

Policy on Research Misconduct

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1 Purpose

Nothing is more damaging to the quality of clinical research performed by the EORTC and its Groups than fraudulent data. Inclusion of such data in any aspect of the study conduct and analyses may invalidate scientific conclusions. Invalid conclusions may lead to the establishment of inappropriate medical practice standards and subject large groups of patients to inappropriate therapy and/or increased risk.

Unreliable data violates the trust between the patient and the healthcare team and erodes the relationships required for the conduct of clinical studies and could bias the public's perception of medical investigations.

2 Scope

This policy applies to

- any record, document or data, in any format, associated with clinical research and any person involved in such research.
- EORTC HQ, EORTC network and anyone involved in the conduct of clinical research activities (e.g., investigational sites, providers and partners).

3 Policy statement

Data integrity, reliability, scientific and methodological rigor are parts of the EORTC many deliverables to patients. Knowledge development and practice changing require the highest standards for data quality before research programmes deliverable are communicated. This sustains the core values of EORTC.

EORTC commits to conduct the investigation to research misconduct in a confidential and independent manner without any conflict of interests and with patient safety and data integrity in mind.

4 Changes since last version

Process step	Changes since last version
All	<ul style="list-style-type: none"> • Supersedes policy on 'Research Misconduct' (POL003 v 2.2) • Update in policy name and removal of technical wording • Alignment of document with the reference documents

5 Policy

5.1 Information

The EORTC encourages individuals who have been asked to falsify data or who believe they have knowledge that others are falsifying data to inform ('informant') their primary contact at EORTC Headquarters as soon as possible preferably by e-mail with Quality@eortc.org in copy.

5.2 Investigation

The EORTC performs an independent and thorough assessment of the credibility of such allegation of research misconduct while preserving the confidentiality to protect those who are involved. Anyone accused of research misconduct ('respondent') is presumed innocent until proven otherwise.

If the EORTC deems the outcome of the assessment to be credible based on the available information, the EORTC conducts a more detailed investigation to determine the validity of the allegation. The investigations are fair, comprehensive, and conducted expediently, without compromising accuracy, objectivity, or thoroughness.

The investigation includes but is not limited to examination of all research records and evidence, and hearing of concerned parties involved (i.e., respondent, informant and any other person with possible information regarding any relevant aspects of the investigation).

The investigation should clearly distinguish between erroneous data that stem from accidental error (e.g., negligence) and intentional error due to the complexity of clinical research.

The person accused of research misconduct are given full details of the allegation(s) and are allowed a fair process for responding to allegations and presenting evidence.

While awaiting the outcome of the investigation, EORTC might take appropriate actions including but not limited to:

- immediate suspension of accrual by the responsible institution,
- delay of the publication of research results,
- closer supervision of one or more researchers, and/or
- notifying relevant legal and regulatory authorities.

5.3 Conclusion

If the investigation shows sufficient evidence of research misconduct, EORTC shall take appropriate follow up actions towards the falsified data and respondent which are endorsed by the EORTC board. These actions should be proportionate to the severity of the violation and include but are not limited to:

- reporting to relevant legal and regulatory authorities,
- prompt correction or retraction of publication,
- loss of authorship,
- suspension of collaboration,
- removal of the responsible person from the project, and/or
- special monitoring or triggered audit.

EORTC shall take restorative actions when the respondents are exonerated of an allegation of misconduct.

6 Definitions

- **Research misconduct:** fabrication, falsification, fraud, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.
 - **Fabrication** is making up data or results and recording them as if they were real.
 - **Falsification** is manipulating research materials, equipment, images, or processes, or changing, omitting, or suppressing data or results without justification.
 - **Plagiarism** is using other people's work or ideas without giving proper credit to the original source.

7 References

- ERC Scientific Misconduct Strategy, 5 October 2012
- ALLEA (2023) The European Code of Conduct for Research Integrity – Revised Edition 2023. Berlin. DOI 10.26356/ECO – section 3. Violation of Research Integrity

8 Signature

This document will be electronically signed.

The signatories acknowledge that electronic signature is legally binding and equivalent to a handwritten signature.

<p>Author</p> <p>Denis Lacombe</p> <p>Chief executive officer</p>	<p>Signed by:</p> <p><i>Denis Lacombe</i></p> <p> Signer Name: Denis Lacombe Signing Reason: I approve this document Signing Time: 09 June 2026 11:39:59 CEST 457339F472784605806FBD4D54FBD7A4</p>
<p>Approved & authorized by</p> <p>Denis Lacombe</p> <p>Chief executive officer <i>on behalf of the Board</i></p>	