

Naval Medical Research Unit Six (NAMRU-6)



Research Misconduct

Policies and Procedures for Managing the Responsible Conduct of Human Subject Research

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INTRODUCTION

The purpose of this policy and procedure manual is to establish a process and procedure for disclosing, reporting and investigating research misconduct in human subject research. This manual is also intended to assist the Naval Medical Research Unit Six (NAMRU-6), investigators and research personnel conducting research at NAMRU-6 and members of the Institutional Review Board (IRB) in reducing, eliminating and managing any research misconduct that may exist in which they are involved.

IRB members should also refer to the “Institutional Review Board (IRB) Policies & Procedures & Forms” manual, which provides additional guidance for reviewing and approving human subject research.

For additional reference materials and resources, researchers and IRB members are welcome to contact the Research Administration Program (RAP).

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Chapter 1

Responsible Conduct of Research

Researchers at institutions receiving federal support for research are subject to mandated institutional mechanisms for the responsible conduct of research, including procedures to investigate fraud and research misconduct. All organizations using Department of Defense (DoD) resources, including funds, personnel, equipment, or facilities, must adhere to this policy. The Peruvian Regulation of Clinical Trials includes a description of the infractions, sanctions and criteria for imposing the sanctions as required by the Peruvian laws.

Research misconduct refers to fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, performing, or reviewing research, or reporting research. Research misconduct does not include honest error or honest differences in interpretations or judgments of data. A finding of research misconduct requires that,

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

Research carried out at NAMRU-6 must comply with both, the Peruvian Regulation of Clinical trials and US federal regulations and recognize professional standards for ensuring scientific integrity. This requirement applies to all research investigators and other personnel (including physician investigators and their research staffs not employed by NAMRU-6) involved in the conduct or support of human subject research (e.g., study planning and design, conduct of the study, data analysis, subject recruitment, subject consent, authorship).

- d. **Peruvian Clinical Trial Regulation, DS 017-2006-SA and its modification from 2007.** This section of the regulation establishes penalties ranging from amonestation to restrictions from conducting clinical trials for fabrication or falsification of data. (Title XII, On safety, infractions and sanctions, Art. 131 and 133)
- e. **Department of Defence (DoD) Regulations.** DoD requires the implementation of policies and procedures to ensure public trust and foster integrity in research activities and respond to allegations of misconduct consistent with applicable law. ((DoD Directive 3216.2 and DoD Instruction 3210.7))
- f. **Department of Health and Human Services (DHHS) Regulations.** Federal regulations at Title 42 Part 93 Subpart A of the Code of Federal Regulations (CFR) require that research institutions establish uniform policies and procedures for investigating and reporting instances of alleged or apparent Misconduct in Science.
- g. **Department of the Navy (DoN) Regulations.** The Secretary of the Navy requires a Naval command or activity with responsibility for the research to review all allegations of research misconduct and take action if appropriate. This requires that these commands or activities report the initiation of all investigations and report results regardless of the findings to the Navy Surgeon General and appropriate sponsors.

h. Definitions.

- **Adjudication** is the stage in response to an allegation of research misconduct when the Investigation's outcome is reviewed, and appropriate corrective actions, if any, are determined. Corrective actions generally will be administrative in nature (e.g. termination of an award(s), debarment, special approvals, or correction of the research record); however, if there is an indication of violation of civil or criminal statutes, civil or criminal sanctions may be pursued.
- **Allegation** means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to a NAMRU-6 or HHS official. .
- **Complainant** means a person who in good faith makes an allegation of research misconduct.
- **Deciding Official** means the individual responsible for making final determinations on behalf of NAMRU-6 concerning allegations of research misconduct and any responsive actions. The Deciding Official may not serve as the Research Integrity Officer and may have no prior involvement in the misconduct Inquiry or Investigation. The Commanding Officer (CO) serves as NAMRU-6's Deciding Official.
- **Fabrication** is making up data or results and recording or reporting them.
- **Falsification** means manipulating research materials, equipment, or processes or changing or omitting data or results such that research is not accurately represented in the research record.
- * **Findings of Research Misconduct** mean the conclusion proven by a preponderance of the evidence that there was research misconduct and that such misconduct represented a significant departure from accepted practices of the relevant research community and has been committed intentionally, knowingly, or recklessly.
- **Good Faith** as applied to a complainant or witness, means 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 that time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for or wilful ignorance of 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 according to regulations. 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** means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures established. To determine whether the allegation has substance and an investigation is warranted.

- **Investigation** means the formal development of a factual record and the examination of that record to determine whether to dismiss the case, recommend for a finding of research misconduct, and/or take other appropriate remedies.
- **OGITT, General Office of Research and Technology Transfer of the Peruvian National Institute of Health** means the office within the Peruvian regulatory system responsible for imposing sanctions for research misconduct in the conduct of clinical trials in Peru.
- **ORI** means the **Office of Research Integrity**, the DHHS office responsible for the research misconduct and research integrity activities of the U.S. Public Health Service.
- **Plagiarism** means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.
- **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.
- **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This applies to all basic, applied and demonstration research in all fields of science, engineering and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, physical sciences, statistics, and research involving human subjects or animals regardless of funding appropriation used to support it.
- **Research Integrity Officer** is the NAMRU-6 official who is responsible for assessing allegations of research misconduct and determining when such allegations warrant Inquiries and for overseeing Inquiries and Investigations. The Research Integrity Officer may not serve as the NAMRU-6's Deciding Official, and vice versa. The Research Administration Program Director serves as NAMRU-6's Research Integrity Official.
- **Research Record** means any data, document, computer file, computer diskette, 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 embodies the facts resulting from research inquiry. It includes, but is not limited to, research proposals, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, whether in physical or electronic form.

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; manuscripts and publications; equipment use logs; laboratory procurement records; human subject protocols; consent forms; medical charts; and patient research files.

- **Respondent** means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the Inquiry or Investigation.
- **Retaliation** means any action that adversely affects the employment or other institutional status of an individual taken by an institution or an employee because the individual has in good faith, made an allegation of research misconduct or of inadequate institutional response thereto or has cooperated in good faith with an Investigation of such allegation.
- **Notifier** is a person who makes an allegation of research misconduct.

i. Rights and Responsibilities.

- 1. Research Integrity Officer.** The Research Administration Program Director serves as NAMRU-6's Research Integrity Officer. The Research Integrity Officer has primary responsibility for implementing the responsible conduct of research-related procedures set forth in this manual. The Research Integrity Officer is to be an official of NAMRU-6 who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will appoint Inquiry and Investigation Committees, as needed, and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an Inquiry or Investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

The Research Integrity Officer will assist Inquiry and Investigation Committees and all NAMRU-6 personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

For DHHS and PHS supported research, the Research Integrity Officer will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the Inquiry or Investigation that may affect current or potential DHHS funding for the individual(s) under Investigation or that the PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.

The Research Integrity Officer will report to the Navy Surgeon General via the Department of the Navy Human Research Protections Program (DON HRPP) at the initiation of an Investigation of research misconduct and will report the results of the Investigation regardless of the outcome. The Research Integrity Officer will also have the ability to go directly to DON HRPP in the event the NAMRU-6 Deciding Official is involved in the allegation or possesses a conflict of interest or if he or she feels that fair proceedings will not take place at NAMRU-6.

- 2. Complainant.** The Complainant will have an opportunity to testify before the relevant Inquiry and Investigation Committees, to review portions of the Inquiry and Investigation reports pertinent to his/her Allegations or testimony, to be informed of

the results of the Inquiry and Investigation, and to be protected from retaliation. Also, if the Research Integrity Officer has determined that the Complainant may be able to provide pertinent information on any portions of the draft report, these portions will be given to the Complainant for comment.

The Complainant is responsible for making good faith allegations, maintaining confidentiality, and cooperating with an Inquiry or Investigation.

- 3. Respondent.** The Research Integrity Officer will inform the Respondent of the allegations when an Inquiry is opened and notify the Respondent in writing of the final determinations and resulting actions. The Respondent will also have the opportunity to be interviewed by and present evidence to the relevant Inquiry and Investigation Committees, to review the draft Inquiry and Investigation reports, and to have the advice of counsel.

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an Inquiry or Investigation. If the Respondent is not found guilty of research misconduct, he or she has the right to receive NAMRU-6 assistance in restoring his or her reputation.

- 4. Deciding Official.** The Commanding Officer (CO) serves as NAMRU-6's Deciding Official. The Deciding Official will receive the Inquiry and/or Investigation report and any written comments made by the Respondent or the Complainant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an Investigation, whether research misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

Chapter 2

Policies and Principles Related to Reporting Research misconduct

- a. Responsibility to Report Misconduct.** All research investigators and other personnel, including physician investigators and their research staffs not employed by NAMRU-6, involved in the conduct or support of human, animal, and other research (e.g., study planning and design, conduct of the study, data analysis, subject recruitment, subject consent, authorship) at NAMRU-6 should report observed, suspected, or apparent misconduct in research to the Research Integrity Officer.

If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the Research Integrity Officer to discuss the suspected research misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials within NAMRU-6 with responsibility for resolving the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counselled about appropriate procedures for reporting allegations.

- b. Protecting the Complainant.** The Research Integrity Officer will monitor the treatment of individuals who bring allegations of research misconduct or NAMRU-6's inadequate response thereto, and those who cooperate in Inquiries or Investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at NAMRU-6 and will review instances of alleged retaliation for appropriate action. Employees and others associated with NAMRU-6 should immediately report any alleged or apparent retaliation to the Research Integrity Officer. NAMRU-6 will protect the privacy of those who report research misconduct in good faith to the maximum extent possible. NAMRU-6 will undertake diligent efforts to protect the positions and reputations of those persons who make good faith allegations.

The Complainant will be advised that if the matter is referred to an Inquiry and Investigation Committee and the Complainant's testimony is required, anonymity may no longer be guaranteed, as the institution must disclose the identify of the complainant (and of the respondents) to ORI pursuant to an ORI review of research misconduct proceedings. NAMRU-6 will undertake diligent efforts to protect the positions and reputations of those persons who make good faith allegations.

The Research Integrity Officer will inform Complainants as quickly as possible and in writing of all determinations made relating to the allegations. In no case may such written notification be delayed beyond four (4) business days after the determination has been made.

- c. Protecting the Respondent.** Inquiries and Investigations will be conducted in a manner that will ensure fair treatment to the Respondent(s) in the Inquiry or Investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the Inquiry or Investigation.

A Respondent 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.

The Research Integrity Officer will notify the Respondent as quickly as possible and in writing of all determinations made relating to the Allegations. In no case may such written notification be delayed beyond four (4) business days after the determination has been made.

- d. Protecting Research Subjects.** NAMRU-6 must maintain confidentiality for any research records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.
- e. Cooperation with Inquiries and Investigations.** All research investigators and other personnel (including physician investigators and their research staffs not employed by NAMRU-6) involved in the conduct or support of human, animal, and other research at NAMRU-6 are required to cooperate with the Research Integrity Officer in the review of allegations and the conduct of Inquiries and Investigations. All such individuals are required to provide relevant evidence to the Research Integrity Officer concerning the allegations.
- f. Preliminary Assessment of Allegations.** Upon receiving an allegation of research misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an Inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the DoD definition of research misconduct. The Research Integrity Officer will notify the Respondent in writing of this determination.

Chapter 3

Conducting the Inquiry and Investigation into Alleged Research misconduct

This chapter describes the process by which NAMRU-6 conducts Inquiries and Investigations into allegations of research misconduct.

a. Conducting the Inquiry.

- 1. Initiation and Purpose of the Inquiry.** If the Research Integrity Officer determines that (i) the allegation provides sufficient information to allow specific follow-up, and (ii) falls under the definition of research misconduct, the Research Integrity Officer will immediately initiate the Inquiry process. In initiating the Inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The Research Integrity Officer shall involve NMRC's Legal Counsel as soon as possible, and preferably no later than when an Inquiry commences.

The purpose of the Inquiry is to make a preliminary evaluation of the available evidence (including testimony from the Respondent, Complainant and key witnesses) to determine whether there is sufficient evidence of possible research misconduct to warrant an Investigation. The purpose of the Inquiry is **not** to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the Inquiry must be set forth in a written Inquiry Report.

- 2. Sequestration of the Research Records.** Upon determining that an allegation falls within the definition of research misconduct, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with DON HRPP, via the chain of command (or ORI for DHHS and PHS supported research) for advice and assistance in this regard. The Research Integrity Officer shall coordinate efforts to sequester and secure records with the NMRC's Legal Counsel.

Where appropriate, the Research Integrity Officer will provide the Respondent with copies of, or reasonable, supervised access to research records.

- 3. Appointment of the Inquiry Committee.** The Research Integrity Officer, in consultation with other officials as he/she deems appropriate, will appoint an Inquiry Committee and an Inquiry Committee Chair within five (5) business days of determining that an Inquiry is warranted. The Inquiry Committee should consist of at least three (3) individuals all of whom (i) are free from real or apparent conflicts of interest in the case, (ii) are unbiased, and (iii) have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principal and key witnesses, and conduct the Inquiry.

Inquiry Committee members may be scientists, subject matter experts, administrators, lawyers, or other qualified persons and should have sufficient expertise and standing to promote respect for the Inquiry process. Members may be from inside or outside NAMRU-6. Upon determination of the Committee membership, the Research Integrity Officer will notify the Respondent in writing of the membership.

If within five (5) business days of receiving written notification of Inquiry Committee membership, the Respondent can submit a written objection to any member of the Committee based on bias or conflict of interest. The Research Integrity Officer will determine whether to replace the challenged member with a qualified substitute and will notify the Respondent in writing of this determination.

By majority vote of its members, the Inquiry Committee may seek consultation with experts as it deems necessary to evaluate specific allegations. Upon such majority vote, the Research Integrity Officer will notify the Respondent in writing of the proposed expert consultation.

The Respondent can submit a written objection, based on bias or conflict of interest, to the proposed expert within five (5) business days of receiving written notification of the proposed expert consultation. The Research Integrity Officer will determine whether to replace the challenged expert with a qualified substitute and so inform the Respondent of this determination.

4. Charge to the Inquiry Committee and the First Meeting. The Research Integrity Officer will prepare a charge for the Inquiry Committee that includes each of the following elements:

- A description of the allegations and any related issues identified during the allegation assessment.
- A statement that the purpose of the Inquiry is to (i) make a preliminary evaluation of the evidence (including testimony of the Respondent, Complainant, and key witnesses); and (ii) determine whether there is sufficient evidence of possible research misconduct to warrant an Investigation in accordance with the Peruvian Regulation of Clinical Trials, the DoD and DHHS regulations at DoD I 3210.7 and 42 CFR 93 Subpart A-E, respectively.
- Clarification that the purpose of the Inquiry is **not** to determine whether research misconduct definitely occurred or who was responsible.

At the Inquiry Committee's first meeting, the Research Integrity Officer will review the charge with the Committee, discuss the allegations, any related issues and the appropriate procedures for conducting the Inquiry, assist the committee with organizing plans for the Inquiry, and answer any questions raised by the committee. The Research Integrity Officer and NMRC's Legal Counsel will be present or available throughout the Inquiry to advise the Inquiry Committee as needed.

5. Inquiry Process. The Inquiry Committee will normally interview the Complainant, the Respondent, and key witnesses and examine relevant research records and materials. The Inquiry Committee will evaluate the evidence and testimony obtained during the Inquiry, and following consultation with the Research Integrity Officer and NMRC's Legal Counsel, will determine whether a) the inquiry falls within the definition of research misconduct, b) the inquiry is sufficiently credible and specific so that potential evidence of research misconduct may be identified; c) there is sufficient evidence of possible research misconduct to recommend further Investigation. The scope of the Inquiry does not include deciding whether research misconduct occurred or conducting

exhaustive interviews and analyses.

The purpose of an interview at the Inquiry stage is to allow each Respondent, Complainant (if he or she is identifiable), or witness to tell his or her side of the story. The Inquiry Committee should not speculate about what happened or might have happened. Also, the Inquiry Committee should not disclose information obtained from interviews unless necessary and can be done without identifying the source of the information.

If the Respondent admits to the research misconduct, the Respondent should be asked immediately to sign a statement attesting to the occurrence and extent of the research misconduct. Normally, an admission is sufficient basis to proceed directly to an Investigation. However, the admission may not be sufficient basis for closing a case. Further Investigation may be needed to determine the extent of the research misconduct or to explore additional issues. If an admission is made, the Research Integrity Officer may consult with DON HRPP (or ORI for DHHS and PHS supported research) in determining whether there is a sufficient basis to close a case after the admission is fully documented and all appropriate procedural steps are taken.

6. **Timelines.** The full Inquiry process will take no more than 60 calendar days to complete from the initiation of the Inquiry unless circumstances clearly warrant a longer period. If the Inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

b. The Inquiry Report.

1. **Elements of the Draft Inquiry Report.** The Inquiry Committee will prepare a written draft Inquiry Report that includes each of the following elements:

- Name and title of the committee members.
- Name and title of experts consulted, if any.
- The description of the allegation.
- The Respondent's name and position or likely position.
- The source and amount of PHS or DHHS support, if any (i.e. grant number, grant applications, contracts, publications listing PHS support, etc.).
- A summary of the Inquiry process.
- A list of the Research Records reviewed.
- Summaries of any interviews.
- Description of the evidence in sufficient detail to demonstrate whether or not an Investigation is warranted.
- The Committee's determination as to whether an Investigation is recommended.

- Whether any other actions should be taken if an Investigation is not recommended.
- The charge (s) for the Investigation to consider.

The Inquiry Committee will normally complete the Inquiry and submit its draft Inquiry Report in writing to the Research Integrity Officer no more than 25 business days following its first meeting, unless the Research Integrity Officer determines that an extension is warranted for good cause. If the Research Integrity Officer so determines, the reason for the extension will be entered into the records of the case and the Inquiry Report. The Research Integrity Officer will notify the Respondent in writing of this determination.

- 2. Comments on the Draft Inquiry Report.** Within four (4) business days of its submission by the Inquiry Committee, the Research Integrity Officer will provide the Respondent with a copy of the draft Inquiry Report for comment and rebuttal.

Within four (4) business days of its submission by the Inquiry Committee, the Research Integrity Officer will provide the Complainant, if he or she is identifiable, with those portions of the draft Inquiry Report that address the Complainant's role and opinions regarding the research misconduct allegations.

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report. For example, the Research Integrity Officer may request the recipient's signature on a confidentiality statement in order to receive the report.

The Respondent and the Complainant will each have five (5) business days to provide their comments, if any, to the Inquiry Committee. Any comments that the Complainant or Respondent submit on the draft report will become a permanent attachment to the final Inquiry Report and record.

Following the end of the five-day comment period, the Inquiry Committee may revise the draft report as appropriate. Within five (5) business days after the end of the comment period, the Inquiry Committee will forward its revised draft report to NMRC's Legal Counsel in the absence of such office at NAMRU-6 for review as to legal sufficiency. Legal Counsel will have five (5) business days to provide comments to the Inquiry Committee. At the end of the five-day comment period, the Inquiry Committee may take five (5) business days to revise the draft report as appropriate and submit its Final Inquiry Report to the Research Integrity Officer.

Within two (2) business days of its submission of the Final Inquiry Report by the Committee, the Research Integrity Officer will provide the Respondent and the Complainant with a copy of the Final Inquiry Report.

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the report. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement in order to receive the report.

- 3. Inquiry Adjudication and Notification.** The Research Integrity Officer will transmit the Final Inquiry Report and any comments to NAMRU-6's Deciding Official. The Deciding Official will determine whether findings from the Inquiry provide sufficient evidence of possible research misconduct to justify conducting an Investigation. The Inquiry is completed when the Deciding Official makes this determination, which will normally be made within 60 business days of the first meeting of the Inquiry Committee. Any extension of this period will be based on good cause and recorded in the Inquiry file.

The Research Integrity Officer will notify both the Respondent and the Complainant in writing of the Deciding Official's determination as to proceeding to an Investigation and will remind them of their obligation to cooperate in the event an Investigation is opened. The Research Integrity Officer will also notify all appropriate NAMRU-6 officials of the determination.

The Deciding Official and the Research Integrity Officer will determine, at the time the decision is made whether to close the Inquiry or to pursue an Investigation, as well as all issues relating to confidentiality and NAMRU-6 and public access to information about the Inquiry or Investigation.

The Deciding Official will submit his or her determination along with the Inquiry Report to the Navy Surgeon General via DON HRPP and via the chain of command for review or concurrence.

c. Conducting the Investigation.

- 1. Purpose of the Investigation.** The purpose of the Investigation is to explore the allegations in detail, to examine the evidence in depth, and to determine specifically 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 allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the Investigation will be set forth in a written Investigation Report.
- 2. Sequestration of Research Records.** The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the Inquiry. This sequestration should occur before or at the time the Respondent is notified that an Investigation has begun.

The need for additional sequestration of records may occur for any reason, including but not limited to, NAMRU-6's decision to investigate additional allegations not considered during the Inquiry stage, or the identification of records during the Inquiry process that had not been previously secured. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry.

- 3. Appointment of the Investigation Committee.** The Research Integrity Officer, in consultation with other NAMRU-6 officials as he/she deems appropriate, will appoint an Investigation Committee and an Investigation Committee Chair within 20 business days of the notification of the Respondent that an Investigation is planned or as soon thereafter as practicable. The investigation may begin within 30 days after determining that an investigation is warranted. The decision to begin the investigation will be communicated to the appropriate officials.

Investigation Committee members may be scientists, subject matter experts, administrators, lawyers, or other qualified persons and should have sufficient expertise and standing to promote respect for the Investigation process. If the research in question involves human subjects, the IRB Chair or Vice Chairs will serve as a member of this Committee. Members may be from inside or outside NAMRU-6, and may also have served on the Inquiry Committee.

Upon determination of the Investigation Committee membership, the Research Integrity Officer will notify the Respondent in writing of the membership.

The Respondent can submit a written objection, based on bias or conflict of interest, to the proposed expert within five (5) business days of receiving written notification of the proposed expert consultation. The Research Integrity Officer will determine whether to replace the challenged member with a qualified substitute and will notify the Respondent in writing of this determination.

By majority vote of its members, the Investigation Committee may seek consultation with experts it deems necessary to evaluate specific allegations. Upon such majority vote, the Research Integrity Officer will notify the Respondent in writing of the proposed expert.

It may be necessary to consult with the NAMRU-6 IRB if the Committee is planning to suspend or terminate the research protocol involving human subjects. If this is the case, the Committee will provide a summary of the allegation and enough information for the IRB to make a reasonable determination as to the safety and ethics of closing the study. The IRB will consider the matter at the next convened meeting or at a special called meeting depending on the urgency of the determination. The IRB's response will be documented as a part of the Meeting Minutes.

Upon such majority vote, the Research Integrity Officer will notify the Respondent in writing of the proposed expert.

If within five (5) business days of receiving written notification of the proposed expert consultation, the Respondent submits a written objection to the proposed expert based on bias or conflict of interest, the Research Integrity Officer will determine whether to replace the challenged expert with a qualified substitute. The Research Integrity Officer will inform the Respondent of this determination.

- 4. Charge to the Committee and the First Meeting.** The Research Integrity Officer will present the charge established in the Inquiry report to the Investigation in a written document to the Investigation Committee that includes each of the following elements:

- Description of the allegations and related issues identified during the Inquiry.
- Definition of research misconduct.
- The name of the Respondent.
- A statement that the Investigation Committee is to evaluate the evidence (including testimony of the Respondent, Complainant and key witnesses) to determine (i) whether, based on a preponderance of the evidence, research misconduct occurred and; if so, (ii) the extent of the research misconduct, who was responsible, and its seriousness.

During the Investigation, if additional information becomes available that substantially changes the subject matter of the Investigation or would suggest additional Respondents, the Investigation Committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the Respondent of the new subject matter or to provide notice to additional Respondents. A new Inquiry will not be necessary. Rather, the Investigation will be expanded to include additional Respondent(s) or evidence as necessary.

The Research Integrity Officer, with the assistance of the NMRC's Legal Counsel will convene the first meeting of the Investigation Committee to review the charge, the Inquiry Report, and the prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific Investigation plan. The Investigation Committee will be provided with a copy of these instructions and, any others as applicable as per funding source.

At the initial meeting, the committee should begin development of its Investigation plan and complete it as soon as reasonably possible. The Investigation plan will include an inventory of all previously secured evidence and testimony; a determination of whether additional evidence needs to be secured; what witnesses need to be interviewed, including the Complainant, Respondent, and other witnesses with knowledge of the research or events in question; a proposed schedule of meetings, briefing of experts, and interviews; anticipated analyses of evidence (scientific, forensic, or other); and a plan for the Investigation Report.

- 5. Investigation Process.** The Investigation Committee will be appointed and the process initiated within 20 business days of the completion of the Inquiry, if findings from that Inquiry provide a sufficient basis for conducting an Investigation.

The Investigation will normally involve examination of all documentation including, but not necessarily limited to the following:

- Relevant research records
- Computer files
- Research proposals, manuscripts, publications, and presentations
- Correspondence, memoranda, and notes of telephone calls

Whenever possible, the Investigation Committee should interview the Complainant (s), the Respondents(s), and other individuals who might have information regarding aspects of the allegations. Respondent interviews should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the Investigation file.

All interviews should be attended by at least two members of the Investigation Committee. The Respondent should be permitted to attend interviews and meetings and have either legal counsel or an advocate, of his or her choosing, present.

At the Investigative stage, interviews should be in-depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the Respondent and other witnesses.

If the Respondent admits to the research misconduct, he or she should be asked immediately to sign a statement attesting to the occurrence and extent of the research misconduct, acknowledging that the statement was voluntary and stating that the Respondent was advised of his or her right to seek the advice of counsel. The Investigation Committee shall consult with Legal Counsel at NMRC on the specific form and procedure for obtaining this statement. The admission may not be used as a basis for closing the Investigation unless the Investigation Committee has adequately determined the extent and significance of the research misconduct and all procedural steps for completion of the Investigation have been met. The Investigation Committee should ask the Research Integrity Officer to consult with DoN HRPP (or the OGITT in case of clinical trials, or ORI where DHHS or PHS funding is involved) when deciding whether an admission has adequately addressed all the relevant issues such that the Investigation can be considered completed. The Investigation should not be closed unless the Respondent has been appropriately notified and given an opportunity to comment on the Investigation Report.

6. **Pursue leads.** The Investigation Committee will diligently pursue all significant issues and leads discovered that are determined to be relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

d. The Investigation Report

1. **Elements of the Draft Investigation Report.** The draft Investigation Report must include each of the following elements:
 - The policies and procedures under which the Investigation was conducted
 - How and from whom information relevant to the Investigation was obtained
 - A statement of the findings

- An explanation of the basis for the findings
 - The actual text or an accurate summary of the views of any individual(s) found to have engaged in research misconduct
 - Recommendations for sanctions to be imposed and administrative actions to be taken by this Institution
2. The Investigation Committee will normally complete the Investigation and submit its draft Investigation Report in writing to the Research Integrity Officer no more than 60 business days following its first meeting, unless the Research Integrity Officer determines that an extension is warranted for good cause. If the Research Integrity Officer so determines, the reason for the extension will be entered into the records of the case and the Investigation Report. The Research Integrity Officer will notify the Respondent in writing of this determination. All aspects of the full Investigation must be completed within one hundred and twenty 120 days of beginning it, including conducting the investigation, preparing the report of the findings, providing the draft report for comments in accordance with the current regulations, and sending the final report to the Navy Surgeon General via the chain of command and DoN HRPP the Director of OGITT in cases of clinical trials, and the Director of ORI.
 3. **Comments on the Draft Investigation Report.** Within four (4) business days of its submission by the Investigation Committee, the Research Integrity Officer will provide the Respondent with a copy of the draft Investigation Report for comment and rebuttal.

Within four (4) business days of its submission by the Committee, the Research Integrity Officer will provide the Complainant, if he or she is identifiable, with those portions of the draft Investigation Report that address the Complainant's role and opinions in the Investigation.

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement in order to receive the report.

The Respondent and the Complainant will each have 10 business days to provide their comments, if any, to the Investigation Committee. Any comments that the Complainant or Respondent submit on the draft report will become a permanent attachment to the final Investigation Report and record.

Following the end of the 10-day comment period, the Investigation Committee may revise the draft report as appropriate. The findings of the revised draft Investigation Report should take into account the Respondent's and Complainant's comments in addition to all the other evidence. Within 10 business days after the end of the comment period, the Investigation Committee will forward its revised draft report to the NMRC Legal Counsel for review as to legal sufficiency. Legal Counsel will have 10 business days to provide comments to the Investigation Committee. At the end of the 10-day comment period, the Investigation Committee may take 10 business days to revise the draft report as appropriate and submit the final Investigation Report to the Research Integrity Officer.

Within four (4) business days of its submission by the Committee, the Research Integrity Officer will provide the Respondent and the Complainant with a copy of the Final Investigation Report. This report must include the following:

- a) Allegations, describe the nature of the allegations of research misconduct
- b) PHS support. Describe and document the PHS support, including for example, any grant numbers, grant applications, contracts and publications listing PHS support.
- c) Institutional charge. Describe the specific allegations of research misconduct for consideration in the investigation.
- d) Policies and procedures. If not already provided to DoN HRPP with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.
- e) Research records and evidence. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
- f) Statement of findings. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so ..
 - Identify whether the research or misconduct was falsification, fabrication or plagiarism, and if it was intentional, knowing or in reckless disregard;
 - Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
 - Identify the specific PHS support;
 - Identify whether any publications need correction or retraction;
 - Identify the person(s) responsible for the misconduct; and
 - List any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.
- g) Comments. Include and consider any comments made by the respondent and complainant on the draft investigation report.
- h) Maintain and provide records. Maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the report. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement in order to receive the report.

- 4. NMRC Review and Adjudication.** The Research Integrity Officer will transmit the final Investigation Report and any comments to the Deciding Official. Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the Investigation Report, its findings, recommended sanctions, and recommended administrative actions.

The Investigation is completed when the Deciding Official makes this adjudication, which will normally be made within 100 business days of the first meeting of the Investigation Committee. Any extension of this period must be based on good cause and recorded in the Investigation file. In the case of Investigations involving research supported by PHS or DHHS, such extensions require the approval of ORI.

The Deciding Official's adjudication will be made in the form of a written Determination Report that will become a permanent attachment to the final Investigation Report and record. If the Deciding Official's determination varies from that of the Investigation Committee, the Determination Report will describe in detail the basis for rendering a decision different from that of the Investigation Committee. The Deciding Official's explanation should be consistent with the DoD definition of research misconduct, NMRC and NAMRU-6 policies and procedures, and the evidence reviewed and analyzed by the Investigation Committee.

The Deciding Official will submit his or her determination along with the Investigation report to the Navy Surgeon General and to DoN HRPP via the chain of command for review or concurrence.

The Deciding Official's Determination Report may present specific issues that require additional fact-finding or analysis on the part of the Investigation Committee. In such cases, the Investigation will conduct further Investigation according to a timetable stipulated in the Determination Report. The Investigation Committee's Investigation will result in a Supplemental Investigation Report, which will undergo the same comment and determination process as a regular Investigation Report.

Regular and Supplemental Investigation Reports, including their relevant Determination Report, must be submitted to the Navy Surgeon General and to DoN HRPP via the Chain of Command. For research supported by PHS or DHHS, they must be forwarded to ORI in accordance with t regulations.

When a Determination Report has been issued, the Research Integrity Officer will notify both the Respondent and the Complainant in writing.

In consultation with NMRC's Legal Counsel, the Deciding Official will determine whether law enforcement agencies; professional societies; professional licensing boards; editors of journals in which falsified reports may have been submitted or published; collaborators of the Respondent in the work; or other relevant parties should be notified of the outcome of the case.

The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

If there is an institutional appeal by the respondent that could result in a reversal or modification of the findings of research misconduct in the investigation report, any such appeal must be completed within 120 days of its filing. Appeals from personnel or similar actions that would not result in a reversal or modification of the actions that would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit. If unable to complete any appeals within 120 days, the institution must ask for an extension in writing and provide an explanation for the request.

Chapter 4

Actions by the Department of the Navy Human Research Protections Program (DoN HRPP)

a. Inquiries or Investigations Initiated by DoN HRPP. DoN HRPP requires immediate notification and explanation of the circumstances if:

- The public health or safety is at risk
- NAMRU-6's resources or interests are threatened or at risk
- Research activities are suspended because of the Inquiry into or Investigation of the allegation
- There is a possible violation of civil or criminal law
- Action to protect the interests of those involved in the Inquiry into or Investigation of the allegation is required from DON HRPP
- A premature public disclosure of the Inquiry into or Investigation of the allegation may compromise the process
- The research community or public should be informed.

In these instances, DON HRPP will determine if NAMRU-6 is capable of adjudicating alleged research misconduct. If DON HRPP determines that it needs to conduct the Inquiry or Investigation, DON HRPP will convene its own Inquiry or investigation into alleged research misconduct. NAMRU-6 and all of its research personnel will be cooperative and follow the guidelines established by DON HRPP.

b. Inquiries or Investigations Forwarded to DON HRPP. Should the Research Integrity Officer and/or the Deciding Official determine that the Inquiry or Investigation should be conducted by DON HRPP instead of at the NAMRU-6 level, the Research Integrity Officer will forward the allegation and related documents to DON HRPP, via the chain of command, for adjudication. Reasons for this action include but are not limited to:

- The Deciding Official's involvement in the alleged misconduct.
- A determination that NAMRU-6 is unable to conduct a through and unbiased Inquiry or Investigation due to conflicts of interest.

In these instances, DON HRPP may convene its own Inquiry or investigation into alleged research misconduct. NAMRU-6 and all of its research personnel will be cooperative and follow the guidelines established by DON HRPP.

Chapter 5

Requirements for Research Supported by DHHS or PHS.

The requirements set forth in this Chapter apply only to research supported by DHHS or PHS.

The determination to initiate an Investigation involving research supported by PHS or DHHS must be reported in writing to the Director of ORI, on or before the date the Investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of research misconduct, and the PHS applications or grant number(s) involved.

Any plans to terminate prematurely an Inquiry or Investigation involving research supported by PHS or DHHS must be prospectively reported to ORI with a description of the reasons for the proposed termination.

ORI must be notified of the final outcome of any Investigation involving research supported by PHS or DHHS and must be provided with a copy of the Investigation Report. Any significant variations from the provisions of NAMRU-6 policies and procedures should be explained in any reports submitted to ORI.

Should NAMRU-6 determine that it will not be able to complete an Investigation in 120 calendar days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.

When PHS or DHHS support, funding, or applications for support or funding are involved and an admission of research misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of research misconduct. When the case involves PHS funds, NAMRU-6 cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an Investigation without ORI's prior approval.

The Research Integrity Officer will notify ORI at any stage of the Inquiry or Investigation if any of the following occur:

- There is an immediate health hazard involved.
- There is an immediate need to protect Federal funds or equipment
- 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.
- It is probable that the alleged incident is going to be reported publicly.
- The allegation involves a public health sensitive issue, *e.g.*, a clinical trial.

- There is a reasonable indication of possible criminal violation. In this instance, NAMRU-6 must inform ORI within 24 hours of obtaining that information.

ORI is authorized by statute and regulation to review NAMRU-6's reports on allegations of research misconduct. In reviewing these reports, ORI may request additional information or other assistance from the Research Integrity Officer or other NAMRU-6 official. NAMRU-6's officials will cooperate with any ORI request for additional documents and information by responding to all requests in a timely and responsive fashion.

If the official receiving the ORI request is unsure how to respond, he or she should consult with the Research Integrity Officer or NMRC's Legal Counsel. NMRC's Legal Counsel may consult with ORI counsel prior to advising the NAMRU-6 official on how to respond.

If ORI concurs with NAMRU-6's findings, ORI should notify the Respondent and appropriate NAMRU-6 officials in writing and should send them a summary or copy of the concurrence and notice of any additional PHS actions. If there is an ORI finding of research misconduct, the Respondent will be notified of his or her opportunity to appeal to the DHHS Departmental Appeals Board (DAB).

If ORI does not concur with NAMRU-6's findings, ORI should notify the appropriate NAMRU-6 official of the basis for that decision. If ORI does not concur with a finding of no misconduct, NAMRU-6 may be requested to conduct a further Investigation, either with the same or a different Investigation Committee, or ORI may conduct its own Investigation. In the latter instance, ORI will notify the appropriate individuals of its Investigation process.

Chapter 6

Administrative Actions and Considerations in Managing Research Misconduct

- a. NAMRU-6 Administrative Actions.** NAMRU-6 will take appropriate administrative actions against individuals when an allegation of research misconduct has been substantiated.

If the Deciding Official determines that the alleged research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.
- Removal of the responsible person 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.
- Restitution of funds as appropriate.

b. Other Considerations

- 1. Termination of Relationship with NAMRU-6.** The termination of the Respondent's employment or other relationship with NAMRU-6, by resignation or otherwise before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct procedures. If the Respondent, without admitting to the research misconduct, elects to resign his or her association with this Institution prior to the initiation of an Inquiry, but after an allegation has been reported, or during an Inquiry or Investigation, the Inquiry or Investigation will proceed. If the Respondent refuses to participate in the process after resignation, the appropriate committee will 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 committee's review of all the evidence.
- 2. Restoration of Reputation.** If NAMRU-6 finds no research misconduct and DON HRPP (and ORI, for DHHS or PHS supported research) concurs, the Research Integrity Officer will undertake reasonable efforts to restore the Respondent's reputation after consulting with the Respondent. The Research Integrity Officer should consider (i) notifying those individuals aware of or involved in the Investigation of the final outcome, (ii) publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or (iii) expunging all reference to the research misconduct allegation from the Respondent's personnel file. Any NAMRU-6 actions to restore the Respondent's reputation must first be approved by the Deciding Official and reviewed by NMRC's Legal Counsel.
- 3. Protection of the Notifier and Others.** Regardless of whether NAMRU-6 or ORI determines that research misconduct occurred, the Research Integrity Officer and other relevant NAMRU-6 officials will undertake reasonable efforts to protect Complainants

who made allegations of research misconduct in good faith and others who cooperate in good faith with Inquiries and Investigations of such allegations.

Upon completion of an Investigation, the Deciding Official will determine, after consulting with the Complainant, what steps, if any, are needed to restore the position or reputation of the Complainant. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the Inquiry and Investigation to prevent any retaliation against the Complainant.

- 4. Allegations Not Made in Good Faith.** If relevant, the Deciding Official will determine whether the Complainant's allegations of research misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the Complainant.
 - 5. Interim Administrative Actions.** NAMRU-6 officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are accomplished.
- c. Record Retention.** After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any Inquiry and/or Investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will maintain the file for seven years after completion of the case to permit later assessment. DON HRPP, and ORI, for DHHS or PHS supported research, or other authorized DHHS personnel will be given access to the records upon request.