THE GENEVA FOUNDATION The future of military medicine. Today.	**Standard Operating Practice**	
SOP Title: RESEARCH SCIENTIFIC MISCONDUCT PRACTICE AND REPORTING	**Original Effective Date:**	01 DEC 2010
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Approval:	**Approval:**
Rachelle Mainard Date Grants and Contracts Director	Elise Huszar Date President

Policy:	It is the policy of The Geneva Foundation (Geneva) to establish guidelines and procedures for the reporting and investigation of scientific misconduct.

1.0 PURPOSE AND BACKGROUND:

The Geneva Foundation considers ethical behavior in science and research to be paramount. Integrity and the highest standards of professional conduct are the keys to the success of The Geneva Foundation. Scientific research relies upon the trust and confidence of both the scientific community and the public. Trust and confidence in the integrity of the scientific process is imperative. Unethical behavior in research represents a breach in confidence in the trust among fellow scientists and the public. For these reasons, The Geneva Foundation takes all allegations of scientific misconduct seriously and will investigate all allegations of scientific misconduct promptly and thoroughly.

2.0 SCOPE AND RESPONSIBILITIES:

This scope applies to all Geneva employees, Principal Investigators, and research team members (paid or un-paid) performing work on Geneva projects.

3.0 REFERENCES:

3.1 45 CFR 46 (Protection of Human Subjects)

4.0 DEFINITIONS:

4.1 Allegation – A disclosure of possible research misconduct made through any means of communication. The disclosure may be made by written or oral statement or any other communication to an institutional official.

4.2 Complainant – The individual(s) who submits an allegation of Research Misconduct in good faith

4.3 Evidence - Any document, tangible item, or testimony offered or obtained during a research misconduct hearing that tends to prove or disprove the existence of an alleged fact.

4.4 Good Faith - 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 come to the same conclusion based on the information known to the Complainant or witness at the time. An allegation or testimony is not in good faith if it is 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. 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.

4.5 DHHS – The U.S. Department of Health and Human Services, the parent agency of the Public Health Service and the National Institutes of Health

4.6 Inquiry – The preliminary information gathering and preliminary fact-finding to determine whether a research misconduct allegation or apparent instance of research misconduct warrants an investigation.

4.7 Investigation – The formal development of a factual record and the examination of that record that leads to a finding with respect to research misconduct.

4.8 Office of Research Integrity or ORI – Office for which the DHHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

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

4.10 Research – All basic, applied, and demonstration research in all fields of knowledge.

4.11 Research Misconduct – as defined by the federal government means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences in opinion. Research misconduct is caused by reckless, intentional behavior. Research misconduct requires a significant departure from accepted practice of the relevant research community and that the allegation is proven by a preponderance of the evidence.

4.12 Fabrication - making up data or results and recording or reporting them.

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

4.14 Plagiarism - the appropriation of another person's ideas, processes, results, or works without giving proper credit.

4.15 Research Record – Any data, document, computer file, compact disc, 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 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; 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.

4.16 Retaliation – An adverse action taken against a complainant, witness, or investigation committee member by The Geneva Foundation or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding.

4.17 Substantial Misconduct – Misconduct that is real and substantiated.

5.0 PRACTICES AND PROCEDURES:

5.1 Research Personnel. Research team members, paid or un-paid by The Geneva Foundation, are responsible for maintaining the highest degree of ethical standards in their research. Principal Investigators are responsible for:

5.1.1 Assuring that these standards are communicated to and maintained by all who work or contribute to their research programs

5.1.2 Assuring the validity of all data collected and information disseminated by their research team and consultants

5.1.3 Assuring adequate citation of contributions from those on the research team

5.2 Administrators. The Executive Team, Grants and Contracts Director and Clinical Trials Director are responsible for ensuring compliance. They disseminate the policy to all Principal Investigators and paid research personnel, and will ensure that all allegations of research misconduct are reported in accordance with this policy. The Executive Team or Program Department Director will provide accurate recordkeeping where required and will ensure that proper and timely reporting to relevant agencies is made for any investigation of substantial misconduct. A member of the Executive Team represents the Foundation when it is determined that present or former paid research personnel are subject of complaints or investigations that involve outside institutions. The Executive Team member works with leadership of the military or government Principal Investigator or research team member when it is determined that the Principal Investigator or team member is the subject of complaints or investigations. The Geneva Foundation will comply with all applicable federal and state laws, regulations, and policies with respect to Research Misconduct.

5.3 Responsibility to Report Misconduct. Individuals subject to this Policy who become aware of a possible incident of research misconduct are required to immediately notify the appropriate Program Department Director at The Geneva Foundation, who will in turn immediately notify Geneva's Executive Team.

5.3.1 Any individual, who has questions about the Research Misconduct policy or is considering making an allegation of research misconduct, may meet privately with the appropriate Program Department Director or Executive Team member. The Geneva Foundation encourages reasonable efforts towards resolution prior to the commencement of a formal investigation, pursuant to this Policy.

5.3.2 If an individual feels there are enough grounds to make a formal allegation of research misconduct, s/he should take the steps outlined in section 5.7.

5.4 Responsibility to Protect the Complainant. Individuals subject to this Policy who learn of or receive an allegation of Research Misconduct must treat the Complainant who has made a Good Faith allegation with respect and will take reasonable and practical steps to protect or restore the reputation of the Complainant. Should the Complainant request anonymity, The Geneva Foundation will make every attempt to honor the request during the initial inquiry to the extent permitted by law. However, if the matter is referred to an Investigation, the Complainant's testimony may be required and anonymity may no longer be granted.

5.5 Responsibility to Protect the Respondent. Individuals subject to this Policy who learn of or receive an allegation of Research Misconduct must treat the Respondent with respect and will take reasonable and practical steps to protect or restore the reputation of the Respondent. A Respondent is assumed to not have committed Research Misconduct unless and until a finding of such has been made in accordance with this Policy.

5.6 Confidentiality. To the extent possible consistent with a fair and thorough investigation, and as allowed by law, knowledge of the allegation and the identity of a Complainant, a Respondent, and any witnesses shall be limited to those persons who need to know. All materials and information with respect to any inquiries, investigations, or any proceedings will be kept confidential.

5.7 Submitting an Allegation. Individuals subject to this Policy who become aware of a possible incident of research misconduct are required to immediately notify the appropriate Program Department Director at The Geneva Foundation, who will in turn immediately notify Geneva's Executive Team. An allegation may be made in writing or orally.

5.8 Preliminary Assessment of Allegations

5.8.1 Upon receiving an allegation of Research Misconduct, the Program Department Director and Executive Team member shall consult with each other to determine whether an Inquiry is warranted.

5.8.2 An Inquiry is warranted when the allegation:

a. Falls within the definition of Research Misconduct stated earlier in this Policy; and

b. Is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified.

5.8.3 If an Inquiry is warranted, the Executive Team member shall:

a. Appoint a panel of three members to conduct the Inquiry and chair the Inquiry committee;

b. In writing, notify the presumed Respondent, Complainant, and if applicable, the Respondent's direct government supervisor; and

c. Take all practical and reasonable steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding.

5.8.4 If is determined that an Inquiry is not warranted, the Executive Team member shall notify the Complainant of the decision in writing. The Complainant may request reconsideration of the decision by addressing a request in writing within 15 business days of the Executive Team's notice.

5.8.5 The purpose of an Inquiry is to determine whether an allegation warrants an investigation. An Investigation is warranted when there is

a. Reasonable basis for conclusion that the allegation falls within the definition of Research Misconduct as defined by this Policy; and

b. Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

5.9 Conducting an Inquiry.

5.9.1 Timing. If it is determined that an Inquiry is warranted, the following procedures shall apply. The Inquiry must be completed within 60 days of the appointment of the Inquiry Panel, unless circumstances require a longer period. Reasons for additional time must be documented in the Inquiry Report.

5.9.2 Designation of Inquiry Panel.

a. Within 15 business days from the determination that an Inquiry is warranted, the Executive Team shall appoint an Inquiry Panel. The Inquiry Panel shall consist of three individuals who do not have any real or apparent conflict of interest in the case, and have the necessary expertise to evaluate the evidence.

b. The Inquiry Panel may determine that additional experts are needed for consultation. If consulted, such experts shall serve in a strictly advisory role and will not be allowed to vote.

5.10 Notification of Complainant and Respondent. The Executive Team member shall notify the Complainant and Respondent in writing of the scheduled Inquiry. The notification should: identify the research project and specific allegations; provide a copy of this Policy; refer to the definition of Research Misconduct; identify funding involved; list the names of the Inquiry Panel members and experts, as applicable; and describe the need to maintain confidentiality.

5.11 Secure all Research Records and Evidence. The Executive Team shall make every reasonable effort to obtain custody of all research records and evidence prior to notification of the Inquiry or upon notification. An inventory of the research records or evidence will be prepared and all documentation will be secured safely by the Executive Team. The Executive Team or his/her designee shall obtain the original set of records and/or evidence, and provide a copy of the record to the Respondent, if requested.

5.12 Review of the Record. Members of the Inquiry Panel shall review the complete set of research records and interview individuals necessary to determine whether the allegation has substance and warrants a full Investigation. An Investigation is warranted if there is:

a. A reasonable basis for concluding that the allegation falls within the above stated definition of Research Misconduct; and

b. Preliminary information-gathering and preliminary fact finding from the inquiry indicates that the allegation may have substance.

5.13 Inquiry Report. Once the review of the record is complete, the Inquiry Panel will work with the Executive Team member to prepare a written report summarizing the findings from the Inquiry.

5.13.1 The report must include:

a. Name and position of the respondent

b. Description of the allegations of research misconduct

c. Award sponsoring agency to include award number

d. The basis for recommending that the alleged actions warrant an investigation; and

e. Any comments on the report by the respondent or the complainant.

5.13.2 Report details will be double checked with the complainant who will sign off agreement that the report is accurate. The complainant's confirmation will be stored separately so that the respondent will not see the complainant's name.

5.13.3 The Respondent shall be provided with a copy of the draft Inquiry Report and be given 10 business days to respond in writing.

5.13.4 The Executive Team member will provide the complainant with regular verbal or written status unless the complainant requests not to be informed.

5.14 Decision of Investigation. The Executive Team member shall notify the Foundation's President of the Inquiry Panel's recommendation for an investigation. The Inquiry is completed when the President makes a determination as to whether an Investigation is warranted.

5.15 Notification of an Investigation. The President or a member of the Executive Team shall notify the Respondent, Complainant, and appropriate Program Director of his/her decision to proceed with an Investigation. The notification shall include a copy of the Inquiry Report. Within 30 days of finding that an investigation is warranted, the President will notify, as required by federal regulations, federal authorities of the results of the inquiry and the need for Investigation. For example, PHS funded research programs require that Geneva notify the Office of Research Integrity and provide a copy of the Inquiry Report.

5.16 Establishing the Investigation Committee. In consult with the President, the Executive Team shall appoint members to an Investigation Committee.

5.16.1 The Committee shall consist of three individuals who do not have any real or apparent conflict of interest in the case, and have the necessary expertise to evaluate the evidence, interview key principals which may include senior administrators and research team members, subject matter experts, and conduct the Investigation. Committee members may include scientists, research administrators, government researchers, lawyers, subject matter experts, or other qualified individuals, and may be from within or external to The Geneva Foundation.

5.16.2 The Committee may determine a need for outside experts other than members appointed to the investigation Committee. If consulted, such experts shall serve in a strictly advisory role and will not be allowed to vote.

5.17 Investigation Timing.

5.17.1 The Committee will make its best effort to complete the investigation within 120 calendar days from initiating the Investigation. This includes conducting the investigation, preparing the report of findings, providing a detailed draft for comments, and sending the final report to federal authorities, as required by federal regulations.

5.17.2 If the Committee is unable to complete a fair and thorough investigation within 120 days, Geneva's President must request an extension from the appropriate federal authority.

5.18 Investigation Process. The Committee will be expected to:

5.18.1 Employ diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relating to reaching a decision on the merits of the allegations.

5.18.2 Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable.

5.18.3 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 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

5.18.4 Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

5.19 Investigation Report

5.19.1 The Investigation Report will contain the same type of information as documented in the Inquiry Report. In addition, the Investigation Report will include for each separate allegation of Research Misconduct identified, a finding for whether Research Misconduct occurred, and if so:

a. Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard

b. Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;

c. Identify specific federal or non-federal funding support

d. Identify whether any publications need correction or retraction

e. Identify the person(s) responsible for the misconduct, and

f. List known applications or proposals and sponsors for which the respondent has pending support requests

5.19.2 A draft copy of the investigation report shall be provided to the Respondent. The respondent shall have 30 days to provide written comment. S/he will be given supervised access to the research records and evidence.

5.19.3 The Investigation Committee shall consider and attach any comments made by the Respondent (and Complainant and/or witnesses, if applicable) to the draft Investigation Report.

5.19.4 At the conclusion of the Investigation, the Executive Team member, chair of the committee, shall forward copies of the final investigation report to the President and the Respondent.

5.19.5 The President shall forward a copy of the final investigation report to the appropriate federal authorities, if applicable, in accordance with federal regulations. Along with the written report, the President shall make known whether The Geneva Foundation accepts the Investigation's findings and describe any pending or completed administrative actions against the Respondent.

5.19.6 If the alleged Research Misconduct is not substantiated, efforts will be made to restore the reputation of the Respondent. If it is further demonstrated that the allegations were not made in Good Faith, and were brought under malicious circumstances, the President may take administrative action against the Complainant or others involved, as noted below in Section IX.

5.20 Appeal: Review by Chairman, Board of Directors.

5.20.1 Within 14 days of receipt of the Investigation report, the Respondent may appeal in writing to the Chairman, Board of Directors on the following grounds:

a. That there has been a failure to follow the procedures described in this policy

b. The Respondent has new material evidence that was not available to the Respondent during the investigation.

5.20.2 If the Chairman, Board of Directors determines that a) there was a procedural error or the Respondent has new evidence that is substantial and not reasonably available during the original Investigation, and b) there is substantial possibility that the new evidence may have affected the outcome of the Investigation, the Chairman may refer the matter back to the Investigational Committee or appoint a new Committee to reopen the case.

5.21 Administrative Action As A Result of Investigation.

5.21.1 If it is determined that Research Misconduct has occurred, the President in consultation with the Executive Team and Program Department Director, shall recommend appropriate actions to be taken. Recommended actions may include:

a. Withdrawal or correction of all pending or published abstracts and papers resulting from the research where Research Misconduct was found;

b. Removal of the Respondent from the research program, disciplinary action which may include close oversight of future work, suspension of work or termination of employment;

c. Restitution of funds as appropriate;

d. Notification of appropriate Commanding Officers, if Respondent is a military or government employee

e. Notify the funding agency.

f. Submit a report to the Office of Research Integrity (ORI) for misconduct associated with federally funded research programs.

5.21.2 If for any reason, The Investigation Committee or President decides to close the investigation on the basis that the Respondent has admitted guilt, a settlement with the respondent has been reached, or if for any other reason, The Geneva Foundation must notify the appropriate federal authority, if applicable.

5.22 Other Geneva Responsibilities.

5.22.1 The Geneva Foundation shall establish permanent records of the Committee reports, exhibits, meeting minutes, transcriptions, and other materials that will be secured by the Executive Team for no less than seven years from the date of Investigation conclusion. These records will be kept confidential and protected from release.

5.22.2 The Geneva Foundation shall renew their research misconduct assurance for federally funded research programs by annually submitting a report to the Office of Research Integrity (ORI) on the allegations, inquiries and investigations they handled in the previous year and other matters related to the regulation.