PROFESSIONAL DEVELOPMENT

RESEARCH MISCONDUCT-I

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Definition

There are many definition s for research misconduct reflecting the complex and varied nature of the subject. Definitions vary from a simple sentence to a whole paragraphs.

For example the Joint Consensus Conference on Misconduct in Biomedical Research in 1999 defined research misconduct as "Behavior by a researcher, intentional or not, that falls short of good ethical and scientific standards". This definition, however, does not differentiate between honest and intended errors or actions in research. On the other, the definition of the Medical Research Council (MRC) in the United Kingdom is more extensive and makes clear that honest errors are not considered research misconduct.

The MRC defines research misconduct as follows "Research misconduct or fraud means fabrication, falsification, plagiarism, or deception in proposing, carrying out or reporting results of research and deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others. It does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct (including gross misconduct) unrelated to the research process."

Spectrum of research misconduct

There are several forms of research misconduct that span a wide spectrum ranging from the very serious to what some would consider minor research misconduct. In one of its reports (COPE 2000), the Committee for Publication Ethics (COPE), presents this wide spectrum of research misconduct as shown in Table1. However, plagiarism, data fabrication and data falsification are universally considered as serious research misconduct. Plagiarism involves taking and passing off the work of others as one's own (extensively covered in the previous two issues of the EJS). Data fabrication is the invention of data or information while data falsification is the alteration of data obtained from research.

Table 1. Spectrum of research misconduct.

Serious Research Misconduct
Fabrication
Falsification
Plagiarism
Failure to get ethical approval
Hiding missing data
Undeclared omission of outliers
Excluding data on side effects or adverse events
Human subject research without informed consent
Publication of post hoc analysis without declaring that they were post hoc
Gift authorship
Ghost authorship
Dual publication
Not disclosing conflict of interest
Failure to publish completed research
Not performing a literature review before starting a new research
Minor Research Misconduct

Diagnosis of research misconduct

Research misconduct can be identified during conduct of research or during the process of its publication or even after its appearance in reputable journals. A large proportion of research misconduct is identified through whistle-blowers. A whistle blower could be a colleague, research partner, research nurse, or even the research subject. The position of a whistle-blower is usually difficult and traumatic as he or she, in many situations, is met with little public gratitude or suspicion of acting from a point of professional jealousy.

The diagnosis of research misconduct during its progress should be done through a formal process of research monitoring which is an essential component of good research practice. It should be conducted by authorized individuals trained to do the job in collaboration with the concerned research ethics committees and sponsors of the research project. Research misconduct is usually spotted through research site visits, examination of returned clinical trial materials, examination of case report forms, patient diaries, and or laboratory note books. Examples of signs that research monitors sometimes take especially in clinical trials indicating the presence of some irregularity are (the list is not exhaustive):

1. Work done during holidays.
2. Bulk completion of records on the same day.
3. The use of the same pen for a large number of records.
4. Lack of variation in data.
5. Similar handwriting in data entry forms, diary cards and informed consent forms.
6. Absence of original laboratory or pathology documents.
7. Similar investigation results such as ECG tracing.
8. Sudden appearance of missing data at previous monitoring visits.
9. Same pattern of usage or return of trial materials in both arms of a clinical trial.

Editors of medical journals can sometimes spot research misconduct at time of publication. This usually includes plagiarism or dual publication. The faultless manuscript with perfect design and perfect English language is one sign that the editors in the Egyptian Journal of Surgery have found many times to indicate serious plagiarism. However, data fabrication and falsification are more difficult to diagnose at this time but some work is being done worldwide to develop mathematical methods for its diagnosis.

Prevention of research misconduct

An intelligent and effective strategy for dealing with research misconduct is that of prevention. The first step in research misconduct prevention is the promotion of good research practice as those proposed by the Joint Consensus Conference on Misconduct in Biomedical Research in 1999 (table 2). The second important step is when new researchers join an institution; it must be made clear that misconduct in their research will not be tolerated. Third, the researchers should be given a guide or manual on good research practice that defines their responsibility and also that of their supervisors. Fourth, all researchers should attend an induction course on the basic principles of research. Fifth, regular meeting should be conducted between researchers and their supervisors. Sixth, free access to research raw data for all participants concerned. If such an environment is created researchers will be less liable to commit any form of research misconduct.

In the forthcoming issue of the EJS we will present ways of responding and investigating a situation of alleged research misconduct.

Table 2. Promoting good research.

- Affirming a culture through example in which honesty and integrity are expected of every individual and misconduct is not tolerated.
- Through education, training and vigilance from the outset, starting with the undergraduate entry and continuing through life-long learning.
- Ensuring formal training of all supervisors of research.
- Establishing effective and efficient mechanisms for monitoring, auditing and ethics review, appropriate to the design of the study.
- Provision of expert advice, guidance and training for ethics committees.
- Respecting consent and confidentiality.
- Framework for and promulgating written guidance on good research practice including publication policy and dissemination results
- Designing procedures to ensure that funds are only allocated within a framework for good research practice ad when local systems for managing allegations of research misconduct are shown to be established and effective
- Investigating all allegations of research misconduct firmly, fairly and expeditiously.
- Developing effective and impartial local systems for employers to manage allegations of research misconduct, including reference to disciplinary procedures or referral for criminal investigation
- Providing access to appropriate support for whistleblowers and researchers.

Manuscript resources

Committee for Publication Ethics (COPE): www.publicationethics.org

International Conference on Harmonisation: www.ich.org