

Research Misconduct

POL003

Version 2.1

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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 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 health care team and erodes the relationships required for the conduct of clinical trials and could bias the public's perception of medical investigations.

2 DEFINITIONS

- ◆ **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.
 - ◆ Fabrication is making up data or results and then recording or reporting these.
 - ◆ 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.
 - ◆ Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- ◆ **Allegation:** any written or oral statement of possible misconduct.
- ◆ **Informant:** a person who in good faith makes an allegation of research misconduct. Once the informant has made an allegation of research misconduct, that person does not participate in the proceeding other than as a witness.
- ◆ **Respondent:** a person who is alleged of research misconduct.

3 ALLEGATION OF RESEARCH MISCONDUCT

Individuals who have been asked to falsify data or who believe they have knowledge that others are falsifying data must inform the Head of the EORTC Quality Assurance and Control Unit (QA&C) at EORTC Headquarters as soon as possible preferably by e-mail qualityassurance@eortc.be

In case of formal notification, the Head of QA&C completes a detailed summary of the notification as provided by the informant.

If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact QA&C to discuss the suspected misconduct informally.

4 REVIEW OF THE ALLEGATION

The Head of QA&C informs the EORTC Directors and implements an independent and thorough review of any allegation of research misconduct and simultaneously takes whatever actions are reasonable and proper to preserve the confidentiality of the informant and, until misconduct is proven, to protect the reputation of those accused in discussion with the EORTC Directors.

The QA&C, together with the EORTC Directors, determines whether the allegation meets the definition of research misconduct and reviews whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

A Short Report documenting the review of the allegation is prepared. It contains the following information:

- ◆ the name and position of the respondent(s);
- ◆ a description of the allegation and the applicable study(ies);
- ◆ Type of partnership (e.g. collaboration with US Group); the basis for recommending or not recommending an investigation.

If reasonable grounds for suspicion of research misconduct are found, further investigation is warranted.

The respondent is informed about the allegation of research misconduct and may already be asked to provide research records. The respondent may comment on the allegation.

The Head of QA&C, along with the EORTC Directors, report the allegation and the further investigation to the EORTC Quality Assurance Committee (QAC).

Depending on the parties involved in the study, other organizations might be informed (e.g. the Office of Research Integrity (ORI) for studies which have received support from U.S. Public Health Service (PHS)) that an investigation of research misconduct will be started.

Meanwhile, other actions might be required. These could include the immediate suspension of accrual by the responsible institution, delay of the publication of research results, closer supervision of one or more researchers.

5 INVESTIGATION OF RESEARCH MISCONDUCT

The EORTC QA&C, together with EORTC QAC, develop and implement a plan to investigate the allegation.

The investigation related to the review of the allegation starts within 30 days of the release of the Short Report and should take no longer than 120 days.

The investigation should be thorough, sufficiently documented, and include examination of all research records and evidence relevant to reaching a decision on the merits of the allegation. Oral and/or written communications will be held with the respondent (s), the informant, and any other person who could have information regarding any relevant aspects of the investigation. All significant issues and information relevant to the investigation will be pursued.

In the investigation report, the performance of the respondent is described, i.e., adherence to protocol, quality of data, and other submitted materials. A distinction should be made between erroneous data that results from careless mistakes or omissions and data which is intentionally erroneous, or untrue.

It is acknowledged that in any process as complex as clinical research occasional errors of many sorts may occur. These may include typographical errors, miscalculations of numeric data, omissions of tests, doses, or procedures, delays of treatments, etc.

Falsification of information should be distinguished from inaccuracies arising from sources. When incorrect information is systematically and/or intentionally provided, this might imply intent to deceive.

Occasional divergence of opinion among investigators is to be expected in any clinical trial, and data arising from such divergences should be distinguished from those that are systematic attempts to deceive.

If sufficient evidence is found 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, this will be considered as research misconduct.

When necessary, the EORTC QA&C, the EORTC QAC and the EORTC Board will render judgment as to whether a given problem represents research misconduct and take appropriate actions as defined elsewhere in these policies.

An Investigation Report is prepared by the EORTC QA&C, which contains the following information:

- ◆ the nature of the allegations of research misconduct;
- ◆ the support provided to the study;
- ◆ the specific allegations of research misconduct considered in the investigation;
- ◆ reference to the procedures and policies under which the investigation was conducted;
- ◆ overview of the research records and the evidence reviewed with mention whether they have been taken into custody or not;
- ◆ for each allegation or research misconduct:
 - ◆ provide a finding as to whether research misconduct did or did not occur;
 - ◆ identify whether it involved falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
 - ◆ summarize the facts and analysis that support the conclusion;
 - ◆ identify the specific support provided to the study;
 - ◆ identify any publications that need to be corrected or retracted;
 - ◆ identify the person(s) responsible for the misconduct;
 - ◆ identify other studies in which the respondent is involved

The respondent should have the opportunity to review and comment on the draft Investigation Report. These comments and feedback from the respondent should be included in the final Investigation Report.

The final Investigation Report is sent to all persons who have been informed about the investigation (e.g. EORTC Board, QAC, Group Chair, if applicable, ORI if applicable ...)

6 OUTCOME OF THE ALLEGATION

Following completion of the Investigation Report, appropriate actions are enforced by the EORTC Board.

If falsified data have been submitted to EORTC Headquarters, the data will be isolated from the other data in the database.

If the data have been used in analyses in preparation of an abstract, the abstract will be revised, if possible, based on a new analysis without the suspect data or a disclaimer will be offered during the presentation of the revised data. If such data have been used for preparation of a manuscript, the paper will be withdrawn until a

new analysis can be conducted. If the manuscript with the falsified data has been published, the journal will be asked to publish a retraction and a re-analysis will be performed at the earliest time possible.

It is understood that correction of published information derived from flawed data is of great importance to the public and the scientific community. The EORTC will issue such corrections to relevant journals within a period not to exceed three months from the time that falsified data are confirmed.

An allegation of research misconduct may result in immediate action to suspend patient registrations by a participant or a member institution.

Subsequently, possible action relevant to the institution will occur such as removal of the responsible person from the particular project, special monitoring of future collaboration, loss of trial authorship, etc.

7 REFERENCES

- ◆ <http://ori.hhs.gov/>

8 ABBREVIATIONS

ORI	Office of Research Integrity (US)
PHS	Public Health Service (US)
QAC	Quality Assurance Committee
QA&C	Quality Assurance and Control Unit of the EORTC Headquarters

9 DOCUMENT HISTORY

Version number	Brief description of change	Author	Effective date
1.0	Initial release	Ann Marinus	1998
1.1	Update of EORTC various committee and function names, addition of further explanations	Magali Klepper	02/09/2003
2.0	Complete revision of the process	Cindy Wyns	28/02/2011
2.1	Final report is sent to the Board, instead of Executive Committee, and decided action is endorsed by the Board. Administrative changes.	Christine de Balincourt	11/02/2014