POLICIES AND PROCEDURES FOR ADDRESSING ALLEGATIONS OF RESEARCH MISCONDUCT

IN PHS-SUPPORTED BIOMEDICAL AND BEHAVIORAL RESEARCH

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI

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Compliant with PHS Policies on Research Misconduct (42 CFR Part 93, 2024)

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1. General Policies and Principles

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI is committed to upholding the highest standards of scientific rigor in research. This institution is committed to fostering an environment that promotes research integrity and the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

All institutional members are expected to conduct research with honesty, rigor, and transparency. Each institutional member is responsible for contributing to an organizational culture that establishes, maintains, and promotes research integrity and the responsible conduct of research.

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI strives to reduce the risk of research misconduct, support all good-faith efforts to report suspected misconduct, promptly and thoroughly address all allegations of research misconduct, and seek to rectify the scientific record and/or restore researchers' reputations, as appropriate.

Research misconduct is contrary to the interests of Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI, the health and safety of the public, the integrity of research, and the conservation of public funds. Both the institution and its institutional members have an affirmative duty to protect those funds from misuse by ensuring the integrity of all research conducted on behalf of Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI.

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI is responsible for ensuring that these policies and procedures for addressing allegations of research misconduct meet the requirements of the PHS Policies on Research Misconduct (42 CFR Part 93, "the PHS regulation"). The institution will establish and maintain these policies and procedures, inform all institutional members about these policies and procedures, and make these policies and procedures publicly available. Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI is committed to following these policies and procedures when responding to allegations of research misconduct.

These policies and procedures complement the existing ethical framework of the Consejo Nacional de Investigaciones Científicas y Técnicas (CONICET), to which Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI is affiliated. In particular, these policies operate in conjunction with CONICET Resolution 540/06 on ethical principles for researchers (https://www.conicet.gov.ar/wp-content/uploads/OCR-RD-20060322-0540.pdf) and the oversight functions of the CONICET Comité de Ética established by Resolution D-1806/2004 (https://www.conicet.gov.ar/wp-content/uploads/Resoluci%C3%B3n-D-1806-2004-Creaci%C3%B3n-Comit%C3%A9-de-Etica.pdf). In the event of any conflict between these PHS-specific policies and CONICET's internal regulations, the institution will seek to resolve such conflict in consultation with both ORI and CONICET, with the goal of full compliance with 42 CFR Part 93.

2. Scope and Applicability

These policies and procedures apply to allegations of research misconduct involving:

1. Applications or proposals for PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training.

2. PHS-supported biomedical or behavioral research.
3. PHS-supported biomedical or behavioral research training programs.
4. PHS-supported activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information.
5. Research records produced during PHS-supported research, research training, or activities related to that research or research training.
6. Research proposed, performed, reviewed, or reported, as well as any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in an awarded grant, contract, cooperative agreement, subaward, or other form of PHS support.

These policies and procedures apply only to research misconduct occurring within six years of the date HHS or the institution receives an allegation of research misconduct, subject to the following exceptions:

- The six-year time limitation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of, republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent ("subsequent use exception").
- The six-year time limitation also does not apply if ORI or the institution, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

These policies and procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling research misconduct involving non-PHS-supported research. In case of any conflict between this document and 42 CFR Part 93, the PHS regulation will prevail.

3. Definitions

The following definitions apply to these policies and procedures:

Accepted practices of the relevant research community. Those practices established by 42 CFR Part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards.

Administrative record. Comprises the institutional record; any information provided by the respondent to ORI; any additional information provided to ORI while the case is pending before ORI; and any analysis or additional information generated or obtained by ORI.

Allegation. A disclosure of possible research misconduct through any means of communication and brought directly to the attention of an institutional or HHS official.

Assessment. A consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS-supported biomedical or

behavioral research; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.

Complainant. An individual who in good faith makes an allegation of research misconduct.

Evidence. Anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.

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

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

Good faith. (a) As applied to a complainant or witness: having a reasonable belief in the truth of one's allegation or testimony, based on the information known at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowledge of or reckless disregard for information that would negate the allegation or testimony. (b) As applied to an institutional or committee member: cooperating with the research misconduct proceeding by impartially carrying out assigned duties for the purpose of helping the institution meet its responsibilities under 42 CFR Part 93.

Inquiry. Preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR §§ 93.307-93.309.

Institution. Any person who applies for or receives PHS support 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.

Institutional Deciding Official (IDO). The institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as both the Institutional Deciding Official and the Research Integrity Officer.

Institutional member. An individual who is employed by, is an agent of, or is affiliated by contract or agreement with an institution, including officials, faculty, researchers, postdoctoral fellows, students, volunteers, and consultants.

Institutional record. Comprises the records compiled or generated during the research misconduct proceeding, including assessment documentation, inquiry and investigation reports, transcripts of interviews, information provided by the respondent, decisions by the Institutional Deciding Official, and the complete record of any institutional appeal, together with a single index of all research records and evidence.

Intentionally. To act with the aim of carrying out the act.

Investigation. The formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of 42 CFR §§ 93.310-93.317.

Knowingly. To act with awareness of the act.

Plagiarism. The appropriation of another person's ideas, processes, results, or words, without giving appropriate credit. Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. Plagiarism does not include self-plagiarism or authorship or credit disputes.

Preponderance of the evidence. Proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

PHS support. PHS funding, or applications or proposals for PHS funding, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, provided through PHS grants, cooperative agreements, contracts, subawards, or salary or other payments under such instruments.

Recklessly. To propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

Research Integrity Officer (RIO). The institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93.

Research misconduct. 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.

Research misconduct proceeding. Any actions related to alleged research misconduct taken under 42 CFR Part 93, including allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals.

Research record. The record of data or results that embody the facts resulting from scientific inquiry, in physical or electronic form, including research proposals, raw data, processed data, laboratory records, progress reports, manuscripts, abstracts, theses, and journal articles.

Respondent. The individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation. 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 good faith cooperation with a research misconduct proceeding.

Small institution. An institution that may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by 42 CFR Part 93 without actual or apparent conflicts of interest.

4. Roles, Rights, and Responsibilities

4.1 Institution

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI will: limit disclosure of the identity of respondents, complainants, and witnesses while conducting research misconduct proceedings to those who need to know; inform all institutional members about these policies and procedures; and make these policies and procedures publicly available on its website. The institution will respond to each allegation of research misconduct for which it is responsible under 42 CFR Part 93 in a thorough, competent, objective, and fair manner.

The institution will sequester and preserve research records relevant to the allegation at the time of or before notifying the respondent of the allegation. The institution will cooperate fully with ORI during any oversight review and will provide all research records and evidence under its control, custody, or possession as necessary to develop a complete record.

The institution will protect complainants, witnesses, and committee members from retaliation and will take reasonable and practical efforts to restore the reputations of persons wrongly accused of research misconduct.

4.2 Research Integrity Officer (RIO)

The Research Integrity Officer (RIO) of Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI is responsible for administering the institution's policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93. The RIO will:

- Receive allegations of research misconduct involving PHS-funded research;
- Assess allegations and determine whether they fall within the definition of research misconduct and warrant an inquiry;
- Sequester and preserve relevant research records promptly upon receiving a credible allegation;
- Notify the respondent of the allegation and the initiation of an inquiry;
- Notify ORI of any inquiry that proceeds to investigation, and of any finding of research misconduct;
- Oversee the inquiry and investigation processes and ensure they are conducted in a timely and thorough manner;
- Maintain the confidentiality of all parties to the extent required by law and institutional policy;
- Coordinate with ORI or appropriate HHS office as needed;
- Submit the Annual Report on Possible Research Misconduct (Form PHS-6349) to ORI by April 30 of each year.

Given the size and structure of Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI as a foreign research institution, the RIO is: Dr. Mariana Maccioni, Chair. Contact: cibicigrants@quimicas.unc.edu.ar | Phone: +54 351 535 3850.

4.3 Institutional Deciding Official (IDO) and CONICET Oversight Framework

Given the size and structure of Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI as a foreign research institution, the Institutional Deciding Official may not be permanently designated in advance. In the event that an inquiry proceeds to a finding of research misconduct, Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI will designate an appropriate senior official — who is distinct from the RIO — to serve as the Institutional Deciding Official for that proceeding. This official will make final determinations on allegations of research misconduct and any resulting institutional actions, and will have no prior involvement in the inquiry or investigation.

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI operates within the institutional and regulatory framework of the Consejo Nacional de Investigaciones Científicas y Técnicas (CONICET), Argentina's national research council. CONICET has established the following normative instruments governing research ethics and misconduct that are applicable to all CONICET-affiliated researchers and institutes, including those at CIBICI:

- CONICET Resolution 540/06 — Principios éticos para el comportamiento del Investigador científico y tecnológico: establishes the ethical principles governing the conduct of CONICET researchers, including honesty, transparency, and integrity in the generation, reporting, and dissemination of research results. Available at: https://www.conicet.gov.ar/wp-content/uploads/OCR-RD-20060322-0540.pdf
- CONICET Resolution D-1806/2004 — created the CONICET Comité de Ética (Ethics Committee), an interdisciplinary body responsible for issuing advisory opinions (dictámenes) on cases involving alleged violations of research ethics standards by

CONICET members. Available at: https://www.conicet.gov.ar/wp-content/uploads/Resoluci%C3%B3n-D-1806-2004-Creaci%C3%B3n-Comit%C3%A9-de-Etica.pdf

- CONICET Reglamento del Sistema de Evaluación (as modified by Resolution 2019-1870-APN-DIRCONICET) — provides that committee members and evaluators shall observe the provisions of Resolution 540/06, and establishes procedures for referral to the Comité de Ética when ethical concerns arise. Available at: https://www.conicet.gov.ar/wp-content/uploads/Reglamento-Modificado-por-RESOL-2019-1870-APN-DIRCONICET-1.pdf

In cases where an inquiry proceeds to investigation and a finding of research misconduct is made, the CONICET Comité de Ética serves as the primary institutional body for review and determination, and may refer matters to the CONICET Dirección de Sumarios for formal disciplinary proceedings under Argentine administrative law. In such cases, the head of the CONICET Comité de Ética, or a senior CONICET official designated for the purpose, will serve as the Institutional Deciding Official for purposes of compliance with 42 CFR Part 93, ensuring that this role is filled by an individual distinct from the RIO.

If neither Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI nor CONICET can identify an official free of conflict of interest to serve as Institutional Deciding Official, the institution will consult with ORI to identify an appropriate approach consistent with 42 CFR Part 93.

4.4 Complainants

A complainant is an individual who in good faith makes an allegation of research misconduct. Complainants have the responsibility to make allegations in good faith, to maintain confidentiality to the extent possible, and to cooperate with any resulting inquiry or investigation. The institution will protect complainants from retaliation for good faith allegations and will maintain the confidentiality of the complainant's identity to the extent permitted by law.

4.5 Respondents

A respondent is the individual against whom an allegation of research misconduct is directed. Respondents have the right to be notified of allegations and proceedings; to be informed of all evidence considered by the inquiry or investigation committee; to comment on the inquiry and investigation reports; to have their identity protected to the extent possible prior to a finding; and to appeal findings of research misconduct. Respondents are expected to cooperate with the research misconduct proceeding and to preserve all relevant research records.

4.6 Committee Members and Witnesses

Committee members are expected to conduct their responsibilities objectively and impartially, to maintain confidentiality, and to disclose and recuse themselves from proceedings in which they have a conflict of interest. Witnesses are expected to cooperate with inquiries and investigations and to provide truthful, complete testimony. The institution will protect committee members and witnesses from retaliation for their good faith participation in research misconduct proceedings.

5. Procedures for Addressing Allegations of Research Misconduct

5.1 Assessment

Upon receiving an allegation of research misconduct, the RIO will promptly conduct an assessment to determine whether: (a) the allegation falls within the definition of research misconduct; (b) the alleged misconduct involves PHS-supported research; and (c) the allegation is sufficiently credible and specific to identify potential evidence of research misconduct. The assessment involves only the review of readily accessible information.

The RIO will document the assessment, including the date the allegation was received, the nature of the allegation, the assessment findings, and the decision on whether to proceed to inquiry. This documentation will be retained as part of the institutional record.

If the RIO determines that the allegation does not warrant an inquiry, the RIO will document this determination and the reasons for it. If the allegation appears to involve an honest error or difference of opinion, the RIO may close the matter without an inquiry, with appropriate documentation.

5.2 Inquiry

If the assessment indicates that an inquiry is warranted, the RIO will initiate an inquiry within a reasonable time after completing the assessment. The RIO will notify the respondent of the allegation and the initiation of the inquiry before or at the time of inquiry initiation, unless notification would compromise the sequestration of evidence.

Prior to or at the time of notifying the respondent, the RIO will take all reasonable and practical steps to obtain and sequester all research records and evidence needed to conduct the research misconduct proceeding.

The inquiry will be completed within 90 days of initiation, including preparation of the inquiry report. If the inquiry cannot be completed within 90 days, the RIO will document the reasons and, if the extension is likely to exceed 30 days, will notify ORI.

The inquiry committee will prepare a written inquiry report that includes: the name and position of the respondent; a description of the allegations; the PHS support involved; the basis for recommending that the alleged actions fall within or outside the definition of research misconduct; and whether an investigation is warranted.

The respondent will be provided with a copy of the inquiry report and will have an opportunity to comment before it is finalized. The RIO will notify ORI of the outcome of the inquiry if an investigation is recommended.

5.3 Investigation

If the inquiry concludes that an investigation is warranted, the RIO will initiate the investigation within 30 days of completing the inquiry. The RIO will notify ORI of the investigation within 30 days of its initiation.

The investigation will be completed within 180 days of initiation, including preparation of the investigation report and the opportunity for the respondent to comment. If the investigation cannot be completed within 180 days, the RIO will document the reasons and will notify ORI, providing an estimated date of completion.

The investigation committee will: conduct a thorough examination of all relevant evidence; interview the respondent, complainant, and key witnesses; and prepare a written investigation report that includes: a description of the allegations; the PHS support involved; a description of the institutional procedures used; findings of fact; a determination of whether research misconduct occurred; if so, who was responsible and the type and extent of the misconduct; and recommended institutional actions.

Each interview conducted during the investigation will be transcribed or recorded. The respondent will be provided with a copy of the draft investigation report and relevant evidence, and will have at least 30 days to submit comments.

The Institutional Deciding Official will review the investigation report and the respondent's comments and will make a final determination of whether research misconduct occurred and what institutional actions, if any, are warranted. The respondent will be notified of the final determination and any institutional actions.

The institution will transmit the institutional record to ORI after the Institutional Deciding Official has made a final determination of research misconduct at the conclusion of the investigation and any institutional appeals.

5.4 Other Procedures and Special Circumstances

Joint proceedings: When an allegation of research misconduct involves individuals from more than one institution, the RIO will coordinate with the other institution(s) to designate a lead institution and to ensure appropriate handling of the proceeding consistent with 42 CFR Part 93.

Interim protective actions: At any point in the research misconduct proceeding, the institution may take interim actions to protect the health and safety of the public, to protect PHS funds and equipment, or to prevent further potential research misconduct. Such actions may include additional supervision, removal from certain research projects, or other measures, and will be taken in a manner that minimizes the impact on the respondent consistent with the need to protect against harm.

Cooperation with ORI: The institution will cooperate fully and continue to cooperate with ORI during its oversight review and with any subsequent HHS proceedings, including providing all research records and evidence under the institution's control as necessary to develop a complete institutional record.

Notification of funding agencies: The institution will notify ORI and the relevant PHS funding agency of any finding of research misconduct, and will take appropriate action with respect to any affected publications, grants, or cooperative agreements.

5.5 Confidentiality

To the extent possible and consistent with applicable law, the institution will limit disclosure of the identities of respondents, complainants, and witnesses to those who need to know in order to conduct the research misconduct proceeding. This limitation on disclosure no longer applies once the institution has made a final determination of research misconduct findings.

5.6 Protection Against Retaliation

The institution will not retaliate against any complainant, witness, or committee member for making a good faith allegation of research misconduct or for cooperating in good faith with a research misconduct proceeding. Any institutional member who believes they have been subjected to retaliation may report this to the RIO or to ORI.

5.7 Records Retention

The institution will retain and provide access to all relevant research records, evidence, and documentation of research misconduct proceedings for a minimum of seven years after completion of the institutional proceeding or the completion of any HHS proceeding, whichever is later. Records will be maintained in a secure manner that preserves their integrity and confidentiality.

6. Annual Reporting and Assurance Maintenance

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI will submit the Annual Report on Possible Research Misconduct (Form PHS-6349) to ORI between January 1 and April 30 of each year, via ORI's secure online submission platform at https://ori.hhs.gov/arprm/. This report will include information on any allegations received during the reporting year and the status or outcome of any proceedings.

The institution will keep these policies and procedures up to date and will revise them as necessary to comply with changes in the PHS regulation. Updated policies and procedures will be submitted to ORI as required.

These policies and procedures are publicly available on the institution's website and are communicated to all institutional members engaged in PHS-supported research.

7. Certification and Signatures

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI certifies that it has established and will maintain the policies and procedures described in this document for responding to allegations of research misconduct in compliance with the PHS Policies on Research Misconduct (42 CFR Part 93, 2024). The institution will comply with its policies and procedures when responding to allegations of research misconduct and will comply with all provisions of the regulation.

Name of Institution:

Consejo Nacional de Investigaciones Científicas y Técnicas - CIBICI

Address: Haya de la Torre y Medina Allende, Ciudad Universitaria, Córdoba, Argentina

Phone: +54 351 535 3850

Email: cibicigrants@quimicas.unc.edu.ar

Institutional Certifying Official's Name:

Title:

Signature:

Date:

Institutional Certifying Official:

Research Integrity Officer:

For questions regarding this document, contact ORI_Assurance@hhs.gov or call (240) 453-8400.