Research Misconduct

STANDARD OPERATING PRACTICE

ORIGINAL EFFECTIVE DATE	01 MAR 2011	REVISED EFFECTIVE DATE	01 OCT 2019

POLICY: The Geneva Foundation (Geneva) investigates promptly and thoroughly all allegations of research misconduct and reports allegations of misconduct in accordance with this policy. Geneva submits annually a report to the Office of Research Integrity (ORI) on the allegations, inquiries and investigations handled in the previous year and other matters related to the regulation. In addition, investigators working on industry sponsored clinical trials must attest compliance with the Generic Drug Enforcement Act of 1992 as required by the Food and Drug Administration.

1.0 PURPOSE AND BACKGROUND

1.1 Geneva 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 Geneva. 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.

2.0 SCOPE AND RESPONSIBILITIES

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

2.2 It is the responsibility of all Geneva personnel, regardless of position or level, to report any misconduct observed, communicated in anyway, told in confidence, or suspected.

2.3 Research team members, paid or un-paid by Geneva, are responsible for maintaining the highest degree of ethical standards in research on Geneva projects. Specifically, PIs are responsible for:

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

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

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

2.4 Geneva's Authorized Officials and Executive Team, or designee, ensure compliance by disseminating this policy to all PIs and research personnel.

2.5 The Executive Team or Authorized Officials provide accurate recordkeeping and ensures proper and timely reporting to relevant agencies for any investigation of substantial misconduct.

2.6 A member of the Executive Team, or designee, represents Geneva when it is determined that present or former research personnel are the subject of complaints, inquiries or investigations that involve outside organizations.

2.7 The Executive Team member works with leadership of the military, government PI, or research team member when it is determined that the PI or team member is the subject of complaints, inquiries, or investigations.

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

2.9 Geneva's Scientific Advisory Board (SAB) is available to the Executive Team as a resource in an advisory capacity.

2.10 Geneva's Compliance Committee is responsible for the record keeping and tracking of incidents such as research misconduct. In addition, a member of the Compliance Committee serves on the Inquiry Panel and Investigation Committee.

3.0 REFERENCES

3.1 GCD-F-007 Affiliate Researcher Appointment

3.2 GEN-S-001 Document Control

3.3 GEN-S-004 Retention of Corporate Records

3.4 GEN-S-008 HIPAA

3.5 GEN-S-011 Code of Conduct

3.6 HRD-S-004 Employee Whistleblower Protection

3.7 HRD-S-027 Corrective Action

3.8 42 C.F.R. §93.301 (Public Health Service Policies on Research Misconduct)

3.9 Generic Drug Enforcement Act of 1992

3.10 45 CFR 46 (Protection of Human Subjects - DHHS)

3.11 32 CFR 219 (Protection of Human Subjects – DoD)

3.12 21 CFR 50, 56, 312, 812 (FDA Regulations)

3.13 45 CFR 160-164 (HIPAA)

3.14 DoD Directive 3216.2 (Protection of Human Subjects – USAMRMC)

3.15 AR 70-25 (Use of Volunteers)

3.16 AR 40-7 (Use of Investigational Drugs and Devices)

3.17 OTSGR 15-2 (Surgeon General Regulation – Human Subjects Research)

3.18 10 USC 980 (DoD – Funds Appropriated for Human Subjects Research

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.

4.2 Authorized Official: An individual who is designated by Geneva's Chief Executive Officer (CEO) to give assurances, make commitments and execute legal documents on behalf of Geneva. In general, this includes Directors and certain members of Geneva's Compliance Committee.

4.3 Complainant: The individual(s) who submits an allegation of Research Misconduct in good faith.

4.4 Conflicts of Interest: A situation in which the concerns or aims of two different parties are incompatible or a situation in which a person is in a position to derive personal benefit from actions or decisions made in their official capacity.

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 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.

4.7 Fabrication: Making up data or results and recording or reporting them.

4.8 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.

4.9 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 helping Geneva 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.

4.10 Inquiry: The preliminary information gathering and fact-finding to determine whether an allegation of research misconduct warrants an investigation.

4.11 Inquiry Panel or Investigation Committee Member: Individuals appointed by the Executive Team consisting of a minimum of three members to conduct the Inquiry or Investigation. The three members must include:

4.11.1 Geneva's Scientific Advisory Board (SAB) Chair, who does not have any real or apparent conflict of interest in the case and has the necessary expertise to evaluate the evidence. The Executive Team and the SAB Chair determines if the Inquiry Panel should include additional members from the SAB or if the entire SAB should be notified of or involved in the Inquiry.

4.11.2 A member of Geneva's Compliance Committee

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

4.13 Office of Research Integrity (ORI): Office for which the DHHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to Public Health Service (PHS) supported activities.

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

4.15 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.

4.16 Research: All basic, applied, and demonstration research in all fields of knowledge.

4.17 Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results as defined by the federal government. 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.

4.18 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; clinical trial source documents; consent forms; medical charts; and patient research files.

4.19 Respondent: A defendant in a lawsuit, especially one in an appeal or a person who replies to something, especially one supplying information.

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

4.21 Substantial Misconduct: Misconduct that is real and substantiated.

4.22 Witness: A person who sees an event take place or a person serving as a subject matter expert during an investigation.

5.0 PRACTICES AND PROCEDURES

5.1 Protection of the Complainant

5.1.1 Individuals who learn of or receive an allegation of research misconduct must treat the Complainant who has made a Good Faith allegation with respect and take reasonable and practical steps to protect or restore the reputation of the Complainant.

5.1.2 Should the Complainant request anonymity, Geneva makes 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.

5.2 Protection of the Respondent

5.2.1 Individuals who learn of or receive an allegation of research misconduct must treat the Respondent with respect and take reasonable and practical steps to protect or restore the reputation of the Respondent.

5.2.2 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.

5.3 Submitting an Allegation

5.3.1 Individuals who become aware of a possible incident of research misconduct are required to immediately notify Geneva through the following available channels of communication:

a. The anonymous hotline service established by Geneva called EthicsPoint; or

b. A written or verbal allegation made to an appropriate Authorized Official at Geneva.

5.3.2 Once notified, the Authorized Official, in turn, immediately notifies Geneva's Executive Team.

5.3.3 If the Complainant is not comfortable speaking to the Authorized Official or does not feel the issue has been properly addressed; they may contact the Human Resources Director or a member of Geneva's Executive Team. If they do not believe that these channels of communication can/should be used to express their concerns, they may utilize EthicsPoint.

5.3.4 Geneva encourages reasonable efforts towards resolution prior to the commencement of a formal inquiry or investigation, pursuant to this policy. If an individual has questions about this policy, they may meet privately with the appropriate Authorized Official or Executive Team member.

5.4 Preliminary Assessment of Allegation

5.4.1 Upon receiving an allegation of research misconduct, the Authorized Official and Executive Team member consult with each other to determine whether an Inquiry is warranted.

5.4.2 An Inquiry is warranted when the allegation:

a. Falls within the definition of research misconduct; and

b. Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

5.8.3 If an Inquiry is not warranted, the Executive Team member notifies the Complainant of the decision in writing (if the Complainant is not anonymous). The Complainant may request reconsideration of the decision by addressing a request in writing within 15 business days of the Executive Team's notice. This decision is routed to the Compliance Committee for review and document storage.

5.9 Conducting an Inquiry

5.9.1 If an Inquiry is warranted, the Executive Team appoints the Inquiry Panel to conduct the Inquiry and the chair of the Inquiry Panel (within 15 business days of the determination).

a. The Inquiry Panel may determine that additional experts are needed for consultation. If consulted, such experts shall serve in strictly an advisory role.

5.9.2 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.

5.9.3 The Executive Team notifies the Complainant (if not anonymous) and Respondent in writing of the scheduled Inquiry. If applicable, the Respondent's direct government supervisor is notified. The notification should: identify the research project and specific allegations; provide a copy of the signed Affiliate Researcher Appointment; provide a copy of this SOP; refer to the definition of research misconduct; identify the funding involved; list the names of the Inquiry Panel members and experts, as applicable; and describe the need to maintain confidentiality.

5.9.4 The Executive Team makes every reasonable effort to obtain all research records and/or evidence prior to notification of the Inquiry or upon notification. An inventory of the research records and/or evidence is prepared, and all documentation secured safely by the Executive Team. The Executive Team obtains the original set of records and/or evidence and provides a copy of the records to the Respondent, if requested.

5.9.5 The Inquiry Panel reviews records and/or evidence and interviews personnel as 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 definition of research misconduct; and

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

5.9.6 Once the review of the records is complete, the Inquiry Panel collaborates with the Executive Team to prepare an Inquiry Report summarizing the findings from the Inquiry. The report must include:

a. Name and position of the Respondent

b. Description of the allegations of research misconduct

c. Award sponsoring agency and award number

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

e. Any comments on the report by the Respondent or the Complainant

5.9.7 If the Complainant's identity is known, The Complainant approves the accuracy of the Inquiry Report, and the Complainant's confirmation is retained separately so that the Respondent does not see the Complainant's name. A copy of the approved report is given to the Compliance Committee.

5.9.8 The Respondent is provided a copy of the draft Inquiry Report and is given 10 business days to respond in writing.

5.9.9 The Executive Team member provides the Complainant with regular verbal or written status updates unless the Complainant requests not to be informed or the Complainant is anonymous.

5.10 Conducting an Investigation

5.10.1 The Inquiry Panel notifies Geneva's CEO and Chief Strategy Officer of the Inquiry Panel's recommendation for an Investigation. The Inquiry is complete when the CEO and CSO determine whether an Investigation is warranted.

5.10.2 The CEO or an Executive Team member notifies the Respondent, Complainant (as applicable), SAB, Compliance Committee and appropriate Authorized Official of the decision to proceed with an Investigation. The notification includes a copy of the Inquiry Report. Within 30 days of the decision to investigate, the CEO notifies, as required by federal regulations, federal authorities of the results of the Inquiry and the need for an Investigation. (For example, PHS funded research programs require that Geneva notify the ORI and provide a copy of the Inquiry Report.)

5.10.3 In consult with the CEO, the Executive Team appoints members to an Investigation Committee. This Committee may be the same or different personnel as the Inquiry Panel.

a. The Committee may determine a need for outside experts other than the members appointed to the Investigation Committee. If consulted, such experts shall serve in strictly an advisory role.

5.10.4 The Committee makes 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.

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

5.10.6 The Investigation Committee is expected to:

a. 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;

b. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practicable;

c. Interview each Respondent, Complainant (as applicable), and any other available personnel 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

d. Pursue 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.

5.11 Investigation Report

5.11.1 The Investigation Report contains the documentation included in the Inquiry Report. In addition, the Investigation Report includes for each separate allegation of research misconduct identified, a finding for whether research misconduct occurred, and if so:

a. Identify whether the research misconduct is falsification, fabrication, or plagiarism, and if it is 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

5.11.2 A draft copy of the Investigation Report is provided to the Respondent. The Respondent has 30 days to provide written comment and is given supervised access to the research records and evidence.

5.11.3 The Investigation Committee considers and attaches any comments made by the Respondent (and Complainant and/or witnesses, if applicable) to the draft Investigation Report.

5.11.4 At the conclusion of the Investigation, the Executive Team and chair of the Investigation Committee provides copies of the final Investigation Report to the CEO, SAB Chair, Compliance Committee and the Respondent.

5.11.5 The CEO provides a copy of the final Investigation Report to the appropriate federal authorities or sponsor, if applicable, in accordance with federal regulations. Along with the written report, the CEO makes known whether Geneva accepts the Investigation's findings and describes any pending or completed administrative or corrective actions against the Respondent.

5.11.6 If the alleged research misconduct is not substantiated, efforts are made to restore the reputation of the Respondent. If it is further demonstrated that the allegations are not made in Good Faith and were brought under malicious circumstances, the CEO may take administrative or corrective action against the Complainant or others involved.

5.12 Appeal

5.12.1 Within 14 days of receipt of the Investigation Report, the Respondent may appeal in writing to the Chair of the Board of Directors on the following grounds:

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

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

5.12.2 If the Chair of the Board of Directors determines that a) there is 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 Chair may refer the matter back to the Investigation Committee or suggest appointment of a new Committee to reopen the case.

5.13 Administrative or Corrective Action

5.13.1 If it is determined that research misconduct has occurred, the CEO in consultation with the Executive Team, recommends 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 misconduct was found;

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

c. Restitution of funds as appropriate;

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

e. Notification to the funding agency;

f. Submission of report to the ORI for misconduct associated with federally funded research programs.

5.21.2 If for any reason, the Investigation Committee or CEO 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, Geneva must notify the appropriate federal authority, if applicable.

5.13.2 Geneva establishes permanent records of the Committee reports, exhibits, meeting minutes, transcriptions, and other materials that are secured by the Executive Team for no less than seven years from the date of Investigation conclusion. These records are kept confidential and protected from release.

5.18 Annual Research Misconduct Assurance Reporting

5.18.1 Geneva renews its research misconduct assurance for federally funded research programs by annually submitting a report to the ORI on the allegations, inquiries and investigations handled in the previous year and other matters related to the regulation.

5.18.2 Prior to renewing the assurance, the CEO request a listing, from the Compliance Committee, of any research findings or investigations of misconduct in the previous calendar year. The Compliance Committee provides the CEO with any Investigation Reports filed in the previous calendar year.

5.19 The CEO, or designee, renews Geneva's research misconduct assurance annually. A copy is provided to the Compliance Committee for record retention.

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