Policy Memorandum No. 41
Subject: Debarment, Suspension, Research Misconduct and Professional Integrity
Departments Affected: ALL
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DEBARMENT, SUSPENSION OR OTHER ADMINISTRATIVE ACTIONS AND THE HANDLING OF ALLEGATIONS OF RESEARCH MISCONDUCT OR ISSUES RELATED TO PROFESSIONAL INTEGRITY

SWOG expects the highest standards of integrity to be observed in the research it conducts. To facilitate the highest quality research, the Group is committed to prevention and detection of research misconduct through procedures that include monitoring of Group investigators and identification of data irregularities through quality control procedures and the audit program. In addition, the Group's policies and procedures incorporate those requirements of the National Institutes of Health to ensure strict compliance with government regulations covering research misconduct applicable to federally funded research. Finally, the Group supports an ethical, and civil culture, committed to multi-stakeholder research where all voices are valued.

This policy addresses key aspects and actions to ensure the Group's scientific process maintains an environment and reputation of trust and integrity. First, this policy discusses the regular monitoring of Group investigators conducted through various federal agency website bulletins boards which post misconduct, debarment, suspension or other administrative actions against investigators. Second, this policy addresses the procedures for, and handling of, allegations of scientific misconduct. Lastly, this policy provides guidance regarding the Vice Chair of Membership and Accrual's role as a confidential resource for members to manage concerns regarding professional integrity.

MONITORING OF GROUP INVESTIGATORS

SWOG monitors four U.S. Department of Health & Human Services (DHHS) website bulletin boards for any misconduct, debarment, suspension or other administrative actions placed against SWOG investigators. The following search criteria are used to ensure compliance to this policy:

Search Criteria

The websites for the Food and Drug Administration and the Office of Research Integrity are monitored monthly for any misconduct, debarment or other administrative actions placed against any active Group investigator. Investigators assuming the role of Principal Investigator for an institution will also be screened against all four websites prior to approval.

Description of Website Bulletin Boards

The **Food and Drug Administration (FDA)** provides two independent bulletin boards; one listing the names of individuals that have been debarred by the FDA and the other listing the names of individuals that have had other restrictions placed against them by the FDA:

Debarment List:
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications

Clinical Investigator – Disqualification Proceedings Database:
http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings

The **Office of Research Integrity (ORI)** bulletin board provides the names of individuals that have had administrative actions imposed against them by the ORI: PHS Administrative Actions Listing:
https://ori.hhs.gov/ORI_PHS_alert.html?d=update

The **Office of Inspector General (OIG)** listing provides information regarding individuals and entities that are excluded from participation in Medicare, Medicaid, and other Federal health care programs: List of Excluded Individuals and Entities: *http://exclusions.oig.hhs.gov/*

Notification

If it is determined that any misconduct, debarment or other administrative action has been taken against an active Group investigator, the investigator will be notified by the Group Chair that their privilege to register participants may be temporarily suspended or permanently withdrawn by the Group, depending on the type of action levied against the investigator. The Principal Investigator of the institution where the investigator is located, the NCI and the Group Quality Assurance Department will also be notified.

ALLEGATIONS OF RESEARCH MISCONDUCT

In order to fulfill its obligations and ensure the public trust, the Group must diligently prevent and inquire into research misconduct. The following policy complies with current federal regulations regarding scientific research misconduct, for example those promulgated by the Public Health Service (PHS). This policy and its procedures apply to all Group members.

This policy is created to prevent, detect, and respond to misconduct in research and authorship. All individuals are primarily responsible for preserving the integrity of truthful research in their scholarly activities. However, this policy outlines the Group's responsibility to:

(1) Promote exemplary ethical standards for research and scholarship;

(2) Initiate an inquiry into any suspected or alleged misconduct;

(3) Conduct a subsequent investigation, if warranted; and

(4) Take action necessary to ensure the integrity of all research, the rights and interests of research subjects and the public, and the observance of legal requirements or responsibilities.

Definition of Research Misconduct

Research Misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. **Research misconduct does not include honest error or differences of opinion.**

Initial Allegation

Any Group member who has reason to believe that an individual has engaged in an act of research misconduct related to Group sponsored or associated research or activities, is required to immediately contact the Quality Assurance Department at the Operations Office at 210/614-8808. Reporting is available 24 hours a day (leave a voice mail) and may be made anonymously.

The Operations Office staff will report the initial allegation of research misconduct to both the Group Chair and the Group's Professional Review Committee (PRC). The PRC is the body responsible for reviewing (inquiry), investigating and reporting any allegations of research misconduct, as described in detail below, against a respondent, i.e., a Group member against whom an allegation of research misconduct is directed or who is the subject of a research

misconduct proceeding. To the extent any member of the PRC is conflicted relative to a particular research misconduct allegation, that member shall recuse themself from the review and investigation while remaining in compliance with the confidentiality requirements set forth below.

Confidentiality

To the extent allowed by law, the PRC, and any applicable Group staff, shall maintain the identity of respondents and complainants securely and confidentially and shall not disclose any identifying information, except to: (1) those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) a federal regulatory agency as it conducts its review of the research misconduct proceeding and any subsequent proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

Research Misconduct Proceedings–Criteria, Reports, and Time Limitations

Promptly after receiving an allegation of research misconduct, defined as a disclosure of possible research misconduct through any means of communication, the PRC shall assess the allegation to determine if: (1) it meets the definition of research misconduct; (2) it involves either federally supported research, applications for federal research support, or research records specified in the applicable federal regulations; and, (3) the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

Notification:
When is HHS Office of Research Integrity (ORI) Notification Required?
Extramural institutions are required to notify ORI of research misconduct cases if an institution concludes that an investigation is warranted (42 C.F.R. § 93.309). The only time ORI need not be notified is when an inquiry committee finds insufficient evidence of possible misconduct to warrant further investigation. However many institutions remain confused about when a misconduct proceeding may be stopped at the inquiry stage without notification and when it must proceed to a conclusion. In the usual situation, the inquiry committee's responsibility is to determine whether there was sufficient evidence to warrant an investigation, not to determine whether there was misconduct and "resolve" the issue. Even if the respondent admits to misconduct at the inquiry stage and the institution believes that no further investigation is necessary, the institution must report its misconduct finding to ORI and state why it believes further investigation is unnecessary. See 42 C.F.R. § 93.316.

Inquiry (within 60 calendar days):
If it is determined that an inquiry (i.e., an initial review of the evidence to determine if the criteria for conducting an investigation have been met) is warranted, the PRC shall complete the inquiry, including preparation of the inquiry report and giving the respondent a reasonable opportunity to comment on it, within 60 calendar days of its initiation, unless the circumstances warrant a longer period. If the inquiry takes longer than 60 days to complete, the PRC shall include documentation of the reasons for the delay in the inquiry record. The inquiry report shall contain the following information:

(1) The name and position of the respondent(s);

(2) A description of the allegations of research misconduct;

(3) The federal support involved, including, for example, grant numbers, grant applications, contracts, and publications listing federal support;

(4) The basis for recommending that the alleged actions warrant an investigation; and

(5) Any comments on the report by the respondent or the complainant.

Investigation (within 120 calendar days):
The PRC will make a written determination of whether an investigation is warranted. If the inquiry results in a determination that an investigation is warranted, the PRC shall begin the investigation within 30 calendar days of that determination and, on or before the date on which the investigation begins, send the inquiry report and the written determination to the applicable federal regulatory agency, i.e., Office of Research Integrity (ORI). The PRC shall use best efforts to complete the investigation within 120 calendar days of the date on which it began, including conducting the investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to ORI. If it becomes apparent that the PRC cannot complete the investigation within that period, the PRC shall promptly request an extension in writing from ORI. This time period does not apply to separate termination hearings.

In conducting all investigations, the PRC shall:

(1) Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations;

(2) 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 investigation;

(3) 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; and

(4) Otherwise comply with the requirements for conducting an investigation in the federal regulations, i.e., 42 CFR Section 93.310.

Report:
The PRC shall prepare the draft and final Group investigation reports in writing and provide the draft report for comment as provided elsewhere in these policies and procedures and 42 CFR Section 93.312. The final investigation report shall:

(1) Describe the nature of the allegations of research misconduct;

(2) Describe and document the PHS support, including, for example any grant numbers, grant applications, contracts, and publications listing PHS support;

(3) Describe the specific allegations of research misconduct considered in the investigation;

(4) Include the Group policies and procedures under which the investigation was conducted, if not already provided to ORI;

(5) Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody, but not reviewed. The report will also describe any relevant records and evidence not taken into custody and explain why.

(6) Provide a finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found, (i) identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard, (ii) summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations, (iii) identify the specific federal support; (iv) identify any publications that need correction or retraction; (v) identify the person(s) responsible for the misconduct, and (vi) list any current support or known applications or proposals for support that the respondent(s) has pending with non-PHS Federal agencies; and (7) include and consider any comments made by the respondent and complainant on the draft investigation report.

The PRC shall maintain and provide to ORI upon request all relevant research records and records of its research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

Ensuring a Fair Research Misconduct Proceeding

The PRC shall take all reasonable steps to ensure an impartial and unbiased research misconduct proceeding to the maximum extent practicable. The PRC shall select those conducting the inquiry or investigation on the basis of scientific expertise that is pertinent to the matter and, prior to selection, shall screen them for any unresolved personal, professional, or financial conflicts of interest with the respondent, complainant, potential witnesses, or others involved in the matter. Any such conflict which a reasonable person would consider to demonstrate potential bias shall disqualify the individual from selection.

Notice to Respondent

During the research misconduct proceeding, the PRC shall provide the following notifications to all identified respondents:

- Initiation of Inquiry. Prior to or at the beginning of the inquiry, the PRC shall provide the respondent(s) written notification of the inquiry and contemporaneously sequester all research records and other evidence needed to conduct the research misconduct proceeding. If the inquiry subsequently identifies additional respondents, they shall be promptly notified in writing.

- Comment on Inquiry Report. The PRC shall provide the respondent(s) an opportunity to comment on the inquiry report in a timely fashion so that any comments can be attached to the report.

- Results of the Inquiry. The PRC shall notify the respondent(s) of the results of the inquiry and attach to the notification copies of the inquiry report and these Group policies and procedures for the handling of research misconduct allegations.

- Initiation of Investigation. Within a reasonable time after the PRC's determination that an investigation is warranted, but not later than 30 calendar days after that determination, the PRC shall notify the respondent(s) in writing of the allegations to be investigated. The PRC shall give respondent(s) written notice of any new allegations within a reasonable time after determining to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.

- Scheduling of Interview. The PRC will notify the respondent sufficiently in advance of the scheduling of their interview in the investigation so that the respondent may prepare for the interview and arrange for the attendance of legal counsel, if the respondent wishes.

- Comment on Draft Investigation Report. The PRC shall give the respondent(s) a copy of the draft investigation report, and concurrently, a copy of, or supervised access to, the evidence on which the report is based and notify the respondent(s) that any comments must be submitted within 30 days of the date on which he/she received the draft report. The PRC shall ensure that these comments are included and considered in the final investigation report.

Notifying ORI of the Decision to Open an Investigation and of Group Findings and Actions Following the Investigation.

On or before the date on which the investigation begins (the investigation must begin within 30 calendar days of our finding that an investigation is warranted), the PRC shall provide ORI with its written finding and a copy of the inquiry report containing the information required by the federal regulations, specifically 42 CFR Section 93.309(a). Upon a request from ORI, the PRC shall promptly send them: (1) a copy of the Group policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges for the investigation to consider.

The PRC shall promptly provide to ORI after the investigation: (1) A copy of the investigation report, all attachments, and any appeals; (2) A statement of whether the Group found research misconduct and, if so, who committed it; (3) A statement of whether the Group accepts the findings in the investigation report; and (4) A description of any pending or completed administrative actions against the respondent. Maintenance and Custody of Research Records and Evidence

The PRC shall take the following specific steps to obtain, secure, and maintain the research records and evidence pertinent to the research misconduct proceeding:

(1) Either before or when the PRC notifies the respondent of the allegation, the PRC shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory those materials, and sequester them in a secure manner, except in those cases where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

(2) Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records.

(3) Undertake all reasonable and practical efforts to take custody of additional research records and evidence discovered during the course of the research misconduct proceeding, including at the inquiry and investigation stages, or if new allegations arise, subject to the exception for scientific instruments in (1) above.

(4) The PRC shall maintain all records of the research misconduct proceeding, as defined in 42 CFR Section 93.317(a), for 7 years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93, whichever is later, unless the PRC has transferred custody of the records and evidence to HHS, or ORI has advised us that we no longer need to retain the records.

Interim Protective Actions

At any time during a research misconduct proceeding, the PRC shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the federally supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals

for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other Groups that may be affected by an allegation of research misconduct.

Notifying ORI of Special Circumstances that may Require Protective Actions

At any time during a research misconduct proceeding, the PRC shall notify ORI immediately if the PRC has reason to believe that any of the following conditions exist:

(1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

(2) HHS resources or interests are threatened.

(3) Research activities should be suspended.

(4) There is a reasonable indication of violations of civil or criminal law.

(5) Federal action is required to protect the interests of those involved in the research misconduct proceeding.

(6) Belief the research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.

(7) Belief the research community or public should be informed.

Group Actions in Response to Final Findings of Research Misconduct

The PRC, on behalf of the Group, will cooperate with and assist ORI and HHS, as needed, to carry out any administrative actions HHS may impose as a result of a final finding of research misconduct by HHS. In addition, the PRC will report to the Group's Board of Governors any action it proposes to be taken, e.g., suspension or loss of Group membership, against the respondent based on its finding of research misconduct. The Board of Governors will thereafter vote on accepting the proposal of the PRC and/or taking any additional actions against the respondent.

Restoring Reputations

Respondents. The PRC shall undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made, if that person or their legal counsel or other authorized representative requests that the Group do so.

Complainants, Witnesses, and Committee Members. The PRC shall undertake all reasonable and practical efforts to protect and restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against those complainants, witnesses and committee members.

Cooperation with Federal Government

The PRC, on behalf of the Group, shall cooperate fully and on a continuing basis with any federal regulatory agency such as ORI during its oversight reviews of this Group and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS administrative actions. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records, and other evidence under our control or custody, or in the possession of, or accessible to, all persons that are subject to the Group's authority.

Reporting to ORI

The PRC will report to ORI any proposed settlements, admissions of research misconduct, or Group findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.

To obtain a copy of the applicable Department of Health and Human Services regulations (42 CFR Parts 50 and 93) referred to in this policy, go to *http://www.gpoaccess.gov/cfr/index.html*.

INVESTIGATIONS RELATED TO PROFESSIONAL INTEGRITY

In order to support a collaborative and respectful community, the Group has empowered the Vice Chair of Membership and Accrual to act as the Group's ombudsman who will be available to any member with concerns related to their participation in SWOG. The objective is to provide a safe and confidential resource so these concerns can be heard, goals clarified, and resolution sought through respectful dialogue among members involved utilizing fair and transparent processes.

Areas covered under professional integrity:

In the context of this policy, professional integrity covers the application of appropriate ethical behavior that strongly adheres to the values of honesty, honor, dependability, and trustworthiness. Key behaviors for professional integrity at SWOG are modified from the competencies set forth by the National Institutes of Health (*https://hr.nih.gov/working-nih/competencies/competencies-dictionary/professional-integrity*) and include:

- Maintenance of confidentiality as it relates to sensitive information.
- Guarding of sensitive or high-risk information appropriately.
- Demonstrating sensitivity to surroundings and acting accordingly in conversations.
- Demonstrating behaviors that are consistent with standards for professional and ethical conduct. This includes in deliberations related to and for the Group, with all members of the Group and those outside of it.
- Maintaining professional composure at all times.
- Refraining from behavior that fosters the appearance of conflict of interest.
- Applying rules and regulations in a consistent, non-biased manner.

Proceedings involving concerns related to Professional Integrity

Any member may bring an issue forward to the Vice Chair of Membership and Accrual either directly or through notification of leadership within SWOG. The Vice Chair will provide a confidential and non-judgmental space to voice concerns, ensuring that all involved parties have a chance to be heard. In contrast to the policy set forth above for research misconduct, the work covered in this section is intentionally informal and meant to provide members of the Group with a neutral and impartial resource who will advocate for fairness and equality.

If initial conversations require follow-up, an action plan may be required. Examples of what this may entail include:

- Clarifying SWOG policies and identifying helpful resources

- Advocating through objective action, including alerting leadership (e.g. Group Chairs, Executive officers, or Committee Chairs)
- Arranging and then mediating meeting of involved parties with the objective of reaching resolution
- Working to identify and resolve systemic issues that led to the issue in the first place

Follow-up of issues related to Professional Integrity:

Members will be provided with a confidential summary of what was discussed, including recommendations of an action plan, if indicated.

The Vice Chair of Membership and Accrual will be responsible for monitoring the situation to ensure that a resolution was reached.
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