

Cardiff School of History and Archaeology

Ethical Approval of Research with Human Participants, Human Material or Human Data

Background

In 2003, following a review of the existing University procedures for research management and for considering ethical aspects of research, University Research Committee decided that a more consistent approach should be adopted throughout the University. From 1 August 2004 the University requires that all research involving human participants or human material or human data is subject to formal ethical review and approval before such work can be started.

Who is Affected?

This guidance applies to all staff and students in the Cardiff School of History and Archaeology undertaking research in their capacity as members of Cardiff University. In the case of students, it covers research undertaken by a student currently registered for a degree within the School as a recognised part of his or her degree programme. In respect of non-student research, the University policy of ethical review and approval of non-clinical research with human participants, human material or human data applies to all individuals carrying out research under the aegis of Cardiff University. This includes all University employees, whether the work is undertaken within or outside University premises and all visiting researchers of the University irrespective of whether they are employed by the University, including persons with honorary positions, conducting research within, or on behalf of, the University.

What Research Does It Cover?

This guidance covers all research involving human participants or human material or human data. It applies whether the research is funded or not and whatever the source of funding. The ethical review process does not include research where the information about human participants is publicly and lawfully available, e.g. information published in the census, population statistics published by government departments, personal letters, diaries etc held in public libraries.

INFORMATION ON SUBMITTING APPLICATIONS TO THE SCHOOL RESEARCH ETHICS COMMITTEE

Introduction

Before you can start any non-clinical research project involving human participants, human material or human data in the School, you have to obtain formal approval from the School Research Ethics Committee (SREC). This is a group of people within the School who discuss research submissions and decide whether, on ethical grounds, the research can proceed as proposed. The Committee's terms of reference are simple: to receive research proposals from students and staff of the School and to consider any ethical issues that might arise from carrying out this research.

The SREC can make three main kinds of decision on the proposal. Either the project is approved as it stands, or it is accepted subject to specified alterations, or it is rejected. You will receive a letter as soon as possible after a decision has been made telling you what the SREC has decided and (if relevant) why it has made the decision and what you now have to do. No contact with research participants may be made before you have received approval from the SREC. Please also note that if your project is approved subject to specified alterations, you may NOT proceed to have contact with research participants until these changes have been made. In certain cases the SREC may require that the changes are approved by the Chair of the SREC.

The Committee, which is a sub-committee of the School's Research Committee, consists of a Chair, two academic members, and a lay-member (who is not formally associated with the School). It meets three times a year (1 October, 1 December, 1 May), but you need to submit your proposal at least **2 weeks** before the appropriate meeting date. In **exceptional** circumstances the Committee will try to assess proposals faster, but this may not always be possible.

It is very important to note that on their application forms many research councils (including the AHRC) ask applications to confirm that the research proposed has been approved by the applicant's home institution. The HISAR SREC is the body to grant that approval. Because of this, it is very important to plan submissions of applications to the SREC well in advance of any research council grant deadline.

How The SREC Decides

The SREC is guided by (but not bound by) the guidelines of the relevant professional organisation. These include research ethics guidelines from the following organisations.

Economic and Social Research Council' Research Ethics Framework
(http://www.esrc.ac.uk/esrccontent/ourresearch/research_ethics_framework.asp)

The European Association of Archaeologists (<http://www.e-a-a.org/eaacodes.htm>)

The Institute for Field Archaeologists
(<http://www.archaeologists.net/modules/icontent/index.php?page=15>)

The International Council of Museums <http://icom.museum/ethics.html>
(see especially the Bogota Declaration's Policy on the Illegal Looting and Export of Antiquities (http://icom.museum/bogota_fr.html))

The Oral History Society (<http://www.oralhistory.org.uk>)

The Vermillion Accord on Human Remains (1989)
(<http://www.wac.uct.ac.za/archive/content/vermillion.accord.html>)

Applicants are advised to consult the guidelines of these organisations. In addition, we are all guided by general principles of ethical research with human participants and by any guidance promulgated by the funders of a specific research project. Links to the relevant guidelines are available on the RACD web-site.

Specific Categories of Ethics Research

While ethical guidance must be sought in all ranges of research, there are particular common types of activities in which HISAR researchers most frequently engage. The majority of these activities concern the collection and analysis of data about living people and the collection and analysis of information about ancient people and artefacts as well as the care of ancient sites, monuments and landscapes. The following list of activities presents some of the activities which particular attention to ethical guidelines.

1. Working With People

The SREC wants to know that the safety and well being of research participants is assured, that the applicant is aware of any possible ethical issues in carrying out the research and that steps have been taken to ensure that best practice is followed. We also draw your attention to the section below entitled 'recruiting participants'. It is very important that people are aware that you

respect their confidentiality and that, where possible, rigorous steps will be taken to preserve anonymity.

2. Working With Children

You must satisfy yourself that there is a real need to involve children in the research and be able to justify this to the SREC. You must check and comply with any legal requirements, such as vetting procedures for working with children, before you proceed with such work. The responsibility for checking and complying with such legal requirements is yours. Where consent is given by parents, it is still important to try and obtain real consent from the child; assuming the child is old enough to understand this principle. For older children, they would normally be expected to give their signed agreement to take part in the same way as adults. Even where children are younger, where the child is capable of understanding, the researcher should explain to the child that what they are doing is entirely voluntary and that they can refuse to take part if they wish.

3. Working With Potentially Vulnerable Adults

You must satisfy yourself that there is a real need to involve potentially vulnerable adults, for example those with severe learning disabilities, and be able to justify this to the Committee. You should ensure that you have familiarised yourself with the relevant legal position, where it is intended to conduct research with adults who may not be able to give a legally valid consent to take part in research.

Where the proposed research participant is in a dependent relationship to the researcher (for example, where the research participant is a student) the researcher must make it clear that a decision to take part or not to take part in the project will in no way affect the individual's relationship with the researcher and the researcher must ensure that this is the case.

Where the proposed research participant is in custody the researcher must make it clear that a decision to take part or not to take part in the project will in no way affect the individual's situation and the researcher must ensure that no informal coercion takes place.

4. Researching Persons Engaged In Potentially Illegal Activities

Before starting a project that will involve research with persons engaged in potentially illegal activities you need to consider under what circumstances you might be legally required to divulge information about your research participants. You need specifically to consider when to anonymise your research data. You also need to consider under what circumstances you might become implicated in the illegal activities and how you will ensure that this does not happen.

5. Excavations and analysis of ancient human remains and artefacts

Before carrying out any research on the objects, people or other remains of the past, all researchers must consider the ethical implications of their research. There are particularly precise issues surrounding the study of human remains, access to the archaeological landscape (i.e., permissions to excavate) and the curation of artefacts. All of the major archaeological associations have published codes of conduct and codes of conduct (the major ones are listed above). Your attention is drawn specifically to the codes for the European Association of Archaeologists, the Institute for Field Archaeologists, and the International Council of Museums. Also to be consulted is the Policy on the Excavation, Conservation, Display and Storage of Human Remains adopted by signatories to the Vermillion Accord on Human Remains.

In any application to the SREC, you will need to show that you are aware of the ethical issues that engage your research and you will need to show how your research programme takes account of these issues in an explicitly and satisfactory manner. Work that is being undertaken outside of the UK may have particular ethical requirements. It is your responsibility to find out what these are.

Recruiting Participants

The doctrine of **valid consent** operates here. That is, participants should enter into the research freely and willingly and know and understand what they are agreeing to when they take part. They should be told they have the right to withdraw from the research at any time. Wherever possible, anonymity and confidentiality should be maintained. If the experimental design necessitates some deliberate deception then, after the experiment is finished, participants should be told the purpose of the experiment and why information was withheld or why they were misled.

Electronic Recruiting

Electronic recruiting is acceptable within the following limitations (some of them set by INSRV to reduce unnecessary web traffic):

- Any mailing to an identifiable group of people (e.g. to all of the students in a School or a class) should be brief and succinctly explain the nature of the research and the criteria for participation;
- Clear indication that this is a request for help from a researcher should be given at the beginning;
- If the reader of the e-mail is interested in participating then he or she should be asked to contact the researcher directly (not a group reply), or referred to a Web page where the research information is located;
- Under no circumstances should University Office telephone numbers be given as contacts for student research. Under no circumstances should file attachments to group messages be used;
- The Cardiff University Information Services Postmaster must be asked for permission to send e-mails to group addresses. As well as complying with data protection principles this will also provide a means of monitoring the use of email across campus for research of this kind. The researcher should check that they are complying with data protection principles in the use of personal information;

Issues to Consider when Providing Information to Potential Participants

By far the greatest number of amendments that Ethics Committees ask to be made concern the information that will be given to participants. You must take time over this aspect as it is essential to explain what you are asking people to do and the possible implications so that they can make a proper decision for themselves whether they wish to take part. You must clearly explain the following matters in terms that an ordinary person, rather than a specialist in your field, can understand:

- that you are inviting them to take part in a research project;
- who you are – a student/your role in the University;

- the nature, risks (if any), benefits (if any), duration and purpose of the research project. This must include clear information about what the participant will be asked to do, where the research will be carried out, any risks to the participant's health and safety and the steps that will be taken to minimise those risks;
- that participation in the project is entirely voluntary;
- if the project is funded (and if so, by whom);
- what the information gathered is intended to be used for, including whether it is intended to publish the results;
- the arrangements concerning confidentiality of, and access to, information about the research participant;
- how the research participant can obtain further information about the project (such as by the provision of work contact numbers/email for the researcher; home contact numbers should not be given nor should university office numbers be given where the researcher is a student.);
- whom the research participant can contact if they are concerned about any aspect of how the research was conducted. This would normally be the Chair of the School Research Ethics Committee. You should give the research participant a copy of the information sheet to keep.

Consent Forms

It would normally be expected that proposed research participants would be asked to give their agreement in writing on a consent form. Ideally, the information sheet should be separate from the consent form and the SREC will wish to receive a copy of both. You should ensure that, before written consent is given, the proposed participant has been given the opportunity of reading the information sheet and asking questions about the research. For this reason, sufficient time must be provided between the request to take part and the signing of the document, unless there are specific reasons why this cannot be done. Participants' signatures do not normally need to be witnessed.

Exceptionally, it may be unnecessary or inappropriate to seek written consent although this will need to be clearly justified to the SREC. For example, in cases where you are, for example, handing out questionnaires that do not ask probing questions and it is clear from the front sheet what is going to be asked then we can assume that the act of accepting the questionnaire implies consent by the respondent. There may be other situations too where provision of an information sheet would be sufficient. Where, for good reason, written consent is not sought, you must still ensure that you give proposed research participants sufficient time to read the information about the research and ask questions.

Confidentiality of Information Obtained During Research

You must familiarise yourself and comply with current legal requirements for storage of and access to data about research participants. You must consider the method of keeping personal data about research participants and how to anonymise information about them, where appropriate.

Payment to Research Participants

If people taking part in your research are to be offered any payment or incentive to do so over and above appropriate expenses, you must explain this in your application. Any form of payment

or incentive to take part will need to be clearly justified to the School Research Ethics Committee.

Informing Research Participants of the Results of Research

You are encouraged to consider the issue of informing research participants of the results of the research or where they may be able to get access to this information, although research participants may not be able to be given their individual results. Taking part in non-clinical research is a voluntary matter requiring good-will on the part of the community and it is appropriate for research participants to be able to receive feedback on research they have been involved in where this is possible.

Making an Application to the School Research Ethics Committee if you are a Member of Staff or a MPhil / PhD Student

There are five stages in preparing an application to the Research Ethics Committee. These are:

1. Discuss any ethical issues you have about the conduct of your research with your coinvestigator(s) and/or supervisor(s).
2. Prepare your submission. Use the **staff proforma** provided on the School web-site for your submission.
3. Append ALL required documents.
4. Sign and date the form and ask any co-investigator/supervisor to sign.
5. Submit two copies of your application to the secretary of the School Research Ethics Committee or one set electronically.

Making an application to the School Research Ethics Committee if you are an Undergraduate or Masters Student

There are four stages in preparing an application to the Research Ethics Committee. These are:

1. Discuss any ethical issues you have about the conduct of your research with your supervisor(s).
2. Fill in the **student proforma** provided on the School web-site for your submission.
3. Sign and date the form and ask your supervisor to sign the supervisor declaration.
4. Submit two copies of your application to the secretary of the School Research Ethics Committee or one set electronically.

The School Research Ethics Committee Meeting

The Committee does not normally interview the researcher or request their attendance when the proposal is considered, although it may invite the researcher to attend if it is believed that this would assist the Committee. Researchers may also request the opportunity to address the Committee. Members of the Committee must withdraw from consideration of any submission in which they are researchers or supervisors. For a list of forthcoming meeting dates, please see the School Research Ethics website pages.

Powers of the School Research Ethics Committee

The Committee may:

- 1) authorise the research to proceed without requiring any amendment. Any such authorisation is granted on the basis of the project proceeding stated on the research submission. Any material changes must be notified to the Committee (see below) and renewed approval obtained before proceeding;
- 2) require clarification or modification of parts of the research submission. The Chair will generally be granted the authority to approve the amendments without requiring to call a further meeting of the full Committee;
- 3) defer consideration of a proposal to a subsequent meeting if substantial modifications are required or where significant additional information is required;
- 4) reject the research proposal in whole or in part;
- 5) refer university students or staff to the University's Research Ethics Committee if issues of concern arise from the conduct of the research.

As part of their assistance to researchers, the Committee will ordinarily give reasons for requiring modification to proposals, rejecting them or for revoking approval. The Committee may call for reports on the conduct of the research during projects and on completion to help the Committee in formulating its guidance and so that the Committee can be assured that projects continue to conform to approved ethical standards. This will not in any way reduce the responsibility of the researcher to ensure such conformity. The Committee will maintain a record of all proposed research projects, and may require a formal report on completion of the project in order to review the outcome of the research.

Appeals

If you are dissatisfied with the decision made by the School Research Ethics Committee you should in the first instance discuss this with the School Ethics Officer. If discussion is unable to resolve the issue satisfactorily an appeal against the decision of the School Research Ethics Committee may be made to the University Research Ethics Committee via the School Ethics Committee and the Head of School. However, it should be noted that the University Research Ethics Committee will not normally interfere with a School Research Ethics Committee decision to require revisions to the project, such as to amend an information sheet or consent form. The University Research Ethics Committee is concerned only with the general principles of natural justice, reasonableness and fairness of the decision made by the School Research Ethics Committee

School Ethics Officer (terms of reference)

At the University's request the Head of School has designated a School Ethics Officer responsible for the management of ethical issues in research in the School. The School Ethics Officer (and also the Chair of the School Research Ethics Committee) is:

Dr Douglass W. Bailey

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The responsibilities of the School Ethics Officer are as follows:

- 1) ensuring that there are effective mechanisms to bring any policy, guidelines or procedures developed with or through the University Research Ethics Committee and the School Research Ethics Committee (SREC) to the attention of staff and students for whom the School is responsible. These mechanisms are intended to clarify that it is a University requirement that these policies, guidelines and procedures are followed;
- 2) keeping School ethical issues in research under review;
- 3) managing and monitoring the procedures in practice;
- 4) advise school staff with regard to research ethics issues (students should primarily be advised by their supervisor);
- 5) respond initially to any complaints that research is carried out that is either 1) not approved by the SREC, or 2) not conducted in conformity with the proposal approved by the SREC;
- 6) ensuring that appropriate records of applications, practices and decisions are made and kept;
- 7) reporting to the Head of School as appropriate;
- 8) reporting to the School through an appropriate forum;
- 9) reporting on an annual basis on behalf of the School to the University Research Ethics Committee;
- 10) conducting a three yearly review of School ethical procedures and reporting the outcome to the University Research Ethics Committee;
- 11) being eligible for membership of the University Research Ethics Committee which entails attending meetings of the University Research Ethics Committee and dealing with the work of that Committee.

Douglass W. Bailey
28 April 2005