Good Research Practice Guidelines

The University of Cambridge's Guidelines on Good Research Practice have been developed to articulate the importance of integrity and rigour in all research carried out at and in partnership with the University. They are informative, rather than prescriptive. They offer assistance to researchers in helping them to determine how to apply the baseline standards set by ordinances and regulations of the University, as well as by wider legal and contractual requirements and ethical norms, to the concrete situations which face them in everyday practice of research.

The practice of research will require adherence to principles of ethics and integrity that may vary in their details according to the type of research undertaken. Thus these general guidelines may need to be supplemented by other research-related policies, guidelines and principles. Links to additional guidance provided by funders, the University and other organisations are provided at the end of this document and in the relevant sections.

This policy will be routinely reviewed every three years unless earlier revision is required due to a major change in the legislation, regulations and guidance that govern good research practice.

The University welcomes feedback on the content of this document. Anyone with comments or suggestions regarding the guidelines is invited to send them to researchintegrity@admin.cam.ac.uk.

Table of contents

Section 1 - Introduction	pp. 1-2
Section 2 - Integrity	p. 3
Section 3 - Openness	p. 4
Section 4 - Professional guidance and legislation	pp. 4-5
Section 5 - Leadership and co-operation	p. 5
Section 6 - Supervision	p. 5
Section 7 - Training	pp. 5-6
Section 8 - Primary data, samples and equipment	pp. 6-7
Section 9 - Dissemination and publication of results	pp. 7-8
Section 10 - Intellectual property	p. 8
Section 11 - Ethical practice	pp. 9-11
Section 12 - Patient and consumer involvement	p. 11
Section 13 - Collaboration	p. 11
Section 14 - Acknowledgements	p. 12
Section 15 - Relevant university policies and guidelines	p. 12
Section 16 - International guidance	p. 12

1. Introduction

The University of Cambridge is committed to conducting its business in accordance with the seven principles identified by the Committee on Standards in Public Life (selflessness, integrity, objectivity, accountability, openness, honesty and leadership)

and is responsible for ensuring that its research is carried out in conformity with current legislation (Council's Statement on Corporate Governance contained in the Reports and Financial Statements for the year ended 31 July 2013, Reporter, No. 6329, 10 December 2013). The University expects all those engaged in research to observe these principles, whether they are employees of the University, or students, and irrespective of the sources of their funding, or their area of research.

Researchers should make efforts to understand and meet the expected standards of integrity and good practice relevant to their work. To facilitate such efforts, this document provides guidelines on good practice in research. It is intended for all staff, including persons with honorary positions, and students carrying out research at or on behalf of the University. Research involving humans, human tissue, personal data and animals raises specific ethical issues, which are addressed in Section 11.

1.1 Funder requirements

Research funders cannot be prescriptive about individual approaches taken by researchers to solving particular research problems. However, funders can reasonably expect the University to ensure that an adequate policy framework exists that promotes and promulgates good research practice, that emphasises integrity and rigour in research, and that facilitates the development of a culture in which the following general principles can be understood and observed. Such expectations are set out in Universities UK's *Concordat to Support Research Integrity* which has been signed by the University's leading funders, including RCUK, HEFCE and the Wellcome Trust. Compliance with the Concordat is a condition of receipt of funding.

Many funders have published their own policies, including RCUK's *Policy and Guidelines on the Governance of Good Research Conduct* and the Wellcome Trust's *Guidelines on Good Research Practice*. A list of relevant policies and guidance from various *funders* is provided at the end of this document. Researchers should ensure that they are aware of and abide by all policies and guidelines that apply to their research.

Research Councils and charities fund for public benefit, and in the case of charities within their charitable objects, and impose certain obligations and restrictions on the use of their funds, for example a requirement to disseminate research findings, and a proscription on funding research for the purpose of direct commercial or private gain. Researchers should be aware of these obligations and seek advice where required. It should be noted that the University also has charitable status and thus has an obligation to disseminate research findings and not undertake research for direct commercial or private gain (see Section 10).

Researchers should report any significant changes in the direction of funded research to the funder or any other relevant body. Best practice would be to discuss any change in direction of the research with the funder prior to its implementation. Most funding agreements will provide a mechanism for handling this process.

The University's Research Operations Office can provide guidance on funder requirements and funding agreements.

2. Integrity

All individuals involved in research at Cambridge are expected to observe the highest standards of integrity, honesty and professionalism in respect of their own actions in research and in their responses to the actions of others. This applies to the whole range of research work including, but not limited to: designing studies and experiments; generating, recording, archiving, analysing and interpreting data; sharing data and materials; applying for funding; presenting and publishing results; training new researchers, staff and students; and peer reviewing the work of other researchers. The direct and indirect contributions of colleagues, collaborators and others should be acknowledged. (see Section 10).

The University expects research results to be checked for accuracy and consistency by the researchers responsible for them before being made public. Researchers must be able to explain and justify how results were reached.

The University is committed to upholding the commitments outlined in Universities UK's *Concordat to Support Research Integrity*. This requires those involved in research to abide by national, European and international standards of research integrity and to embed good practice in every aspect of their work. All researchers should be aware of their responsibilities under the Concordat. A summary of the standards to which researchers are expected to adhere is provided in the *University's Statement on Research Integrity*.

2.1 Research Misconduct

Allegations of misconduct in research are rare but the University takes them very seriously. The University is committed to ensuring that allegations of misconduct in research are investigated with all possible thoroughness and vigour.

All members of the University, and individuals permitted to work in University institutions, have a responsibility to report any incident of misconduct, whether this has been witnessed, or is suspected.

The University's definition of research misconduct and approach to managing these issues is described in detail in the University's policy on "Misconduct in Research".

2.2 Conflict of interest

Researchers should declare and manage any real or potential conflicts of interest, both financial and professional. The University's Financial Regulations contain further information on the declaration of personal interests.

Researchers should ensure that they abide by any conflict of interest requirements of funders or that are otherwise relevant to their research. In particular, researchers should be aware of EU terms and conditions and the specific requirements of the US Public Health Service (which includes the National Institutes of Health).

3. Openness

Whilst recognising the need for researchers to protect their own intellectual property rights (IPR), the University encourages researchers to be as open as possible in discussing their work with other researchers and with the public. The aim in disseminating charity-funded or University research is to increase knowledge and understanding: its purpose should not be primarily to seek publicity for the researcher, for the University or for the funder.

The University is committed to disseminating research and scholarship as widely as possible, whilst affirming academic freedom to choose the location and nature of publication. In keeping with this commitment, the University supports its staff in making their research available through Open Access. Where research funders include Open Access requirements as a condition of grant funding, researchers are expected to ensure that they comply with such requirements.

Once results have been published, the University expects researchers to make available relevant data and materials to other researchers, on request, provided that this is consistent with any ethical approvals and consents which cover the data and materials, confidentiality considerations, and any intellectual property rights in them. Many funders will have data sharing policies that must be abided by where appropriate. Procedures for managing the transfer of materials in and out of the University are described on the Research Operations and Cambridge Enterprise websites and within the University's financial regulations. Funders recognise that publication of the results of research may need to be delayed for a reasonable period pending protection of any intellectual property arising from the research. Any such periods of delay in publication should be kept to a minimum and this should normally be no more than three months.

Researchers should be especially careful when discussing work that is not complete or has not been published, particularly if it has not undergone peer review.

4. Professional Guidance and Legislation

Where available, the University 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, which regulate their work including health and safety legislation, the Data Protection Act and the Freedom of Information Act. Detailed information is available from the University's Health and Safety Division and Information Compliance web sites respectively.

The University maintains a Data Protection Notification (registration) with the Information Commissioner, the independent authority responsible for overseeing compliance with the Act. This outlines, in very general terms, the personal data being processed by the University. The notification can be found on the ICO website (registration number Z6641083).

Legislation that is specific to research involving humans, human tissue, and animals is referred to in Section 11 below.

5. Leadership and Co-operation

Heads of institutions and their senior colleagues should ensure that a research climate of mutual co-operation 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.

Efforts should also be made to foster an environment where research is conducted in accordance with good research practice and to ensure that all those involved in research are made aware of these guidelines and related policies and guidelines (see section 13). Senior researchers should make particular efforts to help new members of the scientific community understand and adopt best practice. Within a research group, responsibility to ensure that good research practice is maintained throughout the research process ultimately lies with the group leader.

6. Supervision

The University wishes to ensure that appropriate training and direction of research and supervision of researchers is available. Training in supervisory skills is provided as part of the University's overall staff development programme.

The University also provides guidance for supervisors and the Code of Practice for Research Students clearly sets out supervisor responsibilities.

Supervisors should supervise all stages of the research process, including outlining or drawing up a hypothesis, preparing applications for funding, the design of experimental or research protocols, data recording and data analysis.

7. Training

The University offers many courses to enable students and new researchers to understand and adopt best practice in research as quickly as possible. Supervisors should encourage students and colleagues to attend relevant courses as part of their overall career development. Lists of courses are available on the Personal and Professional Development web site and relevant courses are increasingly available as part of the University's teaching programme. The University therefore expects researchers, where relevant, to undertake appropriate training in, for example:

- Research design
- Regulatory and ethics approvals and consents
- Equipment use
- Health and safety
- Record keeping
- Data protection
- Management of intellectual property, including confidential information

- Use of materials requiring statutory registration such as radioisotopes, pathogenic and GM organisms
- Data management
- Obtaining Home Office licences when using animals in medical research
- Involvement of patients and consumers in research
- NHS research governance requirements
- Conduct of clinical trials.

8. Primary Data, Samples and Equipment

8.1 Ownership and responsibilities

There should be clarity at the outset of the research programme as to the ownership and use of, where relevant:

- Data and samples used or created in the course of the research
- The results of the research
- Patient questionnaires
- Equipment paid for by funders.

The responsibilities and procedures for the storage and disposal of data and samples (including compliance with the requirements of any ethics committee) should be made clear at the commencement of any project. Any research collaboration agreement relating to the research should contain clauses describing any necessary arrangements.

8.2 Research data

Research data should be generated using sound techniques and processes and accurately recorded in accordance with good research practices by those conducting the research. When collecting personal data, researchers must comply with the Data Protection Act 1998. This will include explaining to any participants in their research what they will be doing with their data, who will have access to it, and who (if anyone) they intend to pass it to outside the University. This is doubly important to researchers who intend to share the personal data of their research participants with any collaborators or funders based outside of the EEA, in which case the consent of the research participants is usually required for the transfer to be deemed lawful. Further guidance on data protection is provided by the Information Compliance Office.

All research data must be managed and curated effectively throughout its lifecycle to ensure integrity, security and quality and where possible to support new research and research data sharing. Data stored locally on a computer should be backed-up. Electronic files containing personal data should be encrypted or password protected and access to them should limited to as few people as possible. Further guidance on storage of NHS data is provided on the Clinical School's Information Governance Website. It is of paramount importance that confidentiality, where required, is maintained.

Retention periods for research data will vary according to specific contractual requirements and the nature and sensitivity of the research. Most funders consider a minimum of ten years after the completion of a project to be an appropriate period. However, research based on clinical samples or relating to public health may require longer storage to allow for long-term follow-up to occur. Researchers should adhere to guidance provided by funding bodies, professional guidance, School or local policies, as well as University requirements as set out here and in the guidance on records management.

8.3 Record keeping

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 the conduct of the research, the results obtained, or inventorship on patentable inventions.

9. Dissemination and publication of results

The University encourages the publication of and dissemination of results of high quality research but believes that researchers must do this responsibly and with an awareness of the consequences of any such dissemination in the wider media. Dissemination will normally be a requirement of research council and charity funding.

The University tries to ensure that any funders who do not require dissemination understand that researchers must have academic freedom and funders should not discourage publication nor the dissemination of research or research findings. Funding agreements will normally require funders to be informed of any potential publication or dissemination of the research findings. This will enable the funder in question to have adequate time and accurate information to protect any arising intellectual property or to plan their own public relations, in conjunction with the University. Publicity may be important to industrial funders and to fund-raising charities and is increasingly important to the University itself. Advice on press releases and publicity can be obtained from the University's Office of External Affairs and Communications.

Arrangements and responsibilities for the publication of results should be taken into account when planning a study and should ideally be agreed by all investigators at the outset. These should be revisited where role and contributions change over the life cycle of the study. Such discussions might include authorship, authorisation for the content of papers, and the intended place of publication. Researchers should take into account the following guidance when publishing or disseminating their research or research findings including any plans they may have to publish or publicise research at conferences or on web sites.

- Research should normally be peer reviewed prior to it being published, publicised or disseminated. If research is placed in the public domain before peer review has been undertaken, the researcher must make this clear in any publicity.

- Funding sources should normally be acknowledged in any publication or publicity.
- Results of research should be published in an appropriate form.
- Anyone listed as an author on a paper should accept responsibility for ensuring that he or she is familiar with the contents of the paper and can identify his or her contribution to it. Honorary authorship is not good practice.
- The contributions of formal collaborators and all others who directly assist or indirectly support the research should be both specified and properly acknowledged.
- Researchers should make every effort to ensure that research is disseminated in a responsible manner, in such a way that results are not overstated or hyped. The Research Communications team can advise on how best to achieve this aim.
- Similarly, in accordance with the Concordat on Openness on Animal Research, where research has been conducted using animal models, this should be clearly stated in press materials and news stories.

Examples of good publication practice can be found in the Committee on Publication Ethics guidelines "*Code of Conduct*", *the International Committee of Medical Journal Editors Recommendations* and on the Nature web site.

10. Intellectual Property

The University's Intellectual Property Policy can be found in Chapter XIII of the University's Statutes and Ordinances. Clarification regarding certain clauses is provided in a Guidance Note approved by the Research Policy Committee.

The Research Operations Office and Cambridge Enterprise have produced a Guidance Note on how the Intellectual Property Policy operates, which has been approved by the Research Policy Committee.

Cambridge Enterprise Ltd., is a wholly owned subsidiary and exists to help University of Cambridge inventors, innovators and entrepreneurs make their ideas and concepts more commercially successful for the benefit of society, the UK economy, the inventors and the University. Further details of the University's approach to managing intellectual property are available on the Cambridge Enterprise website.

The University, which has charitable status, carries out research and the research councils and charities fund research for public benefit and not for direct commercial or private gain. Public benefit may arise from education, i.e. the gain of knowledge that is placed in the public domain, or in the case of biomedical research improvement in the treatment or care of patients or in the prevention or cure of diseases. Although the University cannot carry out research solely for the purpose of commercial gain, commercial benefit from the exploitation of the results of research may, subject to expectations of funders, accrue to their inventor(s), the University and, by agreement, to the funder of the research. Commercialisation may also be the most effective means of disseminating research results and accruing public benefit.

11. Ethical practice

All research carried out at the University must comply with relevant legal, regulatory, professional and ethical requirements and standards. Researchers should be familiar with, and know how to access such requirements including University ethical guidance and policies. Researchers who are unsure whether such requirements apply to their projects should seek advice.

Researchers should work to ensure that, throughout the lifecycle of their investigations, ethical issues relating to their research projects are identified and managed. Ethical issues should be interpreted broadly and may encompass areas where regulation and approval processes exist as well as areas where they do not. All appropriate licences, permissions and approvals must be in place before research starts and be updated as necessary if plans change.

11.1 Ethical practice in research involving human participants, human tissue and personal data

All research involving human participants or personal data carried out by University employees or on University premises must abide by departmental and faculty research ethics policies and the University's Policy on the Ethics of Research Involving Human Participants and Personal Data.

Researchers are required to consider the ethical risk of any procedure within a research project which involves human participation or personal data, consulting the relevant Faculty, Department, School and University policies and personnel before any work is undertaken. Advice must be sought in case of doubt. Where the need for formal review is identified, reasonable and proportionate independent ethical review must be carried out prior to research work commencing.

Details of the University's research ethics review system, including contact details for research ethics committees, are available on the *Research Integrity website*.

The ethical issues that researchers encounter in their work may vary according to the type of research they undertake. As such, researchers should familiarise themselves with the ethical guidance relevant to their subject area or issued by their department or funder. The University's research integrity website provides information on many of the key guidance documents.

There are some particular considerations that will apply to certain types of research involving human participants, human tissue or personal data:

Those undertaking social research involving human participants may find it particularly useful to consult the ESRC's Framework for Research Ethics, compliance with which is compulsory for ESRC-funded research.

Most research involving NHS patients, staff or facilities will come under the Research Governance Framework for Health and Social Care and will require review by a National Research Ethics Service (NRES) Committee. Some other research will also

require NRES review for legal and policy reasons. Details of when NRES review is needed are provided on the Health Research Authority Website. In some cases it may be also appropriate to seek the views of relevant patient groups.

Those undertaking research at the Clinical School should be familiar with and comply with the research governance information provided by the School

Researchers must also comply with the Human Tissue Act. This regulates the removal, storage and use of human tissue – defined as material that has come from a human body and consists of, or includes, human cells. Guidance on the act and links to further information is provided here.

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 Section 4 above).

The University reminds researchers of the importance of obtaining necessary regulatory approval from bodies such as:

- Human Fertilisation and Embryology Authority
- Gene Therapy Advisory Committee.
- Medicine Healthcare Regulatory Authority

11.2 Research involving animals

The University and its funders require that research involving animals should have been subject to the following (through the appropriate bodies):

- Ethical Review Process
- Home Office licence application.

Researchers are required by law to consider the opportunities for Reduction, Replacement and Refinement of animal involvement in research – the principle of "The Three Rs". The University recommends that researchers refer to the relevant national guidelines on the appropriate and ethical use of animals in research. Publications using data acquired from animal research must follow the principles of the ARRIVE Guideline (Animal Research: Reporting In Vivo Experiments.) All animal research is overseen by the University Biomedical Support Service (UBSS) and in compliance with University Animal Welfare Policy, Codes of Practice and Procedures. In accordance with the Concordat on the Declaration of Openness in Animal Research, there is a requirement to support the University's goal of appropriate openness and transparency with respect to our use of animals.

11.3 Research misuse, non-proliferation and dual-use research

Researchers must consider any risks that their research will generate outcomes that could be misused for harmful purposes both when setting up research collaborations,

communicating results and teaching (particularly teaching postgraduates in ATAS regulated subject areas).

Where risks exist, they must seek advice and take active steps to minimise them.

Researchers must also comply with all legal requirements relating to non-proliferation and dual-use, particularly export controls. Export controls apply to the transfer (by any means) of goods, technology, software and/or knowledge from the UK to a destination outside the UK that may be used for military purposes or for Weapons of Mass Destruction purposes. For more information on export control and the types of research that may be affected see the Research Operations Office's guidance.

12. Patient and consumer involvement

Researchers should consider and be aware of the active involvement of patients and consumer groups in research and in the dissemination of research findings. Where possible, and most often for studies involving patients and volunteers, researchers should engage with service-users, carers, representative groups and other stakeholders and beneficiaries in the design, conduct, analysis and reporting of research. It is important that researchers in the biomedical areas consider the impact any publication of research findings may have on patients with the condition under investigation, those involved in their care, those involved in the research and on consumer groups.

Further details about user involvement may be found in the MRC's *Good Research Practice guidelines*.

13. Collaboration

Research is increasingly collaborative, involving individuals from different disciplines and from institutions within and beyond the UK. In establishing research collaborations researchers should be mindful of the University's policies and guidelines, as well as funder, legal and regulatory requirements, and ensure that research partners and their employing institutions are able to meet the required standards of research conduct. There needs to be clear agreement on and articulation of the standards and frameworks that will apply to collaborative work.

This is particularly important in relation to the provenance of intellectual ideas and ownership of research outcomes as well as the specific conditions under which these may be shared. All parties should be clear about their respective roles and responsibilities within the collaboration, which should be set out in any formal collaboration agreement. The Research Operations Office can advise and has various model agreements for use in such collaborations.

Guidance on research integrity in collaborative research is provided by the Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations.

14. Acknowledgements

Association of Medical Research Charities (AMRC), Guidelines on Good Research Practice (2002)
AHRC, Research Funding Guide (January 2014)
BBSRC, Statement on Safeguarding Good Scientific Practice (October, 2013)
EPSRC, Funding Guide (January, 2014)
ESRC, Framework for Research Ethics (September 2012)
ESRC, Research Funding Guide (February, 2014)
MRC, Good Research Practice: Principles and Guidelines (July, 2012)
NERC, Research Grants and Fellowships Handbook (June, 2014)
RCUK, Policy and Guidelines on Governance of Good Research Conduct (February, 2013)
Universities UK, The Concordat to Support Research Integrity (July, 2012)
Wellcome Trust, Guidelines on good research practice (November, 2005)

15. Relevant University Policies and Guidelines

Clinical School research governance website
Export Control
Financial regulations
Health and Safety Office
Information Compliance Office website
Intellectual Property policy
Office of External Affairs and Communications
Open Access Policy Framework
Open Access support site
Policy against bribery and corruption
Policy on Misconduct in research
Policy on the Ethics of Research Involving Human Participants and Personal Data
Policy on the use of animals in research and teaching
Research Operations Office – research policies
Statement on research integrity
University research integrity website
University Library - Data management guidance
'Whistleblowing' policy

16. International guidance

European Science Foundation, The European Code of Conduct for Research Integrity (March 2011)
2nd World Conference on Research Integrity, Singapore Statement on Research Integrity (July, 2010)
3rd World Conference on Research Integrity, Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (May, 2013)
The Office of Research Integrity (ORI)