

SEN11D016

Title: Guidelines on Good Practice in Research
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Issue

To update the UEA Guidelines on Good practice in Research to reflect changes to legislation and other regulatory frameworks.

Recommendation

To recommend that the updated Guidelines be adopted with immediate effect.

Resource Implications

Not applicable

Risk Implications

Without these updates, the Guidelines will become inaccurate and not support UEA researchers in adhering to the most relevant legislation and regulatory frameworks. For example, the MHRA picked up inaccurate references to NHS Research Ethics structures in its report following inspection in January 2011.

Other than updates to external legislation, policy documents and regulatory structures, the content of the guidelines remain the same as approved by Senate in November 2009. This version (with additions to para 7 on the FoIA, EIR and DPA) has been approved by Research Executive on 19 January.

Equality and Diversity

One of the updates required was to references to the equality legislation in para 13.

Timing of decisions

After approval by Senate, the Guidelines will be updated on UEA's website and a notice sent round to all staff. Additionally, a one pager is being prepared to promote the guidelines in other fora (e.g. introductory conference for staff) and the guidelines will be agenda items for the Research Staff Working Group and the PGR Executive to consider any action needed to support its implementation.

Further Information

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Background

The Guidelines form an essential part of UEA's research governance framework and is frequently required by funders of research as evidence of our research management infrastructure.

Discussion

No targeted discussion points identified.

**UNIVERSITY OF EAST ANGLIA
GUIDELINES ON GOOD PRACTICE IN RESEARCH**

The Guidelines on Good Practice in Research were last reviewed in November 2009. A review of the guidelines was required in light of:

- Updates to external policies and organizations already referred to:
 - RCUK Policy and Code of Conduct on the Governance of Good Research Conduct (updated October 2010),
 - Clinical Trials legislation,
 - The body overseeing NHS Research Ethics,
- Increasing requirements from funders to have data management plans in place as reflected in the RCUK Common Principles on Data Policy (April 2011),
- Update to UEA policies governing the conduct of research degrees (October 2011) ,
- Introduction of joint NNUH and UEA standard operating procedures for healthcare research (January 2012),
- A new Pro-Vice-Chancellor for Research and Enterprise (August 2011),
- The formation of Research and Enterprise Services (August 2011).

As a result, very minor changes are incorporated within the existing paragraphs which update references and include minor editing changes.

Research Executive is asked to consider the amended version of the Guidelines of Good Practice in Research for approval by the Senate and to note that a regular review of these guidelines is proposed for every two years.

Sue Steel and Rachael Mold
Research and Enterprise Services, 16 January 2012

UNIVERSITY OF EAST ANGLIA GUIDELINES ON GOOD PRACTICE IN RESEARCH

Foreword by PVC for Research, Enterprise and Engagement:

As a University committed to excellence in the quality of the research our staff and students undertake, it is essential to have a document such as this which provides guidelines on good practice in research.

The following guidelines serve both as a means of developing and supporting a culture of good practice in research and as a means of demonstrating to the organisations we work with that UEA is committed to a culture and environment where high standards of personal and professional conduct are encouraged and expected

There is something in these guidelines for everyone to reflect on during the course of their research: new and experienced researchers, staff and students, and scientific and arts and social sciences disciplines alike.

More detailed information is available on the Research, Enterprise and Engagement website.

I recommend these guidelines to you whatever your role in the conduct of research at UEA. These guidelines have evolved over recent years in response to internal and external requirements. Should you have any comments on the further development of these guidelines, I would be pleased to receive them.

Professor David Richardson
date

GUIDELINES ON GOOD PRACTICE IN RESEARCH

A. The Principles of Good Research Practice

Introduction

1. Honesty, openness, accountability and integrity are vital qualities for any academic researcher no matter what their discipline or level of experience. The University of East Anglia needs to ensure that all research it supports is carried out in a climate where high standards of personal conduct are encouraged and expected. The University expects all staff and students engaged in research to act with the highest standards of integrity irrespective of the source from which their post or research is funded.

2. This document provides guidelines on the issues involved in the proper conduct of research, and on the standards expected. Whilst detailed aspects of these guidelines are more applicable to some subject areas or groups of people than others, the principles of good research practice are relevant to all subject areas.

3. This document is intended for:

- Academic, research and relevant support staff employed by the University, and other individuals carrying out research at, or on behalf of, the University,
- Students undertaking research and their supervisors,
- Any persons with honorary positions conducting research within, or on behalf of, the University.

4. The term 'Researchers' has been used throughout this document to refer collectively to the above groups of people. The term 'Research' has been used throughout this document to refer to all aspects of the research process including outlining or drawing up a hypothesis,

preparing applications for funding, protocol design, generating data, data recording and analysis, writing-up and publishing and other forms of disseminating results.

Principles of Good Research Practice

5. It is important that a culture of honesty, integrity, openness and accountability in research be fostered and maintained. The University cannot be prescriptive about approaches taken by individuals to solving particular research problems. However, in the conduct of all research, the University expects the following general principles to be understood and observed by all researchers:

- Maintaining open and honest professional standards;
- Ensuring leadership, organisation and cooperation in research groupings;
- Taking special account of the needs of inexperienced researchers;
- Planning and conducting research in accordance with the requirements of funders and the University and all relevant codes of practice, legislation and regulatory bodies;
- Documenting fully results and any research material used, questioning one's own findings and acknowledging honestly the contribution of others;
- Ensuring data is stored, shared, preserved and disposed of in an appropriate and responsible manner
- Ensuring the results of the research are disseminated widely
- Taking appropriate measures to protect intellectual property
- Following best current professional, clinical and ethical practice.

B. Management of Good Research Practice

Professional Standards

6. Honesty. At the heart of all research, regardless of discipline or institution, is the need for researchers to be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to all aspects of the research process.

7. Openness. While recognising the need for researchers to protect their own research interests in the process of planning their research and obtaining their results, the University encourages researchers to be as open as possible in discussing their work with other researchers within and outside the University and with the public. Researchers should contact Research and Enterprise Services (REN) for advice on releasing results that might affect the potential to protect the research at a later date. Once results have been published, researchers should make available relevant data and materials to others on request for appropriate purposes, according to current University guidelines.

However, researchers must also take into account legislation affecting the storage and release of data. For example:

The Freedom of Information (FOI) Act came into effect in January 2005 and aims to promote transparency and accountability in the public sector. Under the terms of the Act, individuals have the right to request any information that is held by the University including all digital and print records and information whether current or archived. There are situations where information is not required to be released, or should not be released due to exemptions. The University, as a public body, is obliged to comply with the Act, and all staff have the responsibility to make themselves aware of their obligations under the Act.

The Environmental Information Regulations (EIR) came into effect in 2004 and aims to encourage access to environmental information and to promote wide and systematic dissemination of environmental information to the public. Under the terms of the Regulations, individuals have the right to request any environmental information that is held by the University including all digital and print records and information whether current or archived. There are situations where information is not required to be released, or should not be

released due to exemptions. The University is obliged to comply with the Regulations, and all staff have the responsibility to make themselves aware of their obligations under the Act.

The Data Protection Act 1998 (DPA) places responsibilities and obligations on the University in the way that it processes information about living individuals. The Act gives individuals certain rights and also specifies that those who record and use personal data must be open about how that information is used and must follow the eight Data Protection Principles when processing that information.

8. **Accountability.** Researchers, and in particular those named as Principal Investigators, must ensure that the research that they are undertaking is consistent with the terms and conditions covered by agreements between the University and the funder. This includes, but is not restricted to, ensuring that the research programme carried out is as defined in the original proposal to the funder, unless amendments have been agreed in writing; that the finance is used solely for the research purpose that it was intended; that reports are both accurate and produced on time; and that conditions relating to publication and ownership of Intellectual Property are adhered to.

9. **Integrity.** Researchers must be honest about conflict of interest issues, whether real, potential or perceived, at the earliest opportunity and at all stages of research, e.g. when applying for funding, when identifying collaborators and when reporting results. Plagiarism, deception or the fabrication or falsification of results is regarded as a serious disciplinary offence. All researchers are encouraged to report cases of suspected misconduct or malpractice and to do so in a responsible and appropriate manner in accordance with the University's procedures for dealing with misconduct in research and for disclosing concerns about malpractice.

Leadership and Organisation in Research Groupings

10. Within the University, it is the responsibility of the Vice-Chancellor, Pro-Vice-Chancellors, and Heads of Schools to ensure that a climate is created which allows research to be conducted in accordance with good research practice.

11. Within a research grouping, responsibility lies with the Group Leader/Research Co-ordinator (or equivalent). Where there are no research groupings, the responsibilities of Group Leader shall fall to the Head of School (and may be delegated to a nominee such as the Chair of a relevant Committee). Group Leaders should create a research environment of mutual cooperation, in which all members of a research team are encouraged to develop their skills and in which the open exchange of ideas is fostered. They must also ensure that appropriate direction of research and supervision of researchers is provided, which in the case of students undertaking research should comply with University and National codes of practice and in the case of Research Staff in accordance with the Concordat to Support the Career Development of Researchers. Responsibilities in conducting research should be clearly allocated and understood.

The Needs of New Researchers

12. Researchers who are new to the academic community may face particular difficulties. Responsibility for ensuring that new researchers understand good research practice lies with all members of the community, but particularly with Group Leaders, or Heads of School where there are no Group Leaders or equivalent. Good practice includes the induction of researchers to their new environment and the relevant School and University procedures.

Training and Supervision of Researchers

13. All researchers should receive good supervision appropriate to their experience. Researchers should not be put under unwarranted pressure to produce results. Supervision should include all relevant stages of the research process. Group Leaders, or Heads of Schools where there are no Group Leaders or equivalents, are responsible for ensuring that all new researchers undertake appropriate training in accordance with their specific

requirements and the University's Equal Opportunities and Diversity strategy details of which are available from the Human Resources website. Training in supervisory skills should be provided where appropriate. Particular requirements apply in the case of postgraduate research students and are set out in the "Guide to Good Supervisory Practice" and in "Research Degrees- The Code of Practice 2011".

Planning and Conducting Research

14. In applying for external funding, researchers should take all reasonable measures to ensure accuracy of information and compliance with University procedures.

15. Purchasing and expenditure of funds should be in accordance with the terms and conditions of any grant or contract held for the research and the University financial regulations. The financial regulations are available on the Finance Intranet pages. Any further guidance on compliance with the financial regulations in the conduct of research should be sought from Research and Enterprise Services.

16. Researchers need to establish whether ethical approval is likely to be needed for a research project in accordance with the University's Research Ethics Policy and associated guidance which are available on the Research and Enterprise Services (REN) intranet.

17. All research that includes the appointment of researchers must be carried out in a manner that complies with:

- the University's policies on Equal Opportunities and Diversity,
- the Concordat to Support the Career Management of Researchers,
- the Health and Safety at Work Act (1974) and the Safety Regulations approved under this Act,
- the University's safety policies,
- the University's safety rules
- and other University safety management documents.

School safety policies and handbooks should detail local safety rules that must also be followed. Advice on health and safety issues should be sought from School Safety Advisers or the University Safety Services.

18. All members of research groupings should be made aware of the:

- Legal and ethical requirements, including the UEA/NUH joint Standard Operating Procedures, relating to human participants, animals and personal information
- Requirements on confidentiality of data and publications
- Information legislation including the Freedom of Information Act (2000) and Environmental Information Regulations (2004) as they apply to research www.jisc.ac.uk/foiresearchdata
- Appropriate methods of record keeping, data management, including storage and disposal relevant to the discipline
- The importance of recognising and reporting unforeseen results or incidents
- All other relevant guidance, codes of practice and regulations related to their work

C. Research Results

The Need for a Critical Approach

19. Researchers should always be prepared to question the outcome of their research. The University expects all research results to be checked before being made public. It is important that research ideas can be challenged and tested once published.

20. It is important that researchers or research groupings should not become subject to other pressures such that the normal processes of research inquiry cannot be enforced, e.g. by constraints imposed by the source of funding of the research. Any pressure to produce results that suit the specific interests of a funder must, of course, be resisted. This is particularly the case where the individual researcher(s) could be perceived to have a conflict of interest, e.g. where they might have an equity share in the funder, or may hold a position (e.g. Director) or be involved in consultancy with the funder. Any such conflict of interest, whether real, potential or perceived, should be disclosed at the earliest opportunity to the Head of the School (or other equivalent senior officer in non-School units) or to the Pro-Vice-Chancellor if the office holder is involved.

Documenting Results

21. Throughout their work researchers should keep clear and accurate records of the procedures followed, of the sources of research material where archives, collections etc. are researched and of the results obtained, including interim results. 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 ownership of the data or results. Proper documenting and storage procedures will minimise cases of allegations of research misconduct where original data 'have disappeared' or allegedly been lost or cannot be replicated.

22. It is the duty of the researcher to comply with the regulations of the Data Protection Act currently in force and to ensure that copyright, a third party's intellectual property rights and confidentiality are not breached. The Data Protection Act applies to research that involves personal data collected about living individuals and requires that such data should not be used for purposes other than those for which it was collected. Advice on compliance with the Data Protection Act should be sought from the University's Information Compliance Manager <http://www.uea.ac.uk/is/strategies/infregs/dp/contact>.

23. In cases where transcripts of interviews are the basis for research, these should be kept as confidential according to the procedures in place when ethical approval was given for the research. In clinical studies, consent forms should be kept securely with the raw data. In social sciences and humanities research, any sources (e.g. other published works, archives, collections) should be accurately recorded and any transcription or data archive rules recorded at the start of the project to ensure consistency. The keeping and maintenance of laboratory notebooks, and other data sources, can also help to ensure that intellectual property can be protected. In all cases, research data should be managed in line with the data management plan prepared as part of the research grant application, or at the beginning of the research project.

Storage and Disposal of Data

24. Primary data which is the basis for publications should be securely stored for an appropriate time in a durable form, in accordance with the Data Management Plan, and funder requirements. The means of data storage (paper, disk, electronic data archive etc) should be appropriate to the task, and for studies involving humans and animals must be consistent with the methods set out in the proposal awarded ethical approval. Provision should be made for the automatic back-up of data or software stored on a computer and special attention should be paid to guaranteeing the security of electronic data. Advice should be sought from Information Services (contact Research Computing Services www.uea.ac.uk/is/research-computing)

25. The appropriate period for retaining data depends on circumstances (e.g. in some fields, the importance and relevance of data can be superseded very rapidly). Equally, where the research is externally funded, the time for keeping data may be specified by the funder. The appropriate timescales and mode of data storage and the process for review in the light of changing technology should be confirmed in writing at the outset of the research programme.

26. Disposal of data and samples should be carried out in accordance with the appropriate

internal or external procedures according to the nature of the research data and any ethics committee requirements.

Publishing Results

27. The issue of authorship is important in the context of good research practice, and the University expects the matter to be taken seriously. The University expects anyone listed as an author on a paper to accept personal responsibility for ensuring that they are familiar with the contents of the paper.

28. In order to ensure a high standard of publication, researchers should seek an appropriate form of peer review prior to publication.

29. If an error is found that diminishes the worth of the published results, the researcher should discuss the matter with the lead researcher and notify any co-authors. A correction should be published as soon as possible setting out the basis of the reservation. Where the findings are found to be in serious doubt, a retraction should be published speedily.

30. The standard position of the University is that research should be published when appropriate and wherever possible. This is a necessary adjunct to making research available to the public and is frequently a condition imposed by funders. Delays in publication should be avoided except, for example, in relation to proprietary information of the University or the funder incorporated in the research results or where journals require amendments or modifications. Where the University and/or the funder wish to secure patent protection for inventions made in the course of the research, short delays in publishing are acceptable to allow patents to be filed. Access to a thesis may be restricted in accordance with the Consultation and Borrowing of Theses set out in the University calendar.

Acknowledging the Role of Collaborators and Other Participants

31. Any person who participates in a substantial way in conceiving, executing or interpreting a significant part of the relevant research should be given the opportunity to be included as an author of a publication derived from that research. The practice of honorary authorship is unacceptable, i.e. only those who have participated in the research should be listed. The contributions of formal collaborators and all others who directly assist or indirectly support the research should also be properly acknowledged. This applies to any circumstances in which statements about the research are made, including provision of information about the nature and process of the research, and in publishing the outcome. Where appropriate, the funders of the research and other collaborating bodies should be acknowledged.

D. Exploitation and Protection of Intellectual Assets

32. The University recognises there are instances where the potential for exploiting intellectual property (IP) generated by research is important both to improve economic competitiveness and to generate revenue. The potential to exploit IP should be considered at the application and contract stages and certainly before data are submitted for publication or presented in any other public forum including the internet.

33. The ownership, protection and exploitation of IP is governed by the University's Intellectual Property Regulations published in the Calendar. The advice of Research and Enterprise Services should be sought in all instances where a potential to exploit IP generated by the University is identified or where data or resources belonging to another organisation are required to conduct the research.

E. Professional, Clinical and Ethical Practice

34. The University Research Ethics Policy applies to:

- all University researchers (staff and registered students) who are conducting or contributing to research activities either within or outside the University as an institution;
- all individuals who are not members of the University (including visiting academics and Fellows) but who are conducting or contributing to research activities which take place within the University as an institution;
- all investigations which may have ethical dimensions and put people or the University at risk.

35. The standards of scientific practice set out in guidelines published by scientific societies and other relevant professional bodies should be observed by researchers.

36. Researchers involved in clinical research must comply with:

- the current Good Clinical Practice Guidelines published by the International Conference on Harmonisation,
- the Medicines for Human Use (Clinical Trials) Regulations 2004,
- the Department of Health Research Governance Framework for Health and Social Care,
- the Human Tissue Act 2004,
- the Mental Capacity Act 2005,
- the UEA/NNUH Joint Standard Operating Procedures.

Particular attention should be given to:

- Maintenance of confidentiality,
- Informed consent,
- The allocation and agreement of Sponsor responsibilities for designing, managing, financing, conducting and analysing the research between the individual researchers, the University, appropriate NHS Trusts and any other external organisations involved in the research,
- Noting serious adverse events or serious drug reactions,
- Seeking appropriate NHS Research Ethics Committee approval, NHS Research Governance approval and/or independent review.

37. Research must only be carried out when all the necessary approvals, notifications and licences required by University Committees and legislation, through national and local regulatory bodies, are in place. The Group Leader (or Head of School) should ensure that the appropriate approvals are identified, obtained and documented prior to the start of the research.

38. These are the minimum standards expected of researchers and do not override or replace any professional codes or practices, or those codes or practices governing the terms of any external funding received by researchers to carry out their research work, which must be followed in addition to these guidelines.

F. Misconduct

39. The University takes seriously any allegation of research misconduct and has a written procedure for investigating and resolving any such allegations. Any member of the University who believes that an act of research misconduct has occurred or is occurring should notify the Head of the School (or other equivalent senior office in non-School units) or his/her deputy if the office holder is involved in the allegation, in the first instance in accordance with the Procedures for Dealing with Allegations of Misconduct in Research.

Other References

Internal Documents

- University Calendar
- UEA's Research Ethics Policy (15 June 2011)
- UEA Intellectual Property Regulations (University Calendar)
- Procedures for Dealing with Allegations of Misconduct in Research (March 2006)
- Research Degrees - The Code of Practice (August 2008, amended October 2011)
- Health and Safety Responsibilities for Academic Supervisors, Lecturers and Principal Investigators
<https://intranet.uea.ac.uk/uss/intranet/safetysubjects/Individuals'+Responsibilities+for+Health+and+Safety>
- Equal Opportunities and Diversity <https://intranet.uea.ac.uk/hr/intranet/eod>
- Equal Opportunities in Employment: Code of Practice
- Financial Regulations
- Public Interest Disclosure: A Procedure for Staff to Raise Concerns About Malpractice
- Consultation and Borrowing of Theses (University Calendar)
- Freedom of Information <https://www.uea.ac.uk/is/foi>
- Data Protection <https://www.uea.ac.uk/is/strategies/infregs/dp>
- Environmental Information Regulations

External Information

- RCUK Policy and Code of Conduct on the Governance of Good Research Conduct (updated October 2010)
- UKRIO Code of Practice for Research (2009)
- Research Governance Framework for Health and Social Care, Department of Health (2005)
- Good Clinical Practice Guidelines, International Conference on Harmonisation ICH GCP E6 (2002)
- EU Clinical Trials Directive (2001/20/EC) (as updated)
- Office of Research Integrity
- Committee on Standards in Public Life
- Arts and Humanities Data Services, Guides for Good Practice
- RCUK Common Principles on Data Policy (accessed 13 January 2012)
- National Research Ethics Service (NRES)
- FOIA on ICO webpage -
http://www.ico.gov.uk/for_organisations/freedom_of_information.aspx
- New guide to FOIA in 'plain English' -
http://www.ico.gov.uk/for_organisations/freedom_of_information/guide.aspx
- ICO – Freedom of Information and Research -
http://www.ico.gov.uk/for_organisations/guidance_index/~media/documents/library/Freedom_of_Information/Detailed_specialist_guides/foi_legislation_and_research_guidance_for_the_higher_education_sector.ashx
- DPA at JISC Legal Code of Practice for HE & FE -
<http://www.jisclegal.ac.uk/ManageContent/ViewDetail/ID/125/Data-Protection-Code-of-Practice-for-FE-and-HE-09052008.aspx>
- EIR on ICO website -
http://www.ico.gov.uk/for_organisations/environmental_information.aspx
- Copyright at JISC Legal - Copyright Law Essentials -
<http://www.jisclegal.ac.uk/ManageContent/ViewDetail/ID/2028/Copyright-Law-Essentials-14042011.aspx>

In formulating these guidelines, the University has been informed by:

- Code of Good Practice in Research, University of Edinburgh
- Code of Good Practice in Research, University of Glasgow
- Good Research Practice, Medical Research Council
- Good Clinical Practice Research Guidelines, The Wellcome Trust Clinical Research Facility at the Queen Elizabeth Hospital, Birmingham
- Code on Good Research Practice, University of Surrey
- Guidelines on Good Research Practice, The Wellcome Trust
- BBSRC Statement on Safeguarding Good Scientific Practice
- Association of Medical Research Charities, Guidelines on Good Research Practice
- Policy and Guidelines for Conflicts of Interest, University College London
- Guidelines on Good Practice in Academic Research, Kings College London

University of East Anglia, July 2003 (updated April 2006, November 2009, ADD IN DATE OF REVISION ON APPROVAL)