 <small>THE SCIENCE OF IMPROVING LIVES</small>	Category: Policies 06 Human Subject Research Title: POL 06014		
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POL 06014 Research Integrity and Misconduct

PURPOSE:

To address research misconduct, which is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research studies.

SCOPE:

This policy applies to all individuals at FHI 360 engaged in research activities (regardless of the sponsor, vendor, payer, client, or type of research) and is intended to carry out FHI 360's responsibilities under Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This policy applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

A person who at the time of the alleged research misconduct was employed by, was an agent of, or was affiliated by contract or agreement with FHI 360; and


- Biomedical or behavioral research, research training (or activities related to that research or research training) and the dissemination of research information; or
- Applications or proposals for PHS support for biomedical or behavioral research, research training (or activities related to that research or research training); or
- Research records produced in the course of PHS supported research, research training, or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

This statement of policy does not apply to potential research misconduct by an employee of a partner, vendor, or sub-contracting organization as long as that organization has its own research integrity and misconduct policy in compliance with 42 CFR Part 93.

This statement of policy does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date FHI 360 received the allegation.

DEFINITIONS:


1. *Allegation* A disclosure of possible research misconduct through any means of communication (written, oral, or other) to a person employed by, affiliated with, or acting on behalf of FHI 360 or a sponsor.
2. *Chief Science Officer (CSciO)* Executive officer who provides vision, strategic leadership, and direction to enhance the quality of science at FHI 360. At FHI 360, the CSciO is typically the designated Research Integrity Officer (RIO).

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3. *Clinical Regulatory and Compliance (CRC)* The FHI 360 department that provides regulatory, quality and compliance oversight and regulatory operations management for clinical trials globally. CRC can be designated by the FHI 360 CSciO as the responsible party for handling potential research misconduct investigations and auditing.
4. *Complainant* The individual(s) who originally makes, in good faith, an allegation of research misconduct, or the FHI 360 Executive who receives the allegation.
5. *Ethics and Compliance Hotline* A secure, trustworthy channel through which employees of FHI 360 and the FHI Family of Companies can report any suspected incident of theft, fraud, misconduct, harassment, sexual exploitation and abuse, or other unacceptable behavior directly to the Office of Compliance and Internal Audit. Concerns can be reported anonymously on-line or by phone, or confidentially by email.
6. *Evidence* 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.
7. *Fabrication* Making up data or results and recording or reporting them.
8. *Falsification* The manipulation of research materials, equipment, or processes, or changing or omitting data or results, such that the research is not accurately represented in the research record.
9. *Good faith* As applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony based on the information known to the complainant or witness at the time. Good faith as applied to a committee member means cooperating with the purpose of helping an institution meet its responsibilities under 42 CFR Part 93. A committee member does not act in good faith if his/her/their 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.
10. *Inquiry* Preliminary information-gathering and preliminary fact-finding.
11. *Investigation* The formal development and examination of a factual 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.
12. *Office of Compliance and Internal Audit (OCIA)* The FHI 360 organizational area that provides independent, objective assurance and consulting services to improve FHI 360 operations. OCIA conducts investigations related to code of ethics violations, fraud, abuse or misuse of project or corporate funds, and manages the Ethics and Compliance Hotline. OCIA is the designated financial auditor when applicable and needed regarding clinical research.
13. *Office of International* The organizational area responsible for ethical and regulatory oversight of research involving human subjects at FHI 360. One of OIRE's main

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| <i>Research Ethics (OIRE)</i> | responsibilities is to support the functions of the Protection of Human Subjects Committee (PHSC). |
| 14. <i>Office of Research Integrity (ORI)</i> | The federal office to which the US Department of Health and Human Services (HHS) Secretary has delegated responsibility for addressing research integrity and misconduct issues related to US Public Health Services (US PHS) supported activities. |
| 15. <i>Plagiarism</i> | The appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. |
| 16. <i>Preponderance of the evidence</i> | Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not. |
| 17. <i>Protection of Human Subjects Committee (PHSC)</i> | FHI 360’s institutional review board responsible for approving research activities conducted by FHI 360 and protecting the rights and welfare of human research subjects. |
| 18. <i>Records of research misconduct proceedings</i> | (1) The research records and evidence secured for the research misconduct proceeding, except to the extent that FHI 360 Executives determine - and document that those records are not relevant to the proceeding or that the records duplicate other records that have been 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 the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal within the institution from the finding of research misconduct. |
| 19. <i>Research Integrity Officer (RIO)</i> | The FHI 360 officer responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) the other responsibilities described in this policy. |
| 20. <i>Research misconduct</i> | Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. |
| 21. <i>Research misconduct proceeding</i> | Any actions related to investigation of an alleged research misconduct, including but not limited to, allegation assessments, inquiries, investigations, sponsor or oversight reviews, hearings, and administrative appeals. |
| 22. <i>Research record</i> | Record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records |

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(both physical and electronic), progress reports, abstracts, oral presentations, internal reports, journal articles, and any documents and materials provided to the sponsoring agency or an FHI 360 official by a respondent during the research misconduct proceeding.

23. *Respondent* A person who is the subject of an allegation of research misconduct or who is the subject of a research misconduct proceeding.
24. *Retaliation* An adverse action taken against a complainant, witness, or committee member by persons employed by, affiliated with, or acting on behalf of FHI 360 in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.

POLICY:

1. FHI 360 is responsible for providing an environment that promotes integrity, objectivity, and the highest ethical and quality standards in all research areas, including the biomedical, behavioral, and social science fields. As such, FHI 360 encourages open discussions of research integrity.
 - 1.1. The Chief Science Officer (CSciO) is the FHI 360 officer appointed to the role of Research Integrity Officer (RIO) and also has responsibilities for assuring that FHI 360 fosters a research environment that promotes the responsible conduct of research and discourages research misconduct. In the event the CSciO has a conflict of interest in a specific matter, the FHI 360 General Counsel will appoint an alternate RIO. Hereinafter ‘RIO’ means the CSciO in the role of RIO or any appointed alternate RIO.
 - 1.2. FHI 360 is responsible for dealing with allegations or evidence of misconduct effectively and expeditiously to ensure that the standards of integrity are upheld. However, if misconduct occurs under a vendor, partner, or subrecipient organization, the vendor, partner, or subrecipient organization may have the responsibility of investigating and addressing the misconduct, depending on the specifications of the contract or agreement with FHI 360. If there is any question as to whether to apply FHI 360’s policy related to research misconduct or that of a partner, vendor, or subrecipient, please refer to contract specifications.
 - 1.3. FHI 360 will attempt to distinguish misconduct from honest error or a difference of opinion. In applying this process, FHI 360 will endeavor to:
 - Ensure that the process to resolve allegations or evidence of misconduct does not compromise the science itself, unless unavoidable, to resolve the allegation.
 - Provide leadership in the pursuit and resolution of all allegations or evidence of misconduct.
 - Develop procedures which preserve the highest degree of confidentiality compatible with an effective and efficient response.
 - Treat all parties with justice and fairness and be sensitive to their reputations.
 - Maintain the integrity of the process by avoiding real or apparent conflict of interest or bias.
 - Keep the procedures as expeditious as possible to achieve a resolution in a timely manner.

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- Discharge its responsibilities, both internally to all involved individuals, and externally to the public, the sponsors of the research, and the scientific community to the extent that it is appropriate and allowable.
- Document fully both the initial allegation(s) and the process of resolution of any allegations or evidence of misconduct.
- Involve OCIA when the research misconduct involves financial irregularities; and inform OIRE when needed to address any potential ethical issues related to human subject research.

2. *Promotion of Research Integrity*

- 2.1. FHI 360 will make available a copy of this policy to all applicable staff for review and acknowledgement, prior to their engagement in research activities. Applicable staff must also retrain on the policy every three years.
- 2.2. FHI 360 will provide a copy of this policy to prospective consultants, investigators, and other individuals involved in the research activities conducted by FHI 360 when requested. When applicable, a copy of this policy will be attached to agreements or contracts.
- 2.3. FHI 360 will provide as much help as necessary to assure that all researchers understand the standards for research integrity expected in methods of practice while working for or in association with FHI 360.

3. *Responsibility to Report Misconduct*

- 3.1. All persons employed by, or affiliated with, or acting on behalf of FHI 360 have an obligation to report observed, suspected, or apparent research misconduct to the RIO.
- 3.2. Research misconduct should be reported to the responsible vendor, partner, and subrecipient organization if that organization's misconduct policy supersedes FHI 360's, as described elsewhere in this document.
- 3.3. An allegation can be made in either oral or written format to the RIO and/or the FHI 360 Ethics and Compliance Hotline. The complainant may choose to be anonymous. Concerns reported to the Ethics and Compliance Hotline can be done anonymously on-line or by phone, or confidentially by email.
- 3.4. An allegation containing the following information is most useful:
 - Name of the individual making the allegation;
 - Name of the individual who is alleged to have committed the scientific misconduct;
 - Name(s) of any witness(es) (if known);
 - Description of the misconduct;
 - Approximate date and time when the misconduct occurred;
 - Supporting documentation; and
 - Study title and number (if known).
- 3.5. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices, officials, or manager/supervisor with responsibility for resolving the problem.
- 3.6. At any time, an individual may have confidential discussions and consultations about concerns of possible misconduct with the appropriate FHI 360 managers/supervisors,

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Executives, Directors, or other Administrators, and will be counseled about appropriate procedures for reporting allegations.

3.7. Any individual making an allegation not in good faith may be subject to disciplinary action.

4. *Cooperation with Research Misconduct Proceedings*

4.1. FHI 360 staff and collaborators will cooperate with the RIO and other FHI 360 personnel in the review of allegations and the conduct of inquiries and investigations. FHI 360 staff, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other appointed FHI 360 personnel.

5. *Confidentiality*

5.1. Any persons employed by, or acting on behalf of FHI 360 who receive information about an allegation of research misconduct shall: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding.

5.2. All individuals involved in the allegation (complainant, respondent, RIO, and others involved in the inquiry or investigation of the allegation) should maintain confidentiality of the proceedings and the individuals involved.

5.3. The RIO should use written confidentiality agreements or other mechanisms to ensure that the respondent does not make any further disclosure of identifying information.

5.4. Nothing in this policy is intended or should be construed as prohibiting or discouraging employees from making good faith reports of research misconduct.


6. *Protecting Complainants, Witnesses, Respondents and Committee Members*

6.1. FHI 360 will protect to the maximum extent possible the position and reputation of any individual making or reporting a good faith allegation.

6.2. No individual may retaliate in any way against complainants, witnesses, or committee members. Any individual should immediately report any alleged or apparent retaliation against complainants, witnesses, or committee members to the RIO or Ethics and Compliance Hotline, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

6.3. During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and standard operating procedures of FHI 360.

6.4. As requested, and as appropriate, the RIO and other individuals involved in the allegation shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

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7. *Assessment*

- 7.1. The RIO shall assess an allegation of research misconduct within seven calendar days or less to determine if:
 - The allegation meets the definition of research misconduct and FHI 360 is the responsible party for investigating the allegation;
 - It is sufficiently credible and specific so that potential evidence of research misconduct may be identified; and
 - The allegation involves US PHS supported research, application for research support, or research records specified in 42 CFR §93.102.
- 7.2. The RIO will determine if the criteria for inquiry are met, and if so, the inquiry process will be initiated. [If not, see 3.4.]
- 7.3. The RIO will determine what third-party notification may be required.
- 7.4. The RIO will contact the sponsor of the research, and the Director of the HHS ORI if the research is under the US PHS, as needed, to determine the reporting requirements or guidelines pertinent to inquiry and investigation of allegations of misconduct.
- 7.5. The RIO will inform the respondent(s) that a formal complaint has been made and that an inquiry will be conducted. The RIO will also inform the respondent(s) in writing of the process and procedures to be followed in the inquiry and, if appropriate, the investigation. (It is recommended that all correspondence with the respondent(s) during this process be in writing by certified mail, or international mail, with return receipt requested, or other traceable method). Individuals affected by the inquiry will be notified by the RIO at the same time and informed that the alleged incident will probably be publicly reported.
- 7.6. The RIO shall, on or before the date on which the respondent(s) is notified of the inquiry proceedings, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding.

8. *Interim Administrative Actions and Notifications of Special Circumstances*

- 8.1. Throughout the initial research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to study participants, public health, federal funds and equipment, or the integrity of the US PHS supported research process. In the event of such a threat, the RIO will, in consultation and collaboration with other applicable FHI 360 personnel and, if applicable, the sponsor and/or, Department of Health and Human Services (HHS) Office of Research Integrity (ORI), take appropriate interim action to protect against any such threat. Interim action may include:
 - Reporting to OCIA, CRC, IRB, PHSC, OIRE and HHS ORI;
 - Additional monitoring of the research process and the handling of federal funds and equipment;
 - Auditing of the research process;
 - Retraining of personnel involved;
 - Adding additional quality checks or processes to study procedures and data collection;
 - Reassignment of personnel, or of the responsibility for the handling of federal funds and equipment;
 - Additional review of research data and results; or
 - Delaying publication.

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- 8.2. The RIO shall, at any time during a research misconduct proceeding, notify the ORI or the vendor, partner, or subrecipient organization immediately if he/she has reason to believe that any of the following conditions exist:
- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
 - Federally funded resources or interests are threatened;
 - Research activities should be suspended;
 - Reasonable indication of possible violations of civil or criminal law;
 - Federal action is required to protect the interests of those involved in the research misconduct proceeding;
 - 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; or
 - The research community or public should be informed.

9. *Establishment of a Committee*

- 9.1. If it is determined that an inquiry is warranted, the RIO will appoint an ad hoc committee, naming a chair and a recorder, to conduct the inquiry and, if necessary, investigation into the complaint.
- 9.2. The committee will consist of at least three members, (including the chair) and the recorder, selected for their appropriate scientific expertise, objectivity, and sound knowledge base. Committee members may either be FHI 360 staff or from outside the organization. No one with real or apparent bias or conflict of interest may serve on the committee. If at any time during the process it is determined that a member does have bias, conflict of interest, or has breached confidentiality, the committee chair will inform the RIO, who will determine the course of action.
- The committee chair will be responsible for calling meetings, arranging interviews with the complainant(s) and/or the respondent(s), maintaining documentation of the committee's activities and other necessary activities. The committee chair may request assistance as needed from CRC and/or OCIA in the investigation.
 - An assistant will be appointed to provide any support necessary for the activities of the committee, including meeting logistics, correspondence, and documentation of activities.
 - Each committee member will provide a written confidentiality agreement to not disclose the activities of the committee or the identity of the parties, including the complainant(s) and the respondent(s).
 - If at any time during the process a committee member cannot continue to serve, the RIO will name a replacement.

10. *Inquiry*

- 10.1. The committee will assemble and review all factual information regarding the complaint to determine if further investigation is warranted. This will include, but not be limited to, information provided by the complainant(s) and the respondent(s) in writing or in interviews.

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- 10.2. The committee shall review the pertinent reporting requirements and guidelines of the sponsor of the research. The committee may also wish to review current research integrity practices, including those discussed in recent journals or publications from professional organizations or agencies.
- 10.3. The committee will determine if the complaint is justified or if it is frivolous, mistaken or otherwise unjustified, and will make a report of the inquiry to the RIO and the respondent(s). The inquiry report must reflect applicable regulatory requirements.
- 10.4. The committee shall take no longer than 60 calendar days to complete the inquiry and provide an inquiry report. If the review and report take longer than 60 calendar days, the committee shall notify the RIO in writing of the reasons for the delay and recommendations for informing other parties of the delay (i.e., complainant(s) and/or respondent(s)).
- 10.5. The RIO will review the inquiry report and determine if further investigation is warranted.
 - The RIO will inform the committee, the complainant(s), and the respondent(s) in writing of the decision, including if further investigation is required.
 - If the complaint was made in good faith, but the charges are unsupported, then FHI 360 will complete documentation of the inquiry and inform the respondent(s) and the sponsor, as appropriate, in writing that the complaint was unsupported in fact and that FHI 360 will take no further action regarding this complaint.
 - If the complaint can be demonstrated not to have been made in good faith, and the charges were unsupported, then the Chief Operations Officer (COO) in consultation with the RIO and Chief Human Resource Officer (CHRO) will decide if disciplinary action against the complainant(s) should be applied.
 - If the charges are not confirmed during inquiry and/or investigation, FHI 360 will undertake diligent efforts, as appropriate, to restore the reputations of the persons alleged to have engaged in misconduct.
- 10.6. If an investigation is warranted, and the research is funded by the US PHS, the RIO shall, in accordance with 42 CFR §93.309(a), report to the HHS ORI the decision to initiate the investigation on or before the date the investigation begins. Additionally, the RIO shall inform the sponsor of the research (if required), applicable journals, and any other associated agencies or entities in writing, including the name(s) of the respondent(s), the general nature of the charges, and the grant or contract number(s) involved. Prior to initiation of the investigation, the sponsor's recommendations for action will be considered by FHI 360, as appropriate.
- 10.7. If FHI 360 plans to terminate an inquiry and/or investigation for any reason without completing all relevant requirements, a report of such planned termination, including a description of the reasons for such termination, shall be made and is subject to approval by the FHI 360 General Counsel. If the research is funded by the PHS, a copy of the termination report will be forwarded to HHS ORI.

11. *Temporary Sanctions*

- 11.1. If an investigation is undertaken, FHI 360 may suspend any current research activities by the respondent(s) until the investigation is complete. If the respondent(s) is/are an employee(s) of FHI 360, then appropriate actions will be taken consistent with FHI 360's employee discipline policy.

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11.2. FHI 360 will take appropriate interim administrative actions to protect federal or other donor funds and ensure that the purposes of the federal or other donor financial assistance are being carried out. These administrative actions will be documented by FHI 360 and will become part of the inquiry and/or investigation record.

12. *Investigation*

12.1. The committee shall commence the investigation no later than 30 calendar days after the RIO has informed the committee, the complainant(s), and respondent(s) that an investigation will be made.

12.2. The committee will assemble and review all factual information regarding the complaint, including that from the inquiry and any additional information which has been provided by the respondent(s) in response to the report of the inquiry. Further interviews of the complainant(s), respondent(s) and other individuals may occur. Written summaries of these interviews should be prepared and reviewed by the interviewed party for comment. The committee will pursue any and all issues which are known at the initiation of the investigation, or which arise during the process.

- The committee will inform the respondent(s) and complainant(s) in writing, through the RIO, if there are additional instances of possible research misconduct that would justify broadening the scope of the investigation beyond the initial allegation.
- FHI 360 will promptly advise the ORI or any sponsor or donor of any developments during the course of the investigation which disclose facts that may affect current or potential HHS funding for individual(s) under investigation, or that the PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest. The investigation will proceed to completion. If any respondent confesses to the charges and/or offers to leave FHI 360, or discontinue association with FHI 360, the committee will document these facts, but will continue the investigation. The committee may also recommend to the RIO that the sponsor of the research be informed if this occurs.
- The committee will determine if the charges are substantiated by the information reviewed. The standard to be used is the preponderance of the evidence supporting the charges. The committee may find that: (1) the evidence supports the charge of misconduct; (2) the evidence does not support the charge of misconduct; or (3) the evidence does not support the charge of misconduct but supports serious errors in the research.
- The committee will prepare a written report of the investigation. The investigation report must reflect applicable regulatory requirements.
- The committee will provide opportunity for the respondent(s) to review the report prior to its finalization. The respondent comments, if any, must be submitted within 30 days of the date on which the respondent received the draft report. If the respondent(s) provides comments to the report, the committee shall consider the comments prior to finalization of the report. The committee will submit the final report to the RIO who will determine in writing: (1) whether FHI 360 accepts the investigation report, its findings, and the recommended actions; and (2) the appropriate actions in response to the accepted findings of research misconduct. If this determination varies from the

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findings of the committee, the RIO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the RIO may return the report to the investigation committee with a request for further fact-finding or analysis.


- 12.3. When a final decision on the case has been reached, the RIO will notify the respondent(s), the sponsor of the research (if required), the Chief Executive Officer (CEO), and the HHS ORI (if the sponsor is US PHS). The RIO will also determine whether to notify applicable journals, and any other entities originally informed of the investigation, as well as to the executive of the appropriate department of the outcome of the case. Note: At the option of the RIO, pertinent findings may also be provided to the complainant(s). A copy of the final report will be provided to the respondent(s).
- 12.4. The committee should take no longer than 120 calendar days to complete this portion of the procedure. If the review and report will take longer than 120 days, the committee shall notify the RIO in writing the reasons for the delay (i.e., complainant(s) or respondent(s)). If the research is funded by US PHS, in accordance with 42 CFR §93.311(b), the RIO shall then request an extension of the 120-day investigative period from the ORI and US PHS, including an explanation for the delay, the interim report of the committee, and an estimate for the date of completion of the investigation. If the research is not funded by US PHS, then the sponsor's reporting requirements should be followed.

13. Sanctions

- 13.1. The inquiry committee shall recommend to the RIO, COO and CHRO that FHI 360 take actions consistent and commensurate with the nature of the findings of the investigation.
- 13.2. The COO in consultation with the RIO and CHRO, shall decide what sanctions, if any, will be placed on the respondent(s) in the event the respondent(s) is/are employee(s) or contractor(s) of FHI 360.
- 13.3. If the ORI also investigates the charge(s), then other sanctions may also be imposed by that organization.
- 13.4. If the research was being conducted under an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE), and if the investigation finds that the research investigator did not comply with the signed agreement to conduct the study in compliance with the applicable protocol and US FDA regulations, then the committee shall verify that the Director of FHI 360's CRC department is aware and involved in the research misconduct investigation and resolution if not already involved or designated a role in the process.
- 13.5. If no fraud or misconduct is found, no actions will be taken against the complainant(s), if the allegations have been made in good faith. If it can be demonstrated that the complaint was not made in good faith and the charges were unsupported, then the RIO will decide if disciplinary action against the complainant(s) should be applied.

14. Appeals

- 14.1. The respondent(s) may appeal the committee's recommendation. The appeal should be restricted to the body of evidence already presented. The grounds for appeal should be limited to failure to follow appropriate procedures in the investigation, or arbitrary and

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capricious decision-making. The appeal must be filed in writing within 15 working days of receiving the committee’s final report and should be submitted to the CEO.

14.2. After reviewing the appeal, the CEO, in consultation with the RIO, will make a final decision in the matter.

15. *Additional Reporting*

15.1. To maintain FHI 360’s listing in the ORI Assurance Database and remain in compliance with 42 CFR §93.301(a), FHI 360 will renew its misconduct assurance annually by submitting a report to the ORI on the allegations, inquiries and investigations handled in the previous year and other matters related to the regulation. This report is processed by the Director of CRC with review by the CEO and legal counsel.

16. *Documentation*

16.1. FHI 360 shall maintain full documentation of the proceedings, including:

- The written summary of the allegation (complaint);
- All documents distributed to the committee;
- All correspondence to and from the complainant(s) and respondent(s);
- Transcripts of all interviews;
- Committee meeting minutes; and
- All reports.

16.2. The ORI or other authorized HHS personnel will be given access to the records, as appropriate, upon request.

16.3. All documentation shall be maintained confidentially within FHI 360’s Electronic Document Management System (EDMS).

16.4. All documentation of the inquiry and/or investigation, whether the inquiry and/or investigation is determined to be warranted or not, will be maintained for seven years, and access will be provided to HHS personnel as needed and upon request.

RELATED DOCUMENTS:

1. Policies


- POL 03011: Employee Discipline
- POL 03029: Harassment-Free Workplace Environment

2. Standard Operating Procedures

- N/A

3. Appendices

- N/A

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REFERENCES:

1. 42 CFR 93: *Public Health Service Policies on Research Misconduct*. June 2005.
2. 42 CFR 93.105(b): Time Limitations
3. 45 CFR 75.113 Mandatory Disclosure
4. 45 CFR 689 Research Misconduct
5. 45 CFR 935 Research and Development Contracting
6. *Sample Policy and Procedures for Responding to Allegations of Research Misconduct*
[\(<http://ori.hhs.gov/sites/default/files/SamplePolicyandProcedures-5-07.pdf>\)](http://ori.hhs.gov/sites/default/files/SamplePolicyandProcedures-5-07.pdf) [Retrieved Jan 2012]

POLICY REVISION HISTORY:

POL#	Date Reviewed (DD MMM YYYY)	Summary of Changes
029	12/89	New
029	3/93	Changes reflected in 029A
029A	4/97	Changes reflected in 029B
029B	2/98	Changes reflected in 029C
029C	6/03	Changes reflected in 029D
029D	12/04	Number change to 029.04
029.04	4/05	Changes reflected in 029.05
029.05	4/05	Changes reflected in 029.06
029.06	7/07	Changes reflected in 029.07
029.07	16 Jan 2012	Assigned responsibilities to CSciO. Multiple editorial changes.
POL 06014	Dec 2012	New POL number for migration to EDMS
POL 06014	Mar 2014	Added language to clearly identify the CSciO as Research Integrity Officer with incorporated responsible conduct of research program responsibilities.
POL 06014	Nov 2016	Changed title to include misconduct. Changed RIO responsibilities from COO to CSciO or designee, added role of designee, added information about verifying if details of responsibility for research misconduct are documented in the contract, added details about when other outside parties responsible for investigating potential research misconduct, added responsibilities for CRC and other departments.
POL 06014	24 MAY 2019	Biennial review, delete requirement to collect subcontractor research misconduct policy, clarify appeal escalation to CEO.
POL 06014	10 MAR 2021	Minor administrative change, definition of point 8.
POL 06014	12 JUL 2021	Updates for clarity and process flow. Include information on Ethics and Compliance Hotline.

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REVISION HISTORY

Version 03 Effective on 11-Jul-2019

TI

Version 04 Effective on 27-Aug-2021

Updates for clarity and process flow. Include information on Ethics and Compliance Hotline. Collaboration completed with Kathy, Stroker, Tim Mastro, and Emily Namey

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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I am the author of this document.
Signed 8:06:30 PM UTC 21-Jul-2021

Required Workflow Steps for this Category

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Signed 2:51:08 PM UTC 26-Jul-2021

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