HRB Guidelines for Host Institutions on Good Research Practice

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 Institution on Good Research Practice* are intended to clarify the HRB's expectations in this regard and should complement the Policies and Practices in the host institution, which take account of local working contexts.

1. General principles on which these guidelines are based

These Guidelines are informed by the European Science Foundation (ESF) Policy Briefing on Good Scientific Practice[1] and owe much to the Wellcome Trust Guidelines on Good Research Practice[2] and the Medical Research Council Guidelines on Good Research Practice[3]. The principles on which the HRB Guidelines are based are described in these documents.

2. Host institution policies and procedures

As of October 2002, all HRB approved host institutions are required adopt a policy and published standards on good research practice. In addition, it is a condition of HRB grants that host institutions have formal written procedures for the investigation of allegations of research misconduct. As an example, the HRB has provided *HRB Guidelines for Host Institutions on Handling 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, emphasising integrity and rigor in research, and to create a culture in which the following general principles can be understood and observed.

3. Integrity

a. 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.

b. Intentional deception through plagiarism, fabrication or falsification of research results should be regarded as a serious disciplinary offence by the host institution.

c. Researchers should be encouraged to report cases of suspected misconduct and to do so in a responsible and appropriate manner.

d. Researchers should declare and manage any real or potential conflicts of interest.

4. Openness

a. In keeping with its position on access to published research, the HRB expects the researchers it funds to be as open as possible in discussing their work with other

[1] European Science Foundation (2000). Policy Briefing no. 10: Good scientific practice in research and scholarship. http://www.esf.org/fileadmin/be_user/activities/research_conferences/Docs_NEW/2007/ESPB10.pdf [Accessed 24th September 2007].

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

[3] Medical Research Council (2005). Ethics Series: Guidelines on Good Research Practice. http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/GoodResearchPractice/index.htm [Accessed 19th September 2007].

scientists and with the public in order to help foster an informed public climate within which health research can flourish.

b. Once results have been published, the HRB 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 therein.

c. The HRB 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.

5. Guidance from professional bodies and legislation

a. Where available, researchers should observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies.

b. All researchers should be aware of the legal requirements that regulate their work.

6. Supervision

In keeping with the recommendations of the IUQB[4] National Guidelines on the management of PhD programmes:

a. Host Institutions should ensure that they provide appropriate direction of research and supervision of researchers. Training in supervisory skills should be provided where appropriate.

b. A code of responsibilities should be available for supervisors, based on the IUQB Guidelines, indicating the frequency of contact, responsibilities regarding scrutiny of primary data, the broader development needs of research trainees and so on.

c. 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

a. Host Institutions should have in place systems that allow students and new researchers to understand and adopt best practice as quickly as possible.

b. 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. Ethical practice

The HRB requires Ethical Practice in the use of human subjects and the use of animals. The role of Ethics Committees is detailed and guideline documents on ethical principles in research are available on the HRB webpage:
http://www.hrb.ie/display_content.php?page_id=112 [Accessed 19th September 2007].

8.1 Research on human subjects or materials

The HRB policy is informed by the recommendations of the Irish Council for Bioethics on the collection, use and storage of human biological materials[5].

[4] Irish Universities Quality Board (2005). Good practice in the organisation of PhD programmes in Irish Universities. http://www.iuqb.ie/IUQB_Good_Practice_in_PhD_Programmes_(reprint).pdf [Accessed 19th September 2007].
[5] Irish Council for Bioethics (2005). Human Biological Materials: Recommendations for collection, use and storage in research. http://www.bioethics.ie/pdfs/BioEthics_fin.pdf [Accessed 19th September 2007].

a. Where required, written proof of ethical approval from an appropriate Ethics Committee must be obtained before funding of successful HRB applications can commence.

b. Where ethical approval is not required for work at the beginning of a project, funding will commence on the condition that the grant holder will obtain ethical approval before it is required. The grant holder must produce written confirmation that proper approval will be obtained. This will allow for initial funding to go to the host institution. Any further installments are subject to the same condition as outlined in 8.1(a).

c. 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 1988[6].

8.2 Research involving animals

The HRB policy is informed by the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes and animal experimentation is controlled by the Cruelty to Animals Act (1876) as amended by SI 566/2002 to comply with the EU Directive 86/609/EEC.

a. Where required, written proof of ethical approval and an animal licence must be obtained before funding of successful HRB applications can commence.

b. 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).

c. Where ethical approval and an animal licence are not required for work at the beginning of a project, funding will commence on the condition that the grant holder will obtain documentation before it is required. The grant holder must produce written confirmation that a licence and proper approval will be obtained. This will allow for initial funding to go to the host institution. Any further installments are subject to the same condition as outlined in 8.2(a).

9. Conducting the research

a. All research projects should be conceived, designed and implemented according to the highest standards.

b. The legal and ethical requirements of the research should be familiar to each person involved.

c. Equipment used to generate data should be appropriately located, safe, suitable, fit for purpose, and of adequate capacity. It should be calibrated and serviced regularly by suitably qualified staff so that its' performance is optimal and the results can be trusted.

d. In conducting 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 from their institution and take active steps to minimize them.

e. Experiments should be conducted in accordance with health and safety regulations and guidelines in force in the host institution. All regulations governing the use and disposal of hazardous materials should be followed rigorously.

f. Standard operating procedures (SOPs) should be documented for all routine methods and for individual items of equipment to ensure that data are collected consistently and accurately.

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[6] Data Protection Act (1988). http://www.dataprotection.ie/viewdoc.asp?Docid=64&Catid=47&StartDate=1+January+2007&m=l [Accessed 19th September 2007]

10. Primary data/samples

As a minimum, researchers should ensure the following:

a. There should be clarity at the outset of the research programme as to the ownership of:
   - data and samples used or created in the course of the research
   - the results of the research.

b. 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.

c. Data generated in the course of research should be kept securely in paper or electronic format, as appropriate. The HRB 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.

d. Back-up records should always be kept for data stored on a computer.

e. 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).

f. A comprehensive description of good practice in the gathering, storing and retention of data and samples can be found in the Medical Research Council Guidelines[3].

11. Publication of research results

a. The Principal Investigator should authorise publication of results; authorisation should cover both the content of the paper (integrity, adequacy, appropriate protection of IPR, appropriate authorship) and the intended place of publication.

b. Results should be published in an appropriate form, usually as papers in refereed journals. Results should normally be published as a coherent entity rather than a series of small parts, unless there is legitimate need to demonstrate first discovery by publishing preliminary data.

c. Authors should not publish the same data in different journals.

d. 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.

e. The contributions of formal collaborators and all others who directly assist or indirectly support the research should be properly acknowledged.

f. Where the research has been funded in whole or part by the HRB, this contribution should be acknowledged in any publication, quoting the grant reference no(s) provided in the letter(s) of acceptance.

g. Research findings with substantial implications for clinical practice or which are likely to attract strong public interest should be drawn to the attention of the HRB before publication.

h. An example of good publication practice can be found in the Committee on Publication Ethics Guidelines and Code of Conduct[7].

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

12. Applying and exploiting results

The mission of the HRB is to improve people's health through research and information. This is supported by its strategic goals of advancing the contribution that health research makes to a sustainable knowledge economy and increasing awareness and understanding of both the impact and the value of health research and information.

a. The HRB expects those it supports to play their part in disseminating balanced information on scientific advances and their potential implications for society to the health professionals and policy makers who will be involved in applying them, and to the wider public.

b. HRB-funded researchers are expected to maximise the prospects of research being taken into practice through the commercial route by protecting intellectual property rights (IPR) where these arise.

c. Researchers who collaborate with industry should take special care to keep detailed and accurate records of their research[5].

d. IPR should be considered before data are submitted for publication or presented at meetings.

e. Host institutions are expected to have Intellectual Property and Technology Transfer policies in place and to have procedures for protecting the outputs of research hosted by them.

13. Other relevant information sources:

- Biotechnology and Biological Sciences Research Council (2000). BBSRC Statement on Safeguarding Good Scientific Practice.
- www.bbsrc.ac.uk/funding/overview/good_practice.pdf [Accessed 19th September 2007].
- Nuffield Council on Bioethics: http://www.nuffieldbioethics.org/ [Accessed 19th September 2007].
- The Office of Research Integrity (ORI), USA. http://ori.dhhs.gov/ [Accessed 19th September 2007]
- UK Research Integrity Office (UKRIO) http://www.ukrio.org/home/index.cfm [Accessed 19th September 2007]
- RESPECT Code of practice for socio-economic research.
- http://www.respectproject.org/code/respect_code.pdf [Accessed 19th September 2007]