) Designation of Investigation Committee; Use of Outside Experts

1. If the Steering Board determines that an Investigation is warranted, they shall, within 15 working days after such determination, cause an Investigation Committee to be appointed to explore the allegations in detail, to examine the evidence in depth, and to determine specifically whether Research Misconduct has been committed. For cases in which the respondent is a student, a person holding an academic appointment, or a staff member in a Faculty or other functional unit, the Steering Board shall make appointments to the Investigation Committee in consultation with the responsible Scientific Director. In other cases, the Steering Board shall make appointments to the Investigation Committee in consultation with the General Manager. The Investigation Committee shall consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the Investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside ACHUCARRO. One of the members shall be appointed to serve as chair.

2. If there is an allegation involving individuals from different categories of employees and/or students, the Steering Board shall confer with the appropriate Scientific Directors or other responsible officers listed above and determine a single, coordinated process for conducting the Investigation.

3. The Investigation Committee shall determine whether experts other than those appointed to the committee need to be consulted during the Investigation to provide special expertise regarding the analysis of evidence. If consulted, such experts shall provide a strictly advisory function to the committee and shall not vote. At the request of the chair, they may interview witnesses and participate in committee deliberations. The experts chosen may be from inside or outside of ACHUCARRO.

b) Investigation Process

1. In conducting its Investigation, the Investigation Committee shall:

- Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all Research Records and evidence relevant to reaching a decision on the merits of the allegations;
- Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent, and maintain detailed records. The Committee shall record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the Investigation; and
- Pursue diligently all significant issues and leads discovered, including any evidence of additional instances of possible Research Misconduct, and continue the Investigation to completion.

c) Time Limit for Completing Investigation

The Investigation Committee shall use its best efforts to complete the Investigation within 120 days. If the Committee is unable to complete the Investigation within 120 days, the chair shall ask the Steering Board for an extension of time. An extension may require approval of the responsible agency.

For example, in cases involving PHS-funded research, it is necessary to obtain ORI approval to extend the Investigation beyond 120 days. (See Code of Federal Regulations, Vol. 42, Sec. 93.311)

d) Investigation Report

1. The Investigation Report shall contain the same type of information as the Inquiry Report regarding the nature of the allegations, sources of external support, and Research Records and evidence reviewed. In addition, the Investigation Report shall provide, for each separate allegation of Research Misconduct identified during the Investigation, a finding as to whether Research Misconduct did or did not occur, and if so:

- Identify the person(s) responsible for the misconduct;
- identify whether the Research Misconduct was falsification, fabrication, or plagiarism, and whether it was intentional, knowing, or reckless;
- summarize the facts and the analysis which supports the conclusion and consider the merits of any reasonable explanation by the Respondent;
- identify the specific external support involved, if any;
- identify whether any publications need corrections or retraction; and
- list any current support or known applications or proposals for support that the Respondent has pending with any agencies, regardless of their relationship to the misconduct.

2. The Respondent shall be provided with a draft of the Investigation Committee report and concurrently a copy of, or supervised access to, the evidence on which the report is based. The Respondent shall have 30 days (which time shall be part of the total time for the Investigation) to provide written comments on it. The Investigation Committee may also make relevant portions of the report available to the Complainant and/or witnesses (but not give them a copy), for comment. The Committee shall, in preparing its final report, consider and attach any comments made by the Respondent (and by the Complainant and/or witnesses, if applicable) on the draft Investigation Report.

3. The chair of the Investigation Committee shall forward copies of the final Investigation Report to the Steering Board and the Respondent. Following submission of the Investigation Report to the Steering Board and the Respondent, no additional evidence may be introduced into the record as a matter of course.

e) Appeal; Review by Steering Board

1. Within 14 days of receipt of the Investigation Committee report, the Respondent may appeal in writing to the Steering Board solely on the following grounds:

- that there has been a material failure to follow the procedures prescribed in this Policy and that the Respondent called the error to the attention of the Investigation Committee or had reasonable grounds for not doing so. The appeal must specify the nature of the procedural error and why the Respondent believes it is likely to have affected the outcome of the Investigation; or

- that the Respondent has new and material evidence that was not reasonably available to the Respondent during the Investigation. The appeal must specify the nature of the new evidence, why it was not reasonably available during the Investigation, and why the Respondent believes it is likely to have affected the outcome of the Investigation.

2. If the Steering Board, on his or her own motion or upon appeal by the Respondent, finds that (a) there was procedural error or the Respondent has new evidence that was not reasonably available during the Investigation, and (b) there is a substantial possibility that the error or new evidence may have affected the outcome of the Investigation, the Steering Board may refer the matter back to the Investigation Committee or to a new Investigation Committee appointed to reopen the case.

3. In addition to the review procedure under Section 6/e/2, the Steering Board, in his or her discretion, may return the report to the Investigation Committee for further fact-finding or analysis or may appoint a new Investigation Committee to reevaluate the record and submit supplemental findings.

f) Notification of Outside Parties.

When the report has been accepted, the Steering Board shall forward copies to the responsible agencies and may, as appropriate, notify other external sponsors, law enforcement agencies, professional societies, professional licensing boards, journals, collaborators of the Respondent, or other parties with a legitimate need to know the outcome of the proceeding.

7) Administrative Action As a Result of Investigation

- If it is determined that Research Misconduct occurred, the Steering Board, in consultation with the Scientific Director and other responsible officials, shall recommend the appropriate actions to be taken according to applicable disciplinary procedures for faculty, staff, and students. The recommended actions may include:

    1. withdrawal or correction of all pending or published abstracts and papers emanating from the research where Research Misconduct was found.
    2. removal of the Respondent from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment.
    3. restitution of funds as appropriate.

- If it is determined that no Research Misconduct occurred, the Respondent shall meet with the Steering Board to discuss how the Respondent's record shall be cleared and what reasonable efforts will be taken to restore the Respondent's reputation. See Section 3/c.

8) Other Considerations

a) Termination of Employment or Resignation Prior to Completion of Inquiry or Investigation

If the Respondent, without admitting to misconduct, elects to resign his or her position after an allegation of Research Misconduct has been received, proceedings under this Policy shall continue. If the Respondent refuses to participate in the process after resignation, the Inquiry Panel and/or Investigation Committee shall use its best efforts to reach a conclusion concerning the allegations, noting in its report the Respondent's failure to cooperate and its effect on the review of the matter.