HRB Guidelines for Host Institutions on the Handling of Allegations of Research Misconduct

Background

The HRB funds a wide range of health-related research in approved host institutions, after open calls and international peer review. The HRB expects all of the researchers that it funds, both clinical and non-clinical, to adhere to the highest standards of integrity in the conduct of their research. These *HRB Guidelines for Host Institutions on the Handling of Allegations of Research Misconduct* are intended to clarify the HRB's expectations in this regard and should complement the policies and practices within the host institution, which take account of local working contexts. The HRB takes allegations of research misconduct very seriously and expects host institutions to do likewise.

1. Definitions of Research Misconduct

a. The general understanding of research misconduct is *intention to cause others to regard as true that which is not true*[1].

b. The elements of research misconduct are fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results which can be defined as follows[2]:

- *fabrication* is the making up of data or results and recording or reporting them
- *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 or another person's ideas, processes, results or words without giving appropriate credit.

c. Research misconduct also 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[3].

d. Research misconduct further includes intentional, unauthorized 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[4].

e. The examination of misconduct must, therefore, focus not only on the particular act or omission but also on the *intention* of the researcher.

f. A finding of research misconduct requires that:[2]

- there is a significant departure from accepted practices of the relevant research community; **and**
- the misconduct is committed intentionally, or knowingly or recklessly; **and**
- the allegation can be proven by a preponderance of evidence

g. Research misconduct does **not** include honest error or honest differences in the design, execution, interpretation or judgment in evaluating research methods or results, or misconduct unrelated to the research process. Nor does it include poor research unless this encompasses the intention to deceive.

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[1] The Cope Report (2003). Guidelines on good publication practice. http://www.publicationethics.org.uk/guidelines [Accessed 19th September 2007].

[2] Federal policy on research misconduct. http://www.ostp.gov/html/001207_3.html [Accessed 20th September 2007]

[3] Wellcome Trust (2005). Guidelines on Good Research Practice: http://www.wellcome.ac.uk/doc_WTD002753.html [Accessed 19th September 2007].

[4] Adderbrooke's NHS Trust (2003). Policy and procedures: Good Research Practice – misconduct and fraud. http://www.addenbrookes.org.uk/resources/pdf/research/good_research_pract_270503.pdf [Accessed 24th September 2007]

2. Host institution policy and procedures

As of October 2002, all HRB approved host institutions are required to have adopted a policy and published standards on good research practice. In addition, it is a condition of HRB grants that host institutions must have formal written procedures for the investigation of allegations of research misconduct. Through these policies and procedures the HRB expects institutions to ensure that adequate structures exist to promote and disseminate good research practice, and to act quickly and fairly where allegations of research misconduct come to light.

3. Essential content of the host institution policy and procedure

a. The main requirement is that institutions should establish clear procedures for dealing with allegations of research misconduct that are written, agreed, disseminated and clearly understood by all those who may be involved[5].

b. The procedures should be seen to be even-handed to both the complainant (person(s) making the allegation) and the respondent (subject(s) of the allegation).

c. The procedure should protect both the complainant from undue pressure and the respondent from ill-founded, frivolous, mischievous or malicious allegations, and both should expect a just decision following a fair and speedy process.

d. *Bona fide* allegations must be pursued with integrity, in confidence and without detriment to the complainant. Equally, researchers who are subject of such allegations are entitled to expect that their work will be regarded as honest unless proven to be otherwise.

e. The procedures should indicate the sanctions that could apply if research misconduct were proven.

f. A senior person in the host institution should be clearly identified as being responsible for overseeing and directing the process.

g. The stages in examining the allegations should be clearly laid out and the time limits for enquires and investigations should be specified.

h. The procedures should include the provision to appoint an independent body (e.g. an *ad hoc* committee of relevant expertise) to act in cases of suspected research misconduct so that there is a demonstrable separation from the normal line management chain where the alleged incident has arisen.

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[5] Based on the description give in the EPSRC Good practice in Science and Engineering Research. http://www.epsrc.ac.uk/ResearchFunding/GrantHolders/GuideToGoodPracticeInScienceAndEngineeringResearch.htm [Accessed 20th September 2007] and the Deutsche Forschungsgemeinschaft (1998). Recommendations of the Commission on Professional Self Regulation in Science: Proposals for safeguarding good scientific practice. http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/download/self_regulation_98.pdf [Accessed 22nd September 2007].

4. Stages of the investigation process

Even if not set out explicitly, a procedure should include some or all of the following stages, the outcomes of which should be clearly recorded[6].

Stage 1: Preliminary action

This would at least involve the identified senior person (or if unavailable, his/her nominated deputy) receiving any allegation, establishing whether or not the allegation falls within the definition of research misconduct (see Section 1 for a definition) and whether an inquiry is warranted. The senior person should notify all who need to be involved and speedily gather evidence.

Stage 2: An inquiry stage

a. The purpose of the inquiry stage is to determine fairly rapidly whether there is, *prima facie*, a case to answer.

b. For this stage the senior person should set up a small, independent panel to assess the evidence. This Assessment Panel should consist of 2 members as a minimum and should specifically limit its scope to that of only evaluating the facts to determine whether there is sufficient evidence of research misconduct to warrant a formal investigation.

c. A written report should be prepared that states what evidence was reviewed, summarizes relevant interviews and includes the conclusion of the Assessment Panel as to what actions should be taken.

d. The respondent and complainant should be informed in writing of the outcomes of the inquiry.

e. This stage may lead to the following outcomes/actions:

- No case is established: the respondent and complainant should be informed.
- No case is established but malicious intent is suspected: the respondent should be informed and relevant action should be taken in respect of the complainant.
- Minor concern: panel to recommend actions for resolution of the concern. Necessary parties to be informed.
- Major concern: Proceed to stage 3.

Stage 3: Formal investigation

a. If there appears to be a case to answer the senior person should inform the respondent and the complainant of the panels' decision to instigate a formal investigation by the Investigation Committee.

b. The purpose of the formal investigation is to examine and evaluate all relevant facts to determine whether research misconduct has been committed, and if so, the responsible person(s), the seriousness of the misconduct and the actions that should be taken.

c. The Investigation Committee should consist of at least 3 persons, some of whom have served on the assessment panel. The Investigation Committee should appoint one of their number as Chair. There should be no conflicts of interest with either the respondent or complainant, and they should have the necessary expertise to examine the evidence, interview witnesses and conduct the investigation.

d. The respondent should be advised in detail of the complaint, be given written notice of the process in order to prepare their defense, and be advised of the membership of the Investigation Committee.

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[6] Based on the Medical Research Council (1997). Ethics Series: Policy and procedure for inquiring into allegations of scientific misconduct. http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002454 [Accessed 24th September 2007] and the Dudley Group of Hospitals NHS Trust (2005). Policy to address research misconduct and fraud. http://www.dudley.nhs.uk/sections/publications/documents%5CFOI26184297891.pdf [Accessed 24th September 2007]

e. Where possible, the investigation should include examination of all relevant documentation, including, but not limited to:

- relevant research data
- laboratory notebooks
- computer files
- other materials
- proposals
- publications
- correspondence
- memoranda
- notes of telephone calls.

f. Interviews may 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.

g. The final report of the Investigation Committee should:

- state how the investigation was conducted
- describe how and from whom information was obtained (including the full verbatim reports of interviews)
- state the findings and explain the basis of the findings
- contain an accurate agreed summary of the views of the respondent
- contain a description of any further actions (sanctions, disciplinary action, legal proceedings etc.) recommended by the committee.

5. Right of appeal[3]

a. The respondent has a right of appeal against the decision and/or sanctions made by the Investigation Committee and senior person. The complainant has no right of appeal.

b. The respondent may appeal within a limited period (e.g. 14-20 days) of receiving notification of the final outcome of the investigation.

c. The appeal must be made in writing and should state the basis for the appeal. The respondent may submit any relevant supplementary evidence in support of his/her appeal.

d. The senior person should appoint an Appeals Board consisting of three or more persons, at least one of whom is independent of the host institution.

e. The appeal should normally include examination of all evidence called into question by the respondent and the respondent may also be invited to attend to give oral evidence.

f. An appeal should normally be completed, with the report submitted to the senior person, within 90 days of its initiation, with the initiation being defined as the appointment date of the Appeals Board.

g. The appeal report should 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 Appeals Board; and explain the basis for those findings.

6. Final decision

a. The senior person will decide, on the basis of the appeal report, whether to endorse, amend or overturn the recommendations of the Investigation Committee and/or resultant sanctions imposed on the respondent.

b. The senior person should notify the respondent in writing of the recommendations of the Appeals Board and provide a copy of the appeal report and evidence considered by the appeals board.

c. The senior person should consider informing other interested parties, including journals in which the research was published and any external agencies involved in funding the research, of the outcome of the investigation.

d. The decision of the senior person, following all of the above considerations, should be final.

7. Possible sanctions

a. If the senior person determines that the alleged misconduct is substantiated by the findings, they should determine appropriate sanctions and impose theses on the respondent. Sanctions may apply separately or combined. Actions that may be implemented include:

- Removal from the particular project
- Final written warning
- Special monitoring of future work
- Removal of eligibility for salary increments or promotion for 1 or more years
- Demotion.

b. If the research misconduct is so serious that the above sanctions are insufficient; the senior person may recommend dismissal from the host institution, through the normal HR channels.

c. Where the research in question is funded by an external agency, the funding body may also impose sanctions (e.g. termination of funding, debarment from further applications for a stated period) as they see fit.