

Guidelines on Good Research Practice

Including Statement on the Handling of Allegations of Research Misconduct

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The Wellcome Trust is an independent research-funding charity, established under the will of Sir Henry Wellcome in 1936. It is funded from a private endowment, which is managed with long-term stability and growth in mind. Its mission is to foster and promote research with the aim of improving human and animal health.

The Wellcome Trust is a registered charity, no. 210183. Its sole Trustee is The Wellcome Trust Limited, a company registered in England, no. 2711000, whose registered office is 215 Euston Road, London NW1 2BE.

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Guidelines on Good Research Practice

The Wellcome Trust expects the researchers it funds to adhere to the highest standards of integrity. To facilitate this it has drawn up these Guidelines on Good Research Practice.

The Wellcome Trust funds a wide range of research, including biomedical science, biomedical ethics, social sciences and history of medicine. These Guidelines on Good Research Practice are designed to apply to all the research that the Wellcome Trust funds.

Institutions are expected to have in place their own published standards of good research practice. In addition, it is a condition of Wellcome Trust grants that host institutions in the UK and the Republic of Ireland have in place formal written procedures for the investigation of allegations of research misconduct. The Wellcome Trust has also drawn up a Statement on the Handling of Allegations of Research Misconduct, which should be read in conjunction with the Guidelines on Good Research Practice.

1 Introduction

- The Wellcome Trust cannot be prescriptive about individual approaches taken by researchers to solving particular research problems. But the Trust expects institutions to ensure that an adequate structure exists to promote and promulgate good research practice, emphasising integrity and rigour in research, and to create a culture in which the following general principles can be understood and observed.

2 Integrity

- Researchers should be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research work, including experimental design, generating and analysing data, applying for funding, publishing results, and acknowledging the direct and indirect contribution of colleagues, collaborators and others.
- Plagiarism, deception or the fabrication or falsification of results should be regarded as a serious disciplinary offence.
- Researchers are encouraged to report cases of suspected misconduct and to do so in a responsible and appropriate manner.
- Researchers should declare and manage any real or potential conflicts of interest.

3 Openness

- While recognising the need for scientists to protect their own research interests, the Trust expects the researchers it funds to be as open as possible in discussing their work with other scientists and with the public in order to help foster an informed public climate within which biomedical science can flourish.
- Once results have been published, the Trust expects researchers to make available relevant data and materials to other researchers, on request, provided that this is consistent with any ethics approvals and consents that cover the data and materials and any intellectual property rights in them.
- The Trust recognises that publication of the results of research may need to be delayed for a reasonable period pending protection of intellectual property arising from the research. Any such periods of delay in publication should, however, be kept to a minimum.

4 Guidance from professional bodies

- Where available, the Trust expects researchers to observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies.
- All researchers should be aware of the legal requirements that regulate their work.

5 Leadership and cooperation

- Heads of institutions and their senior colleagues should ensure that a research climate of mutual cooperation is created in which all members of a research team are encouraged to develop their skills and in which the open exchange of ideas is fostered.

6 Supervision

- Institutions should ensure that they provide an appropriate direction of research and supervision of researchers. Training in supervisory skills should be provided where appropriate.
- A code of responsibilities should be available for supervisors indicating, for example, the frequency of contact, responsibilities regarding scrutiny of primary data, and the broader development needs of research trainees.
- The need should be stressed for supervisors to supervise all stages of the research process, including outlining or drawing up a hypothesis, preparing applications for funding, protocol design, data recording and data analysis.

7 Training

- Institutions should have in place systems that allow students and new researchers to understand and adopt best practice as quickly as possible.
- All researchers should undertake appropriate training, for example in research design, regulatory and ethics approvals and consents, equipment use, confidentiality, data management, record keeping and data protection.

8 Primary data/samples

- There should be clarity at the outset of the research programme as to the ownership of, where relevant:
 - data and samples used or created in the course of the research
 - the results of the research.
- Researchers should keep clear and accurate records of the procedures followed and the approvals granted during the research process, including records of the interim results obtained as well as of the final research outcomes. This is necessary not only as a means of demonstrating proper research practice, but also in case questions are subsequently asked about either the conduct of the research or the results obtained.
- Data generated in the course of research should be kept securely in paper or electronic format, as appropriate. The Trust considers a minimum of ten years to be an appropriate period, but research based on clinical samples or relating to public health might require longer storage to allow for long-term follow-up to occur.
- Back-up records should always be kept for data stored on a computer.
- Institutions should have guidelines setting out responsibilities and procedures for the storage and disposal of data and samples (including compliance with the requirements of any ethics committee).

9 Ethical practice

9.1 Research involving human participants

- Approval is required from an appropriate ethics committee for all Trust-funded research involving human participants or biological samples. Approval should also be sought from other regulatory bodies such as the Human Fertilisation and Embryology Authority or the Gene Therapy Advisory Committee in the UK where necessary.
- Researchers should ensure the confidentiality of personal information relating to the participants in research, and that the research fulfils any legal requirements such as those of the Data Protection Act 1998.

9.2 Research involving animals

- Research involving animals should have approval through the appropriate ethical review process, and may require Home Office licences for the institution, the investigator and the project.
- Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for reduction, replacement and refinement of animal involvement (the three Rs).

9.3 Risks of research misuse

- In progressing their scientific investigations, researchers should actively consider any risks that their research will generate outcomes that could be misused for harmful purposes. Where such risks exist, they should seek advice and take active steps to minimise them.
- Institutions should have in place mechanisms to ensure that risks of misuse associated with ongoing research programmes are identified and managed, and to provide advice to the researchers that they employ on these issues.

10 Publication practice

- Results should be published in an appropriate form, usually as papers in refereed journals.
- Anyone listed as an author on a paper should accept responsibility for ensuring that he/she is familiar with the contents of the paper and can identify his/her contribution to it. The practice of honorary authorship is unacceptable.
- The contributions of formal collaborators and all others who directly assist or indirectly support the research should be properly acknowledged.
- An example of good publication practice can be found in the Committee on Publication Ethics guidelines Good Publication Practice.

References

Medical Research Council:

Principles in the Assessment and Conduct of Medical Research and Publicising Results. London: Medical Research Council; 1995.
MRC Policy and Procedure for Inquiring into Allegations of Research Misconduct. London: Medical Research Council; 1997.
MRC Guidelines for Good Clinical Practice in Clinical Trials. London: Medical Research Council; 1998.
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Other sources of information:

General Medical Council. Research: The role and responsibilities of doctors. February 2002. www.gmc-uk.org/standards/research.htm [accessed 6 September 2005].
Biotechnology and Biological Sciences Research Council. BBSRC Statement on Safeguarding Good Scientific Practice 2000. www.bbsrc.ac.uk/funding/overview/good_practice.pdf [accessed 6 September 2005].
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Nimmo WS (ed.). Joint Consensus Conference on Misconduct in Biomedical Research. Proceedings of the Royal College of Physicians of Edinburgh 2000;30(1) Suppl 7.
Danish Committee on Scientific Dishonesty. Guidelines for good scientific practice. Copenhagen; March 1998. http://forsk.dk/portal/page?_pageid=407,889357&_dad=portal&_schema=PORTAL [accessed 6 September 2005].
The Office of Research Integrity (ORI), USA. www.ori.hhs.gov.

Statement on the Handling of Allegations of Research Misconduct¹

It is a condition of Wellcome Trust grants that host institutions in the UK and the Republic of Ireland have in place formal written procedures for the handling of allegations of research misconduct. Host institutions outside the UK and the Republic of Ireland will be expected to adhere to the spirit of the Trust's Guidelines on Good Research Practice.

This statement sets out the minimum criteria that a host institution's procedures for handling such allegations should satisfy. It should be read in conjunction with the Trust's Guidelines on Good Research Practice.

The Trust identifies integrity, openness and partnership as key values: this statement has been produced, and is intended to be applied, in line with those values. The expectation is that the necessity to invoke these procedures will be a rare event but that by following these general principles the process of investigating allegations of research misconduct will be a fair process that protects the interests of all the parties involved.

Useful models for procedures for handling allegations of research misconduct may be found in the Medical Research Council's *Policy and Procedure for Inquiring into Allegations of Research Misconduct* (December 1997) and the General Medical Council's report *Good Practice in Medical Research* (December 1999).

Throughout this statement:

- **'Appropriate Director'** means the Trust's Director of Science Funding or the Trust's Director of Medicine, Society and History (as applicable), or any person notified to a host institution, from time to time
- **'host institution'** means any institution in receipt of Trust funds
- **'the Trust'** means the Wellcome Trust, a registered charity (number 210183)
- **'Trust-funded researcher'** means all Trust-salaried researchers and non-Trust-salaried researchers in receipt of funds in any form from the Trust in order to advance their research.

1 Definition of research misconduct

1.1 'Research misconduct' is defined by the Trust as:

The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research or 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 also includes intentional, unauthorised use, disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings, data, hardware or software or any other substances or devices used in or produced by the conduct of research.

¹ In formulating these guidelines, the Trust has drawn on the Medical Research Council's Ethics Series, in particular *Good Research Practice* (December 2000) and *Policy and Procedure for Inquiring into Allegations of Scientific Misconduct* (December 1997) and the General Medical Council's *Good Practice in Medical Research* (2002). It has also been informed by the *Joint Consensus Conference on Misconduct in Biomedical Research*, Royal College of Physicians of Edinburgh (January 2000) and the Biotechnology and Biological Sciences Research Council's 'Statement on Safeguarding Good Scientific Practice'.

- 1.2 It does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct unrelated to the research process. Similarly it does not include poor research unless this encompasses the intention to deceive.²

2 Responsibilities of the host institution

- 2.1 The Trust considers that it is the responsibility of the host institution to investigate all allegations of research misconduct made against its staff and students. Findings of research misconduct may be matters for consideration under the host institution's disciplinary procedures.
- 2.2 Host institutions will need to give consideration to the procedures that will apply to visiting researchers while based in the host institution and the host institution's staff while based in another institution.
- 2.3 It is the responsibility of the host institution to inform the Appropriate Director, in confidence, at the earliest opportunity, about allegations of serious research misconduct that concern Trust-funded researchers where it seems that there are reasonable grounds to believe that the allegation may be substantiated on investigation. It is at the discretion of the host institution to determine what constitutes 'serious misconduct'. The host institution is also responsible for informing the Appropriate Director of the outcome of any such investigation.
- 2.4 It is the responsibility of the host institution to inform the Appropriate Director, in confidence, of *all* instances of research misconduct involving Trust-funded researchers that have resulted in the allegations being substantiated.
- 2.5 The host institution should have in place a policy statement relating to the treatment of whistleblowers under the Public Interest Disclosure Act 1998, including a clear statement that research misconduct is taken seriously in the institution and that any member of staff raising *bona fide* concerns can do so confidentially, and without fear of suffering any detriment. The statement should include a clear indication of the procedures in which such *bona fide* concerns by staff may be brought to the attention of a designated individual within the institution.

3 Principles for investigation by host institutions of allegations of research misconduct

- 3.1 Each host institution must have in place formal written procedures³ for dealing with allegations of research misconduct against its staff and students. Host institutions should, where appropriate, take legal advice on implementing these procedures to ensure that the procedures comply with all legal obligations for the conduct of such investigations from time to time in force.

² Based on the definitions given in the MRC's *Policy and Procedure for Inquiring into Allegations of Scientific Misconduct* (December 1997) and the GMC's report *Good Practice in Medical Research* (2002).

³ Useful models of such procedures may be found in the MRC's *Policy and Procedure for Inquiring into Allegations of Scientific Misconduct* (December 1997) and the GMC's *Good Practice in Medical Research* (2002).

- 3.2 Host institutions should endorse the following principles when implementing these procedures:
- the responsibilities of those dealing with the allegation should be clear and understood by all interested parties
 - measures should be in place to ensure an impartial and independent investigation and to ensure that line management obligations or other interests of those dealing with the allegation do not conflict with these procedures
 - those undertaking research at the host institution should be contractually obliged to participate in and comply with the procedure
 - the host institution should consider the confidential nature of the investigation and how to safeguard the rights to confidentiality of the interested parties
 - anyone accused of misconduct should have the right to respond
 - in line with the Public Interest Disclosure Act 1998, a policy should be in place to ensure that no employee shall suffer a detriment who makes an allegation in good faith against another employee, but equally that disciplinary procedures are in place to deal with malicious allegations
 - all interested parties should be informed of the allegation at an appropriate stage in the proceedings
 - the allegation should be dealt with in a fair and timely manner
 - proper records of the proceedings should be kept
 - the outcome should be made known as quickly as possible to all interested parties
 - anyone found guilty of misconduct should have the right to an appeal
 - appropriate sanctions should be in place for cases when the allegation is upheld
 - if appropriate, efforts should be made to restore the reputation of the accused party if the allegation is dismissed.

4 Involvement of the Wellcome Trust

4.1 Receipt of allegations

The Trust recognises that there may be instances where an allegation of research misconduct is made directly to a member of the Trust's staff or a Governor rather than to an individual within the host institution. In such instances, the Appropriate Director will contact an appropriate individual at the host institution and the host institution will then be responsible for taking suitable action in line with its formal written procedures for handling allegations of research misconduct.

4.2 Investigations by the Trust

As stated above, it is the host institution's responsibility to investigate allegations of research misconduct made against its staff and students and this would be the Trust's preferred course of action in most cases. In exceptional cases, however, the Trust may wish to undertake its own investigation into alleged cases of research misconduct that concern Trust-funded researchers (for example where the Trust's reputation is at risk or where the Trust is dissatisfied with the investigation undertaken by the host institution). Any investigations by the Trust would only be undertaken following consultation between the Appropriate Director and the appropriate representative(s) of the host institution.

In such cases the procedure described in Annexe A will apply.

5 Sanctions

- 5.1 If the host institution or the Trust determines that the allegation of scientific misconduct is substantiated, the Trust may consider appropriate sanctions. These may include, but are not restricted to:
- letter of reprimand
 - withdrawal of funding
 - requiring the withdrawal or correction of pending or published abstracts and papers emanating from the research in question
 - changes to the staffing of the particular project
 - special monitoring of future work
 - barring of the Trust-funded researcher from applying for Trust funds for a given period
 - repayment of grant plus interest at the Trust's discretion
 - discussion with the host institution on the implementation of appropriate disciplinary procedures.
- 5.2 At all times, in line with its Grant Conditions, the Trust reserves the right to withdraw funding with immediate effect.

Annexe A: Procedures for investigation of research misconduct by the Wellcome Trust

1 Instigation of proceedings

- 1.1 Where the Trust has decided to carry out its own investigation of an allegation of research misconduct, the Appropriate Director [the Trust's Director of Science Funding or the Trust's Director of Medicine, Society and History (as applicable), or any person notified to a host institution, from time to time] shall inform the host institution, the subject of the allegation ('the respondent') and the person(s) making the allegation ('the complainant') of his/her decision to instigate a formal investigation. The Trust's investigation will follow the principles that the Trust expects host institutions to follow in the investigations of allegations of research misconduct.

2 Appointment of investigation committee

- 2.1 The Director of the Trust (or his/her nominee) will appoint an investigation committee, which will consist of five people, including three representatives of the Trust, one of whom may be a member of Trust staff nominated by the respondent. The fourth and fifth representatives will be independent of the Trust⁴ and, prior to appointment, will be required to declare any conflicts of interest and to agree to a duty of confidence. In the event that any representative declares a conflict of interest, or in the opinion of the Director of the Trust (or his/her nominee) any conflict of interest is or becomes apparent in respect of any representative, the Director of the Trust (or his/her nominee) shall in his/her discretion have the power to remove that representative from the investigation committee. The investigation committee will elect one of the two independent representatives as chair. The host institution, the respondent and the complainant will be notified of the proposed investigation committee membership.
- 2.2 The Appropriate Director will define the scope of the investigation in written terms of reference to the investigation committee. The Trust will provide the secretariat to the investigation and will keep a fair and accurate record of the proceedings.

3 Investigation

- 3.1 Where possible, the investigation will include examination of all relevant documentation, including, but not limited to: relevant research data; laboratory notebooks; computer files; other materials; proposals; publications; correspondence; memoranda; and notes of telephone calls. Interviews will be conducted with the complainant and the respondent, and any other individuals involved in making the allegation and other individuals who might have information regarding key aspects of the allegations.
- 3.2 Details of the allegation and the investigation will be made available by the Trust only to the investigation committee and to such members of Trust staff as are necessary to conduct the investigation. All individuals interviewed during the investigation will be asked to respect the confidential nature of the investigation.

⁴ 'Independent of the Trust' in this document means that the individuals appointed will be neither Governors of the Wellcome Trust nor members of its or its subsidiaries' staff nor current members of its committees.

4 Investigation report

- 4.1 The investigation committee will produce a report stating: the procedures under which the formal investigation was conducted; how and, where appropriate, from whom, information was obtained; the findings of the committee and the basis for these; a summary of the views of the respondent; and a description of any sanctions recommended by the committee.
- 4.2 The host institution and the respondent will receive a copy of the investigation report and have an opportunity to comment on it. Comments may be submitted to the investigation committee and will be attached as an addendum to the investigation report.

5 Right of appeal

- 5.1 The respondent has a right of appeal, against the decision and/or sanctions made by the investigation committee. The complainant has no right of appeal.
- 5.2 The respondent may appeal within 14 days of receiving notification of the final outcome of the investigation. The appeal must be made in writing and should state the basis for the appeal. The Deputy Chairman of the Wellcome Trust will appoint an appeal board consisting of three or more persons, at least one of whom will be independent of the Trust. The Deputy Chairman of the Wellcome Trust will notify the respondent of the proposed appeal board membership.

6 Appeal process

The appeal will normally include examination of all evidence called into question by the respondent. The respondent will also be invited to attend to give oral evidence. The respondent may submit any relevant supplementary evidence in support of his/her appeal.

An appeal should normally be completed, with the report submitted to the Deputy Chairman of the Wellcome Trust, within 90 days of its initiation, with the initiation being defined as the appointment of the appeal board.

7 Appeal report

The appeal report must state how the appeal was conducted; describe how and, where appropriate, from whom, further information was obtained relevant to the appeal; state the findings of the appeal board; and explain the basis for those findings.

8 Final decision

- 8.1 The Deputy Chairman of the Wellcome Trust will decide, on the basis of the appeal report, whether to endorse, amend or overturn the conclusions of the investigation committee and/or resultant sanctions imposed on the respondent.
- 8.2 The Deputy Chairman of the Wellcome Trust will notify the respondent and the host institution in writing of the outcome of the appeal board and will provide a copy of the appeal report and evidence considered by the appeal board.
- 8.3 The Deputy Chairman of the Wellcome Trust will give consideration to informing other interested parties, including journals in which the research was published, of the outcome of the investigation.
- 8.4 The decision of the Deputy Chairman of the Wellcome Trust is final.