

Scientific Misconduct

POL003

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(Always refer to the Intranet to check the validity of this document)

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Distribution

Trial participants, Data Center staff, Quality Assurance
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1. Introduction

In recent years there has been wide publicity concerning instances of clinical trial fraud and misconduct.

No event is more damaging to the reputation of clinical research performed by the EORTC and its Groups than the discovery of false or fraudulent data. Inclusion of such data in analyses may invalidate scientific conclusions. Invalid conclusions may lead to establishing inappropriate medical practice standards assigning large groups of patients to an inferior therapy.

Moreover the violation of the trust between the patient and the health care team by such an event erodes the relationships required for the conduct of clinical trials and poisons the public's perception of all medical investigations.

It is therefore necessary to standardize procedures in order to minimize these effects and if possible prevent them from occurring.

2. Definitions

Allegation: any written or oral statement or other indication of possible misconduct made to the EORTC

Good faith: honest belief that misconduct may have occurred

Scientific misconduct: fabrication (or construction of data and matching up of results), falsification (manipulation, change, or omission of data in order to represent results), plagiarism (appropriating someone else's work without credit) [Powledge, 1999], or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data

3. Scientific misconduct identified by the EORTC

EORTC data managers review all incoming case report forms containing a patient's medical data. If the data manager suspects for any reason that the data may have been falsified, the data managers will contact their coordinating physicians who will decide, in conjunction with the head of the EORTC Data Center Quality Assurance Unit (QAU), on the next step to be taken (see section 5).

The EORTC Data Center QAU periodically reviews the performance of the individual EORTC institutions. It furnishes a report on a systematic and regular basis to the EORTC Quality Assurance Committee (QAC) concerning their performance. The QAC, in turn, reports to the EORTC Board. The QAC bases its recommendations concerning an institution's performance on the findings of the QAU and on any additional sources of information it may choose to employ. The EORTC Board, or the Executive Committee thereof, may find that institutions are in good standing, place them on probation, or remove them from membership in the EORTC.

Evidence of any systematic or intentional attempt to submit false data of any sort to the EORTC will be dealt with in the most rapid and vigorous manner possible. In addition to the possibility of withdrawing EORTC membership from those affected and suspending accrual from the institution, the EORTC will assist appropriate governmental bodies in the prosecution of the individuals involved.

Through its Data Center, the QAU audit program, and other mechanisms, the EORTC will search for any evidence of the submission of false data.

The EORTC publicizes its policies concerning scientific misconduct during data management workshops, on its web site, and by other means.

4. Receipt of allegations of scientific 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 QAU at the EORTC Data Center as soon as possible via whatever means (phone, letter, fax, e-mail personal contact) is practical. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the Data Center QAU to discuss the suspected misconduct informally.

In case of formal notification, the head of the QAU will complete a detailed account of the notification. If this notification occurs by phone, the QAU head will ask the party making the call if a witness to the call is desired. The EORTC will implement a thorough investigation of any allegation of scientific misconduct while at the same time taking 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.

Although anonymous calls for the purpose of notification are discouraged since they may lead to less effective resolution of the matter, they will, nevertheless, be accepted. This notification does not supersede or replace any notification also required by the institution from which the report originates. EORTC members should ascertain the correct procedures for reporting such matters at their own institution.

5. Processing of allegations within the EORTC Data Center

If there are reasonable grounds for suspicion of scientific misconduct, the head of the QAU must immediately bring the matter to the attention of the Director of the EORTC Data Center, the Chairman of the Clinical Research Division, the chairman of the EORTC QAC and the chairman of the EORTC Group concerned. In instances when the notification is done by phone, one of the other members of the QAU or a coordinating physician should serve as a witness to the phone call.

When notification by the QAU is complete, the head of the QAU, along with the Director of the EORTC Data Center or the Coordinating Physician as a witness, will immediately inform the EORTC QAC to report the incident. Subsequent to this notification, other actions may be required. These may include the immediate suspension of accrual to protocols in the involved institution.

6. Investigation of the allegation

In concert with pertinent individuals, bodies or agencies, the EORTC Data Center QAU will develop and implement a plan to investigate the allegation. With data that has already been submitted, this investigation will usually consist of a thorough audit, to determine whether misconduct has been committed, by whom, and to what extent.

The terms to be used by various committees and officers in connection with the investigation of possible episodes of scientific misconduct have been deliberately chosen to remove any restriction or impediment to whatever action the EORTC QAC and the EORTC Executive Committee may eventually choose to take in a given case. The EORTC may take action against a member or an institution independently of whether or not the individual is found guilty in civil or criminal proceedings by others.

The terms used in the audit reports to define institutional performance are used to describe adherence to protocol as well as the quality of data and other submitted materials. In this policy we distinguish between erroneous data that results from careless mistakes and omissions and data which is systematically 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 mistakes, miscalculations of numeric data, omissions of tests, doses, or procedures, delays of treatments, etc. These events when encountered will be characterized by the terms used in the audit reports and may generate actions concerning the institution as specified elsewhere in auditing procedures (“Audit organization for EORTC institutions” (Ref.: WP5102)).

Falsification of information is to be distinguished from inaccuracies arising from sources in the

preceding paragraph. Examples of falsification would be an ineligible patient falsely made eligible, a non-responding patient said to have responded, an abnormal laboratory result made normal, omitted doses of treatment said to have been given, etc. When wrong information is provided systematically, an intent to deceive may be inferred.

Occasional divergence of opinion among investigators is to be expected in any clinical trial and data arising from such divergences are to be distinguished from those that are systematic attempts to deceive. When necessary, the EORTC Data Center QAU, the EORTC QAC and the EORTC Executive Committee will render judgment as to whether a given problem represents scientific misconduct and take appropriate actions as defined elsewhere in these policies.

7. Actions to be taken if allegation of scientific misconduct is proved

Notwithstanding procedures for revoking membership, halting institutional accrual and any functions in group structures or taking other action as defined in these policies or in the EORTC Constitution and Bylaws, the Director of the EORTC Data Center may take immediate action as defined here when allegations or proof of scientific misconduct occurs within the EORTC.

If false data have been submitted to the EORTC Data Center, it is segregated and dealt with according to the Data Center procedures for the handling of the data (“Data management and computerized data validation tools at the Data Center” (Ref.: WP1202)).

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 false data has been published, the journal will be asked to publish a retraction and a re-analysis at the earliest possible time.

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 3 months from the time that false data are discovered.

8. Actions against individuals

An allegation of scientific misconduct may result in immediate action on the part of the EORTC Data Center Director to suspend patient registrations by a participant or a member institution. Subsequently, possible action relevant to the institution will occur through usual committee processes, e.g. removal of the responsible person from the particular project, special monitoring of future collaboration, loss of trial authorship, etc.

Allegations of scientific misconduct by individuals may be brought by Data Center staff, the QAU, or others to the EORTC QAC for investigation. Those accused may be asked to appear before the QAC. In such matters, because of the possibility of injury to patients or public health, time is of the essence.

The QAC will set the schedule for the appearance and testimony of the accused. On the basis of the investigation, the Committee may either take no action or may make recommendations to the EORTC Executive Committee. Recommendations to the Executive Committee may include severing the membership of the accused, removing the accused from study chairmanship or authorship, censure, or any other action the QAC feels is appropriate.

The accused will be provided with the written recommendation of the QAC to the Executive Committee. At this time the accused may offer a rebuttal of the QAC recommendations, but may not offer evidence not previously considered by the QAC. The Executive Committee will act on the recommendation of the QAC, accepting it, rejecting it, or changing it as the Executive Committee deems appropriate.

9. Confidentiality

The action of the EORTC Executive Committee is final and will be a matter of record. It will be documented in the minutes of the Executive Committee and communicated to the relevant EORTC institution and EORTC Group. The deliberations of the Executive Committee, the QAC, the evidence and audits collected by the QAU, the Data Center and the EORTC Group, and the statements of the accused will all be held confidential by the EORTC. However, any and all evidence of misconduct will be shared with the National Cancer Institute (NCI) and/or other appropriate governmental bodies.

10. List of abbreviations

Abbreviation	Full name
NCI	National Cancer Institute
QAC	Quality Assurance Committee
QAU	Quality Assurance Unit

11. Appendices and references

Document title	Reference (file name)
Data management and computerized data validation tools at the data center	WP1202
Audit organization for EORTC institutions: practical guide	WP5102