Royal Holloway
University of London

Guidelines on Research Governance, Research Ethics and Good Research Practice

Introduction

1.   Royal Holloway, University of London seeks to encourage research of the highest quality. As part of this endeavour it wishes to ensure that research governance, research ethics and research good practice are characteristics of all of its research activities, including work carried out under consultancy and technical services. From here on the word activities will be used to refer to all the work that falls into these categories. These guidelines have been drawn up to promote good practice, including integrity and rigour, and to create a culture in which good practice can be understood and observed. They are based on model guidelines and documents listed under References.

2.   Many UK and international funders have now placed greater emphasis on ensuring that research they fund meets good practice, is ethically sound and is performed to the highest standards (ref 1, 2,3,4,5,6, 7, 8, 9, 10, 11 and 19). In order to meet these standards, funders require organisations to give assurances that they have in place appropriate policies and procedures to ensure that activities performed in the organisation meet the necessary requirements. This document aims to encompass guidelines on issues to do with research good practice, research ethics and research governance in order to ensure the work done at Royal Holloway:
   * Is ethically sound and of highest scientific quality.
   * Promotes good research practice.
   * Reduces adverse incidents and ensures we learn from any mistakes.
   * Prevents poor performance and does not lead to misconduct.

A recent OSI document summarises the above key principals that all organisations and individuals involved in research should observe (19).

3.   These guidelines apply to all those involved in the wide range of activities carried out at the College, including staff, students, honorary fellows and others, whether working on the College's premises or elsewhere. The guidelines should be adhered to from inception of the activity through to dissemination and its application by external users. It is the duty of Heads of Department to draw the guidelines to the attention of all staff, particularly new researchers, and for research group leaders and supervisors to ensure that they are promulgated within their sphere of responsibility. It would be appropriate for them to be introduced to undergraduate students as part of a research training course and certainly before they undertake any research project.

4.   It is recognised that some of the principles in this document will not have direct relevance to certain areas of activities but in general most of these principles should be adhered to by those carrying out the activities and the guidelines should be followed by all such individuals. Some departments may wish to implement their own additional discipline-specific requirements where this is appropriate.

5.	These guidelines set out the responsibilities and standards that must be applied to work managed within the formal context of activities.

Integrity, Allegations of Misconduct and Adverse Events

6.	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.

7.	Plagiarism, deception or the fabrication or falsification of results may be a criminal offence and is regarded by the College as a serious matter, covered by the *Code of Practice for Inquiring into Allegations of Misconduct in relation to Academic, Research and Scientific Activities* (12.). Researchers are encouraged to report cases of suspected misconduct and to do so in a responsible and appropriate manner as covered by this Code. The UK Panel for Research Integrity in Health and Biomedical Sciences has set up a helpline offering advice and guidance on reporting suspected misconduct (20). Where possible, systems and procedures should be put in place by the leader of the activity to monitor the output of the activity and to ensure that incidences of misconduct are minimised.

8.	Researchers should declare and manage any real or potential conflicts of interest. Declarations should be given in the first instance to the Head of Department. If the project is a collaborative activity then the lead partner must ensure all the partners highlight any conflicts of interest at the start of the project.

9.	For particular activities, such as work involving the NHS, the HEI (lead academic) designated as Research Sponsor should ensure they have in place a suitable procedure for reporting adverse events and where necessary adhering to specific issues of relevance to that work only. This could involve:
   i.	Developing a Form for reporting adverse events.
  ii.	Ensuring that there is a system by which all collaborators are made aware of any patient or participant experiencing adverse reaction to the clinical trials and that the funder and the patient's doctor are immediately made aware of this or in the case of work involving collection of sensitive personal data if this has been inadvertently leaked eg to the press, that procedures are in place to bring this to the attention of relevant authority. Participants must be made aware at the start of the work that if there is an adverse event then the procedure to deal with adverse events will be implemented, eg in the case of the patient this could involve making their doctor aware of the event.
 iii.	Making the participant in the research aware of the procedures to follow if they need to contact the lead applicant within a reasonable timescale in the case of an adverse event.

10.	On a more general level the lead Principal Investigator (PI) needs to ensure that all relevant staff attached to the activity are aware of the College's policies on reporting Intellectual Property (IP), scientific fraud and ethical matters. These policies are

available on the College intranet at the following weblink: http://www.rhul.ac.uk/For-Staff/intranet.html .

Openness

11.	The College encourages researchers to be as open as possible in discussing their work with other researchers and with the public. Where it is appropriate, activity must take account of either the user's perspective or involve them in the planning and implementation stage of the activities that will have a direct impact on them.

12.	While 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 delay should be kept to a minimum.

13.	Once results have been published, researchers should make available relevant data and materials to other researchers, on request, provided that this is consistent with any ethical approvals, consents that cover the data and materials intellectual property considerations and the conditions of any grants or sponsorship.

Guidance from professional bodies and Clinical Governance

14.	Where available, researchers must observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies. It is the responsibility of supervisors to draw the attention of new researchers to such standards.

15.	All researchers should be aware of the legal requirements which regulate their work. It is the responsibility of supervisors to ensure that new researchers are provided with adequate training in such requirements, particularly in relation to copyright issues. Further advice on this area can be sought from the Royal Holloway Research and Enterprise Office.

16.	Where there are activities involving clinical work then it may be necessary for those involved to develop links with clinical governance, which will involve a) some common membership of committees and b) complementarity between clinical and research governance monitoring systems (eg recording of adverse events). Where this is applicable then the relevant College staff must ensure they contact the relevant NHS trust to seek their advice in relation to the requirements of the Trust's clinical governance procedures.

Leadership, Cooperation and Supervision

17.	Heads of Department, senior academic staff and research group leaders 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.

18.	Heads of Department should ensure that appropriate direction of research and supervision of researchers is provided. All staff must receive training in appropriate

skills before undertaking supervisory duties, and in particular the supervision of postgraduate and undergraduate research students.

19. The Code of Practice for the Academic Welfare of Postgraduate Research Students should be followed by supervisors (12).

20. Supervisors should monitor all stages of the research process, including outlining or drawing up a hypothesis, preparing applications for funding, protocol design, data recording and data analysis, and the sorting of primary data. Supervisors must also be aware of the broader development needs of research trainees in accordance with best practice in their discipline.

Training

21. Departments should have in place systems that allow students (both undergraduate and postgraduate) and new researchers to understand and adopt best practice as quickly as possible. In the case of undergraduate students who carry out research projects they must receive relevant training at the start of the project, however for postgraduate research students this should be mandatory as part of their first year training.

22. All researchers should undertake necessary training appropriate to their discipline, for example in research design, regulatory and ethical approvals and consents, equipment use, safe methods of working, confidentiality, data management, record keeping, and data protection. Records should be kept by the department of all such training.

23. Where appropriate all staff, researchers and students should, as part of their training, be made aware of relevant College policies such as the Research Good Practice, Ethics Guidelines, Financial regulations, PI Statement of Responsibilities, Health and Safety, Data Protection, IP policy and any other relevant guidelines which may come into force from time to time. All of Royal Holloway Policies are accessible from the following weblink: http://www.rhul.ac.uk/For-Staff/intranet.html .

Primary data/samples and consent form participants

24. 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, and of the results of the research. In areas of work where it is appropriate, the data should be obtained and handled in accordance with the relevant national and international guidelines and funders' requirements (eg Human Rights, Data Protection, European Directives and Conventions)

25. Researchers, including undergraduates and postgraduates, 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 of queries about either the conduct of the research or the results obtained. Where there is work which follows required procedures this must be documented and a process must be in place to track any document revisions. As good standard practice it is suggested that departments should

implement a system of sign off by the Head of the Department or for laboratory work there should be sign off by the supervisor of the laboratory notebook.

26. Where appropriate, systems must be in place to enable samples that have been used to be tracked either during the progress of the work or following the completion of the work. Periods of storage should be agreed with funders. In the case of clinical research or social science research, where applicable, a system should be put in place to monitor that appropriate practices are followed in seeking patient consent.

27. Where the work is using experimental facilities or tools, whether hardware or software, implement a system of regular checks to ensure the quality of the data the facilities or tools provide is accurate and, where applicable, that the facilities are safe to operate. Where appropriate, the maintenance or quality control records should be kept or documented for further reference.

28. Data generated in the course of research should be kept securely in paper or electronic format, as appropriate and in accordance with the relevant national and international guidelines (eg ref Human Rights, Data Protection, European Directives and Conventions). A minimum of ten years is an appropriate retention period. However, research based on clinical samples or relating to public health might require longer storage periods to allow for long-term follow-up. Back-up records should always be kept for data stored on a computer.

29. Researchers should follow any guidelines issued by the College or relevant professional bodies, or best practice in the discipline, in relation to responsibilities and procedures for the storage and disposal of data and samples (including compliance with the requirements of the Ethics Committee).

Ethical practice

30. The College has detailed procedures to ensure that all research, whether it be carried out by staff or students, is conducted ethically. These should be adhered to and followed where applicable and requested by the funder. In the case of a collaborative project it maybe sensible to get agreement between the partners that one HEI's Research Ethics Committee (REC) will review the proposals on behalf of all the partners.

31. Individual researchers should follow their department's ethical approval process, if one exists. These departmental processes allow for any research proposals to be referred to the College Ethical Committee for further advice. If there are no departmental processes, an application can be made directly to the Ethics Committee. Where the work involves access to NHS patients, staff and resources, data then it is important that all college staff and students associated with the research activity are aware that they need to get approval from the appropriate NHS Ethics Committee. Approval from other regulatory bodies such as the Human Fertilisation and Embryology Authority or the Gene Therapy Advisory Committee in the UK should also be sought where necessary.

32. The approval of the College's Ethics Committee must be obtained in advance for any experiment/study involving human subjects which might give rise to ethical problems.

Research proposals must be scrutinised with reference to the Notes for Guidance produced by the Committee. The Committee's remit covers any study involving human participants which might give rise to ethical problems eg. involving the use of drugs, invasive procedures or hypnosis; involving people receiving medical treatment or in care; utilising deception techniques; asking participants directly about sensitive issues; and studies which may cause changes to behaviour or life expectations of participants. The Committee reserves the right to give approval conditional on amendments to research design/methodology or to refuse approval. Where necessary, for example in new and emerging activities, the College Ethics Committee may recommend a continual process for ethical monitoring.

33.   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. See the College's Data Protection Policy on the web site at http://www.rhul.ac.uk/For-Staff/Codes-of-practice/Data-Protection-Policy-Jul02.pdf

Independent Review, Costing and Financial Management

34.   Where activities have not undergone external review, consideration should be given to putting in place some form of review. This also applies to commercially sensitive work and, where appropriate, this will also apply to research work carried out by students. The review should be a) independent (ie no conflicts of interest) and will reflect the nature of the work (eg for students' projects this could be review by a staff member with relevant expertise)   b) carried out by an expert with understanding of the clinical and research methodologies and outcomes and c) recorded. For confidential and commercially sensitive work, the issue of confidentiality needs to be considered. A Non-Disclosure Agreement (NDA) can be signed with the 3rd party reviewer but permission must be secured from the commercial partner or users in such cases. The Research and Enterprise Office can assist with this.

35.   Researchers should ensure that they are familiar with and adhere to the policies and procedures laid down by the College's financial regulations with regards to expert accounting input (usually from the Finance Department) into costing and monitoring of research. These include meeting the requirements of the internal monitoring of grant finance and the reporting of expenditure statements to funders. If Royal Holloway is the lead organisation then the lead researcher must also ensure that, where appropriate, all collaborators are aware of these requirements and that their organisations are able to comply with these requirements as necessary.

36.   The lead researcher from Royal Holloway must ensure that the proposal has been produced in line with the College's costing and pricing procedures and policy, as laid down in the internal authorisation procedures at the following web link: http://www.rhul.ac.uk/research-and-enterprise/CategoryTemplate.asp?LEVEL=SECONDARY&DID=1&CID=19&TID=0

37.   and http://www.rhul.ac.uk/restricted/finance/Finreg2006.html.

38.   Attention is also drawn to the relevant College policy and procedures at the following web link: http://www.rhul.ac.uk/For-Staff/intranet.html and the PI Statement of

Responsibility http://www.rhul.ac.uk/research-and-enterprise/CategoryTemplate.asp?LEVEL=SECONDARY&DID=1&CID=19&TID=0 .

Monitoring

39. Activities should be monitored effectively and the level of audit should be commensurate with the volume of research and the level of risk. All activity leaders must be aware of the College internal audit procedures which are there to monitor the financial aspects related to the activity. The College Ethics Committee or a departmental ethics committee may sample a random selection activities to ensure that they are meeting the requirements of this policy document.

Publication practice, knowledge transfer and IP protection

40. Results should be published in an appropriate form, for example as papers in refereed journals or at conferences.

41. 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.

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

43. More specific processes maybe required where the publication relates to an activity that has either potential for being protected or involves the NHS or deals with an area that has sensitive implications eg personal health data. In such cases the activity leader must ensure that a procedure is in place for reviewing and approving work prior to publication and that all the partners are aware of these procedures. Particularly where the work is likely to impact on health care and service delivery patterns, mechanisms should be in place to follow up and record publications or other forms of dissemination and the impact they will have on these areas.

44. Where the activity has potential for being commercialised the activity leader must ensure that they contact the Research and Enterprise Office as early as possible in order to access where the work has any value in generating third stream revenue and whether it is worth protecting it. Where Royal Holloway is the lead partner we should ensure all collaborators are aware of the requirements on them to bring to our attention activities that have a potential for being protected. In this respect all relevant parties must be familiar with the College's IP policy.

External collaboration, external participants and research sponsors

45. All collaboration with researchers outside the College including Visiting Researchers must be carried out under terms that are fully understood by all parties concerned. In the case of a short-term, small collaboration a simple letter may suffice. In the case of

a longer-term collaboration involving considerable resources of staff time or money, additional care must be taken; if the contribution of each party is not spelled out in a research proposal made to a funding body or similar, this must be outlined in the Collaborative Agreement or a Memorandum of Understanding (MoU). This must be approved by the Research Committee and the collaboration must be governed by a Management Committee whose responsibilities are clearly defined in the Collaborative Agreement or MoU. Written records of meetings of such Management Committees must be kept.

46.   In the case of activities that involve non clinical and clinical work and which involves NHS staff or patients, human organs, tissue or patients' data the following should be observed:

   i.   Where there are no collaborators then Royal Holloway assumes the role of Research Sponsor. In the case of a collaborative project one of the partners must take the role of the Research Sponsor. Only organisations that have signed up to the DH Research Governance Framework can act as Research Sponsors. Royal Holloway has signed up to the DH Research Governance Framework. The DH Research Governance Framework places particular responsibilities on the Research Sponsor and activities that fall under this area must meet the requirements laid down in this framework. Keys aspects of this framework have been incorporated into this policy document. If Royal Holloway takes on the role of Research Sponsor then it is the College's responsibility to ensure that all partners are aware of the requirements of the Research Governance Framework and that by signing the Collaborative Agreement they have indicated their ability to meet the requirements of the framework. If a researcher works with a particular NHS Trust on a regular basis it maybe possible to draw up a generic agreements with that Trust that will cover all future activities. In such cases contact the relevant Ethics Committee for that NHS Trust.

  ii.   For non NHS staff an honorary contract may be required with the relevant NHS trust.

47.   Assistance with developing collaborative agreements can be obtained from the Research and Enterprise Office.

15 February 08

References and acknowledgments

1. Economic and Social Science Research Council (ESRC) Research Ethics Framework www.esrc.ac.uk

2. Department of Health (DH) Research Governance for Health and Social Care www.dh.org.uk

3. BBSRC, DFERA, FSA and NERC Joint Code of Practice

4. Economic and Social Science Research Council (ESRC) Guidelines on Safeguarding Good Scientific Practice www.esrc.ac.uk

5. Wellcome Trust Guidelines on Good Research Practice www.wellcome.ac.uk

6. Engineering and Physical Science and Research Council (EPSRC) Guidelines on Safeguarding Good Scientific Practice www.epsrc.ac.uk

7. MRC Good Research Practice: Medical Research Council Ethics Series www.mrc.ac.uk

8. AHRC Research Good Practice

9. NERC Research Good Practice

10. STFC Research Good Practice

11. BBSRC Research Good Practice

12. Royal Holloway Code of Practice for Inquiring into Allegations of Misconduct in relation to Academic, Research and Scientific Activities. www.rhul.ac.uk/For-Staff/Codes-of-practice/Allegations-of-Misconduct.pd

13. Committee on Publication Ethics – The COPE Report 1999 www.publicationethics.org.uk and the COPE guidelines on Good Publication Practice www.publicationethics.org.uk/cope2002/pdf2002/21330_pp48_52.pdf

14. Association of Medical Research Charities Guidelines on Good Research Practice www.amrc.org.uk

15. Code of Good Practice in Research – University of Glasgow www.glasgow.ac.uk

16. Good Practice and misconduct in academic research: a policy document, August 2000 – University of Kent at Canterbury www.ukc.ac.uk

17. Scientific Misconduct: Procedures for raising and inquiring into allegations – Public Health Laboratory Service http://www.phls.co.uk/

18. Department of Health Research Governance Framework http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/index.htm

19. DIUS - Rigour, respect and responsibility: A universal ethical code for scientists http://www.berr.gov.uk/dius/science/science-and-society/public_engagement/code/page28030.html

20. The UK Panel for Research Integrity in Health and Biomedical Sciences http://www.ukrio.org.uk/home/

We would like to acknowledge reference to Research Good Practice documents developed by University of Glasgow and University of Kent in developing these guidelines.