



UNIVERSITÀ
DI TRENTO

RESEARCH MISCONDUCT POLICY FOR PUBLIC HEALTH SERVICE (PHS) FUNDING (IN ACCORDANCE WITH 42 CFR PART 93)



**RESEARCH MISCONDUCT POLICY FOR PUBLIC HEALTH SERVICE (PHS) FUNDING (IN
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PREAMBLE

The University of Trento (from now on UniTrento) is committed to fostering a research environment that promotes research integrity and discourages research misconduct.

UniTrento is committed to ensuring that all allegations of research misconduct are assessed and investigated thoroughly, fairly, in a timely manner, and with care and sensitivity. This includes taking 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.

UniTrento undertakes to take all reasonable and practical steps to protect the positions and reputations of good-faith complainants, witnesses, and committee members, and to protect these individuals from retaliation by respondents and/or other institutional members. Furthermore, it provides confidentiality to all respondents, complainants, and witnesses in a research misconduct proceeding, as well as to research subjects identifiable from research records or other evidence.

UniTrento pledges to take all reasonable and practical steps to cooperate fully with the U.S. Department of Health and Human Services (HHS) during any research misconduct proceedings or compliance reviews.

UniTrento undertakes to inform its members about this policy and the procedures for addressing allegations of research misconduct related to research activities funded by agencies under the Public Health Service of the U.S. Department of Health and Human Services (hereinafter USPHS), including any components or agencies such as the National Institutes of Health (NIH), while also making this policy publicly available via its website.

This policy constitutes an annex to the Guidelines of the University of Trento for Research Integrity and shall be interpreted and applied in a manner consistent with those Guidelines and the other related policies adopted thereunder.



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PART I – INTRODUCTION

Art. 1 – Purpose and Applicability

This policy defines the operational procedures on dealing with and reporting allegations of possible research misconduct related to research activities funded by agencies under the Public Health Service of the U.S. Department of Health and Human Services (from now on USPHS), including any components or agency such as the National Institutes of Health (NIH).

These procedures are an integration of the Code of Ethics of the University of Trento, consistent with [U.S. Federal regulation, 42 CFR Part 93](#), and apply to all personnel involved in proposing, conducting and reviewing research activities funded by USPHS: professors and researchers affiliated with UniTrento on permanent and fixed-term contracts or who carry out research activities there, even on a temporary basis; research fellows, doctoral students, and holders of positions and collaborations of any kind, including occasional ones; students; technical and administrative staff involved in research activities.

These procedures shall be interpreted and applied in full conformity with U.S. Federal regulation, 42 CFR Part 93, as amended from time to time.

All definitions, standards of proof, evidentiary requirements, time limits, reporting obligations, and procedural safeguards set forth in 42 CFR Part 93 are hereby incorporated by reference and shall govern all proceedings under this Policy.

In the event of any conflict between this Policy and 42 CFR Part 93, the Federal Regulation shall prevail.

Art. 2 – Definitions

Research misconduct: the definition of research misconduct adopted in this document is the one set forth in the U.S. Federal regulation, 42 CFR Part 93 and refers to actions such as:

- *Fabrication:* making up data or results and recording or reporting them;



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- *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;
- *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, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

These actions are considered research misconduct when they occur during the proposal, conduct, or review of research, or when reporting research findings. Research misconduct does not encompass honest mistakes or differences in opinion. 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.

Allegation: any communication received by the Rector of University of Trento concerning potential research misconduct.

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

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

Code of Ethics: The Code of Ethics of the University of Trento.



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The Commission: Academic Senate Commission for the Implementation of the Code of Ethics; its composition and role are indicated in the Code of Ethics (Articles 17 and 18).

The President: The President of the Academic Senate Commission for the Implementation of the Code of Ethics; his/her role is indicated in the Code of Ethics (Articles 17 and 18).

UniTrento: University of Trento.

USPHS: Public Health Service of the U.S. Department of Health and Human Services, including any components or agency such as the National Institutes of Health (NIH).

ORI: U.S. Office of Research Integrity

Art. 3 – Institutional Roles

In order to ensure full compliance with U.S. Federal Regulation, 42 CFR Part 93 and to safeguard the integrity of PHS-supported research activities, UniTrento designates specific institutional officials responsible for the administration, certification, and final determination of research misconduct proceedings.

These roles are assigned consistently with both U.S. Federal Regulation and the Code of Ethics, ensuring clarity of responsibilities, independence of functions, and avoidance of conflicts of interest.

The Research Integrity Officer (RIO), the Institutional Deciding Official (IDO), and the Institutional Certifying Official (ICO) are identified as follows:

- **Research Integrity Officer (RIO):** UniTrento has designated the President of the Academic Senate Commission for the Implementation of the Code of Ethics as Research Integrity Officer (RIO), responsible for administering the University's written policies and procedures for addressing allegations of research misconduct in compliance with U.S. Federal Regulation, 42 CFR Part 93. The President is supported in his/her activities by the Commission and coordinates with the Research



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Ethics and Integrity Office for matters related to the implementation and procedural requirements of the research misconduct proceedings.

- **Institutional Deciding Official (IDO):** UniTrento has designated the Rector as Institutional Deciding Official, responsible for issuing the final institutional determination regarding findings of research misconduct pursuant to U.S. Federal Regulation, 42 CFR Part 93.
- **Institutional Certifying Official (ICO):** UniTrento has designated the Rector as Institutional Certifying Official, responsible for developing procedures to enable institutional members or others to make an allegation of research misconduct involving PHS funds; assuring on behalf of the institution that UniTrento has a written policy and procedures for addressing allegations of research misconduct, in compliance with U.S. Federal Regulation, 42 CFR Part 93; receiving allegations of research misconduct involving PHS funds and notifying the U.S. Office of Research Integrity (ORI) when an allegation of research misconduct involving PHS funds is received; certifying the content of the institution's annual report and ensuring the report is submitted to ORI.

PART II – OPERATIONAL PROCEDURES

Art. 4 – Operational Procedures

The operational procedures described in the following supplement the procedures contained in Article 18 of the Code of Ethics for dealing with and reporting possible research misconduct when USPHS funds are involved.

Art. 5 – Submission of an allegation of research misconduct

UniTrento has designated its Rector as *Institutional Certifying Official* for receiving any allegation concerning potential research misconduct and for developing procedures (with the support of the competent offices of UniTrento) for use by research staff or others who wish to report potential research misconduct involving USPHS funds.



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Any university member who believes that the conditions and prerequisites are met can report to the Rector an incident they believe violates the Code of Ethics. This includes allegations for research misconduct actions under this policy.

The report must be in writing, non-anonymous, signed by the university member, and must specify the type of research misconduct actions object of the allegation. The allegation should be submitted promptly and within a reasonable period relative to the occurrence of the contested facts. As provided by Article 18 of the Code of Ethics, the Rector will inform the President of the Academic Senate Commission for the Implementation of the Code of Ethics of any possible received allegation. The Rector forwards the report to the President within 30 days from the receipt of the complete report. If the alleged misconduct involves the Rector or the members of the Academic Senate, the report should be sent directly to the President of the Commission. If the alleged misconduct involves the members of the Commission, the investigative process is carried out by the Academic Senate. In this case, the Rector sends the report directly to the Academic Senate.

The Rector will also inform of any allegation of potential research misconduct involving USPHS funds the Research Ethics and Integrity Office. The office will notify ORI when an allegation of potential research misconduct involving USPHS funds is received.

The Research Ethics and Integrity Office and the Commission will then work with ORI or other appropriate offices of the U.S. Department of Health and Human Services (HHS) to implement the process for responding to the research misconduct allegation that is consistent with U.S. Federal regulation, 42 CFR Part 93.

The procedure described shall be carried out in a manner that ensures confidentiality for the person reporting the facts and all other parties involved, guaranteeing the right of defense and of the adversarial principle. No access to the report or other acts of the procedure or any form of communication of the same to entities other than the Commission and ORI, which are bound to secrecy about its contents, is permitted until the procedure has been completed.



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Art. 6 – Institutional Assessment

The President promptly assesses the allegation to determine whether:

- a. it falls within the definition of research misconduct under this policy;
- b. it appears to involve research activities funded by USPHS; and
- c. is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

Art. 7 – Institutional Inquiry

If the allegation meets the three assessment criteria, the President immediately communicates the initiation of the procedure to the complainant and to the respondent or respondents involved.

In order to determine whether an allegation warrants an inquiry, the President interviews the involved respondent, possibly in contradiction with the complainant. The respondent parties must always be invited to participate in the procedure to defend themselves and must be able to view the report, make submissions, and identify witnesses within a reasonable time, not less than 10 days. The President may summon the complainant, the respondent, and, at their request or on their own initiative, members of the university community involved in the events under investigation.

The President may decide to close the case if it is believed that there are no grounds for proceeding. The President communicates the closure to the complainant and the respondent and informs the Rector. When the report is closed and in the event the report is found to be persecutory or defamatory, the President will initiate proceedings against the complainant for violating the Code of Ethics.

Art. 8 – Institutional Investigation

If the facts suggest a possible violation of the Code of Ethics and of this policy and the President does not consider immediate closure under the previous point, he or she will convene the Commission to carry out the necessary investigation.

The Research Ethics and Integrity Office will notify ORI within 30 days of determining that an investigation is warranted, providing a copy of the inquiry report.



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The Commission will investigate the potential research misconduct according to the standard procedure defined in the Article 18 of the Code of Ethics.

The involved parties must always be invited to intervene in the procedure to defend themselves, be allowed to view the report, make deductions, and identify witnesses with an adequate time period, not less than 10 days. The Commission may summon the complainant, the respondent, or, at their request or on its own initiative, members of the university community involved in the events under investigation or otherwise present.

Following its investigation, the Commission may:

- a. Archive the report if it is believed that there are no grounds for proceeding: The President will promptly communicate the closure to the respondent and the complainant.
- b. Forward the documentation to the Rector, along with a report of the findings of the Commission's investigation. If research misconduct is identified, the relevant documents shall also be transmitted to the Academic Senate.

The President suspends the proceedings and forwards the documentation, along with a detailed report, to the Board of Discipline or the Office for Disciplinary Proceedings, depending on whether the author of the alleged violation is a member of the teaching and research staff or a member of the administrative, technical, or managerial staff, if the investigative work reveals that the reported behavior may also constitute also a disciplinary violation. The suspension is promptly communicated to the involved party and the reporter by the President, via the Secretariat.

The President will seek the opinion of the Ethics Committee, the Committee for Equal Opportunities (Comitato Unico di Garanzia - CUG), or the Confidential Counsellor if the reported behaviors concern issues relating to these bodies. Once these bodies have completed their work, they will forward the documentation, along with a report, to the Commission, which will continue the procedure.

If the documentation is forwarded to the Academic Senate, the Senate adopts the final decision and may take any necessary disciplinary measure within 60 days of receiving the documents from the Rector or the



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disciplinary authority. The sanction is promptly communicated to the involved party and the reporter. All communications are sent via email using the official UniTrento institutional accounts.

Art. 9 – Transmittal of the institutional record to ORI

The Research Ethics and Integrity Office of UniTrento will submit to ORI appropriate reports (in English), previously validated by the Commission and its President, that describe the process followed in conducting the investigation, the evidence on which the conclusions of the investigation are based, and if a finding of research misconduct is made, the administrative actions that are taken against the respondent as also defined in the Code of Ethics (Article 18).

Art. 10 – Transmittal of the annual report of possible research misconduct to ORI

The Research Ethics and Integrity Office of UniTrento submits the “Annual Report on Possible Research Misconduct” to ORI by April 30th of each year, following validation by the Commission and its President.