DEPARTMENT: Clinical Operations Group	**POLICY DESCRIPTION**: Research Misconduct in PHS Grants
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EFFECTIVE DATE: November 1, 2016	**REFERENCE NUMBER:** COG.FED.002 (formerly CSG.FED.002)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy relates to the Institution's (defined herein and includes all HCA-affiliated hospitals, ambulatory surgery centers, physician practices, and all other HCA-affiliated facilities) obligations to assure the recognition, review and reporting of research misconduct with any federally-funded clinical research project. This policy does not pertain to non-federally funded research. This policy is specific to Public Health Service (PHS) funded research. Research with other funding sources may require or adopt a similar structure but there will be no reporting requirements to PHS.

PURPOSE: The Institution has the responsibility to follow all procedures set forth in this policy to ensure compliance with federal regulations 42 CFR parts 50 and 93 when conducting PHS funded studies.

DEFINITIONS:

These definitions are rooted in 2CFR200 and 42CFR93 and are applicable to this policy.

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 an Institutional or HHS official.

Charge letter means the written notice, as well as any amendments to the notice, that are sent to the respondent stating the findings of research misconduct and any HHS administrative actions. If the charge letter includes a debarment or suspension action, it may be issued jointly by the ORI and the debarring official.

Complainant means a person who in good faith makes an allegation of research misconduct.

Contract means an acquisition instrument awarded under the HHS Federal Acquisition Regulation (FAR), 48 CFR Chapter 1, excluding any small purchases awarded pursuant to FAR Part 13.

Debarment means the Government wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contracts, and cooperative agreements under the HHS regulations at 45 CFR part 76 (nonprocurement) and 48 CFR subparts 9.4 and 309.4 (procurement).

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Funding component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, e.g., agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS.

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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 the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to 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 under this part. 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 of an investigation as set forth in this policy.

Institution means any individual or person that applies for or receives support directly from PHS for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. Institution

Institutional member or members means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an Institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and sub awardees, and their employees.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Notice means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee.

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

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

Public Health Service or PHS means the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency

for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.
PHS support means PHS funding, or applications or proposals therefor, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an Institutional official by a respondent in the course of the research misconduct proceeding.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.
Retaliation means an adverse action taken against a complainant, witness, or committee member by an Institution or one of its members in response to a good faith allegation of research misconduct or a good faith cooperation with a research misconduct proceeding.

Secretary or HHS means the Secretary of HHS or any other officer or employee of the HHS to whom the Secretary delegates authority.

POLICY:

SECTION I: Explanation of Research Misconduct

1. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
   a. Fabrication is making up data or results and recording or reporting them.

b. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
c. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
d. Research misconduct does not include honest error or differences of opinion.

2. A finding of research misconduct made under this policy 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 (as defined by this policy).

3. This policy applies only to research misconduct occurring within six years of the date HHS or an Institution receives an allegation of research misconduct. Exceptions to the six-year limitation:
   a. Subsequent use exception: The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.
   b. Health or safety of the public exception: If ORI or the Institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.
   c. ''Grandfather'' exception: if HHS or an Institution received the allegation of research misconduct before the effective date of this part.

SECTION II: Evidentiary Standards

The following evidentiary standards apply to findings made under this part:

1. An Institutional (or HHS) finding of research misconduct must be proved by a preponderance of the evidence (as defined by this policy).

2. The Institution (or HHS) has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide materials documenting the questioned research is evidence of research misconduct where the Institution (or HHS) establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

3. The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether the Institution (or HHS) has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.
4. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

SECTION III: Rule of interpretation

Any interpretation of this policy must further the protection of the health and safety of the public, the promotion of the integrity of research, and the conservation of public funds.

SECTION IV: Confidentiality

Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however, that:

a. The Institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings (also noting that HHS administrative hearings must be open to the public).
b. Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified.

SECTION V: Responsibilities for Compliance

This Institution must:

1. Respond to each allegation of research misconduct for which the Institution is responsible in a thorough, competent, objective and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses.

2. Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

3. Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other Institutional members.

4. Take all reasonable and practical steps to ensure the cooperation of respondents and other Institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence.

5. Cooperate with HHS during any research misconduct proceeding or compliance review.

6. Assist in administering and enforcing any HHS administrative actions imposed on its Institutional members.

7. Have an active assurance of compliance.

SECTION VI: Responsibility for Maintenance and Custody of Research Records and Evidence

The Institution must:

1. Either before or when the Institution notifies the respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that 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 or evidence that is discovered during the course of a research misconduct proceeding, and on or before the date on which the respondent is notified or the inquiry begins, except that 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; and

4. Maintain the research records and evidence as required by the “Retention and custody of the research misconduct proceeding record” section of this policy.

SECTION VII: Notice to Respondent and Custody of Research Records

At the time of or before beginning an inquiry, an Institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the Institution must make a good faith effort to notify them as well.

SECTION VIII: Inquiry Process

The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a full review of all the evidence related to the allegation.

Time for completion
The Institution must complete the inquiry within 60 calendar days of its initiation 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.

Notice of the results of the inquiry
The Institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy or reference to this policy. The Institution may notify the complainant who made the allegation whether the inquiry found that an investigation is warranted. The Institution may provide relevant portions of the report to the complainant for comment.

Reporting to ORI on the decision to initiate an investigation
Within 30 days of finding that an investigation is warranted, the Institution must provide ORI with the written finding by the responsible Institutional official and a copy of the inquiry report which includes the following information:
1. The name and position of the respondent;
2. A description of the allegations of research misconduct;
3. The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS 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.

The Institution must provide the following information to ORI on request:
1. The Institutional 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.

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Institutions must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the Institution decided not to conduct an investigation. The Institution must keep these records in a secure manner for at least 7 years after the termination of the inquiry, and upon request, provide them to ORI or other authorized HHS personnel. The Institution must notify ORI and other PHS agencies, as relevant, of any special circumstances that may exist.

SECTION IX: Institutional Investigation

Institutions conducting research misconduct investigations must:

1. Begin the investigation within 30 days after determining that an investigation is warranted.

2. Notify the ORI Director of the decision to begin an investigation on or before the date the investigation begins, and provide an inquiry report if the allegation falls within the description of research misconduct and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

3. The inquiry report needs to include the following:
   a. The name and position of the respondent;
   b. A description of the allegations of research misconduct;
   c. The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
   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.
   f. The Institution must also provide the following information to ORI on request:
      i. The Institutional policies and procedures under which the inquiry was conducted
      ii. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
      iii. The charges for the investigation to consider.

4. Notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins. The Institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation.

5. To the extent not already done so at the allegation or inquiry stages, take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that 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.

6. Whenever possible, the Institution must take custody of the records:
   a. Before or at the time the Institution notifies the respondent; and
   b. Whenever additional items become known or relevant to the investigation.

7. 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.

8. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation.

9. 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.

10. 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.

Investigation Time Limits

An Institution must complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with the “Opportunity to comment on the Investigation report” section of this policy, and sending the final report to ORI. If unable to complete the investigation in 120 days, the Institution must ask ORI for an extension in writing. If ORI grants an extension, it may direct the Institution to file periodic progress reports.

Opportunity To Comment On The Investigation Report

The Institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of (or supervised access to) the evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within 30 days of the date on which the respondent received the draft investigation report.

The Institution may provide the complainant a copy of the draft investigation report or relevant portions of that report. The comments of the complainant, if any, must be submitted within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.

Institutional Investigation Report

The final Institutional investigation report must be in writing and include:

1. Allegations-- Describe the nature of the allegations of research misconduct.
2. PHS support-- Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
3. Institutional charge-- Describe the specific allegations of research misconduct for consideration in the investigation.
4. Policies and procedures-- If not already provided to ORI with the inquiry report, include the Institutional policies and procedures under which the investigation was conducted.
5. Research records and evidence-- Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
6. 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:
   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 the specific PHS support
   d. Identify whether any publications need correction or retraction;
   e. Identify the person(s) responsible for the misconduct; and
   f. List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.
7. Comments-- Include and consider any comments made by the respondent and complainant on the draft investigation report.
8. 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.

SECTION X: Institutional Appeals

If there is an appeal by the respondent that could result in a reversal or modification of the findings of research misconduct in the investigation report, the Institution must complete any such appeal within 120 days of its filing. Appeals from personnel or similar 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 ORI for an extension in writing and provide an explanation for the request, ORI may grant requests for extension for good cause. If ORI grants an extension, it may direct the Institution to file periodic progress reports.

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SECTION XI: Notice to ORI of Institutional Findings and Actions

The Institution must give ORI the following:

1. Investigation Report-- Include a copy of the report, all attachments, and any appeals.

2. Final Institutional action-- State whether the Institution found research misconduct, and if so, who committed the misconduct.

3. Findings-- State whether the Institution accepts the investigation's findings.

4. Institutional administrative actions-- Describe any pending or completed administrative actions against the respondent.

SECTION XII: Completing the Research Misconduct Process

ORI expects the Institution to carry inquiries and investigations through to completion and to pursue diligently all significant issues. An Institution must notify ORI in advance if the Institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except (i) the closing of a case at the inquiry stage on the basis that an investigation is not warranted or (ii) a finding of no misconduct at the investigation stage, which must be reported to ORI not in advance but under those required timeframes.

The Institution shall additionally cooperate with ORI should they conduct an oversight review of the Institution's handling of the case and take appropriate action including:

1. Approving or conditionally approving closure of the case;

2. Directing the Institution to complete its process;

3. Referring the matter for further investigation by HHS; or,

4. Taking a compliance action.

SECTION XIII: Retention and Custody of the Research Misconduct Proceeding Records

The term "records of research misconduct proceedings" includes:

1. The records that the Institution secures for the proceeding pursuant to the custody of the research requirements set forth in this policy, except to the extent the Institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;

2. The documentation of the determination of irrelevant or duplicate records;

3. The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate

4. The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview; and

5. The complete record of any Institutional appeal.

Unless custody has been transferred to HHS, or ORI has advised the Institution in writing that it no longer needs to retain the records, an Institution must maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding.

SECTION XIV: Notifying ORI of Special Circumstances

At any time during a research misconduct proceeding, an Institution must notify ORI immediately if it 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 reasonable indication of possible violations of civil or criminal law.

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

6. The research Institution believes the research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved.
7. The research community or public should be informed

REFERENCES:

1. 42 CFR 93
2. ATTACHMENT I: General Process Flowchart

ATTACHMENT I: General Process Flowchart