

ETHICAL APPROVAL OF RESEARCH WITH HUMAN PARTICIPANTS, HUMAN MATERIAL OR HUMAN DATA WITHIN THE SCHOOL OF DENTISTRY AT CARDIFF UNIVERSITY

SCOPE OF THE GUIDANCE

WHO DOES IT APPLY TO?

This guidance applies to all staff and students in the School of Dentistry 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. While in general work carried out as part of the teaching of the programme falls outside the scope of this guidance, consideration should be given to the ethical implications of experiments involving the use of student volunteers.

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.

BACKGROUND

In 2003, following a review of the existing University procedures for research management and for considering ethical aspects of research, it was decided by the University Research Committee 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.

Scope of Research involving Human Participants, Human Material and Human Data in the School of Dentistry

The great majority of research involving humans conducted with the School of Dentistry will be deemed “Clinical-research” and as such is subject to rules for ethical approval laid down by the National Research Ethics Service (NRES).

Therefore any research involving humans within the following categories fall within the remit of the Dental School Research Ethics Committee:

1. patients and users of the NHS. This is intended to mean all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.
2. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
3. access to data, organs or other bodily material of past and present NHS patients;
4. fetal material and IVF involving NHS patients;
5. the recently dead in NHS premises;
6. the use of, or potential access to, NHS premises or facilities;

All research in the above categories must receive ethical approval from the appropriate NHS Local / Multi-centre Research Ethics Committee (LREC / MREC).

In addition studies which:

- are defined as clinical trials by the Medicine for Human Use (Clinical Trials) Regulations Act 2004
- involve patients who lack or will potentially lack mental capacity as defined in the Mental Capacity Act 2005

also require review via the NHS LREC/MREC mechanism.

However, you may be conducting **non-clinical research**, which involves healthy volunteers. Research may also be undertaken on tissue or fluid samples taken from healthy volunteers. Surveys and questionnaires on issues such as lifestyle, housing and working environments, attitudes and preferences may also form part or the whole of research projects.

Undergraduate or postgraduate students may undertake research as part of their degree work. It may also be undertaken by members of staff either as part of individual or team research work within the University or as externally contracted or funded work.

Such research, which falls within the NHS Ethical approval scheme, should be submitted to the School Research Ethics Committee for approval.

Outline Procedures for Considering Ethical Issues in Research Projects

SCHOOL ETHICS OFFICER

The School has designated a School Ethics Officer responsible for the management of ethical issues in research in the School. The responsibilities of the School Ethics Officer are as follows:

- (a) 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 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;

- (b) keeping School ethical issues in research under review;
- (c) managing and monitoring the procedures in practice;
- (d) ensuring that appropriate records of applications, practices and decisions are made and kept;
- (e) reporting to the Head of School as appropriate;
- (f) reporting to the School through an appropriate forum;
- (g) reporting on an annual basis on behalf of the School to the University Research Ethics Committee;
- (h) conducting a three yearly review of School ethical procedures and reporting the outcome to the University Research Ethics Committee;
- (i) 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.

The contact details for the School Ethics Officer are given below.

Dr Vaseekaran Sivarajasingam
 School of Dentistry
 College of Biomedical and Life Sciences
 Cardiff University
 Tel: 02920 742441
 E mail: sivarajasingam@cardiff.ac.uk

SCHOOL RESEARCH ETHICS COMMITTEE

The School Research Ethics Committee has been established to advise on ethical issues in research in the School and to assess for approval research proposals involving the issues outlined above.

Constitution and Membership of the School Research Ethics Committee

The committee will comprise:

The Chair

6 members nominated by the Dental School Research Strategy Committee

1 member from a school other than DENTL

1 lay member

Terms of Reference

The School Research Ethics Committee's terms of reference are:

- (a) to consider **non-clinical** research proposals (from both the School's staff and its students) involving human participants, human material or human data;
- (b) to either give written approval for such proposals in the form of minutes or provide written information as to why approval has not been given;
- (c) to consider revised submissions;

- (d) to refer to the University Research Ethics Committee cases which cannot be satisfactorily resolved or about which there is uncertainty;
- (e) to operate procedures no less rigorous than those suggested or required by relevant professional bodies or other organisations in the subject domain (e.g. sponsoring bodies).
- (f) to inform the University Research Ethics Committee of any changes in the ethical codes of professional bodies in relevant discipline areas, in order that the University's procedures remain valid.

Application Procedure

The procedures for considering these ethical issues are as follows:

1. Research proposals involving human participants, human material or human data will be submitted to the School Research Ethics Committee through the School Ethics Officer.
2. The School Research Ethics Committee will specify the format in which proposals should be submitted. Much of the information will be entered onto a proforma although additional information may be required in certain circumstances.
3. In the case of proposals involving an externally funded contract or sponsorship, the applicant will be provided with a checklist, which includes the requirement to confirm that academic freedom and publication rights are not compromised in any agreement. The completed checklist will be filed along with a copy of the application and any contract relating to the project.
4. The School Research Ethics Committee will consider the application in accordance with the procedures set out in Appendix A. The Committee will inform the applicant of the decision and any amendments that need to be made or reasons for not approving the research.
5. If the research application has not been approved by the School Research Ethics Committee the applicant may make an appeal concerning this decision through the School Research Ethics Committee to the University Research Ethics Committee.
6. The University Research Ethics Committee hearing the application, either as the initial review body or on appeal, will follow the procedures set out in the document '*Constitution and Operation of the University Research Ethics Committee*'.

Operating Procedures for the School Research Ethics Committee

Decisions regarding ethical approval will where possible, be by consensus following discussion. In the event that consensus is not achieved, a vote will be taken with the Convenor or Chair having the casting vote.

In the event that the committee is unable to form an opinion on the basis of the application form and protocol submitted, a decision on approval may be deferred and the applicant invited to attend the next meeting of the committee to discuss the proposed research.

Applications will be informed of the decision by letter within five working days of the committee meeting.

At the Chairman's discretion, business may be conducted through correspondence as well as by formal meetings.

MEMBERSHIP OF THE SCHOOL RESEARCH ETHICS COMMITTEE

Dr Vaseekaran Sivarajasingam (Chair)
Reader and Hon Consultant Oral Surgeon

Dr Ilona Johnson (Vice-Chair)
Senior Lecturer/Hon Consultant in Dental Public Health

Dr Charlotte Emanuel
Clinical Lecturer in Oral Surgery

Dr Damian Farnell
Lecturer in Statistics

Mr Martin Langley
Deputy Laboratory Manager

Dr Matthew Locke
Senior Clinical Lecturer/Director of H&T Programme

Professor Bing Song
Professor, Oral & Biomedical Sciences

Dr Xiao-Qing Wei
Senior Lecturer in Immunology

Dr Fiona Morgan
Staff in Healthcare Sciences
External Member

Vacant (Lay member)

Contact

Application forms and a copy of this guidance are available at
<http://www.cardiff.ac.uk/dentistry/research/ethics>

Completed application forms (3 copies) should be submitted to:

Mrs Beverley Jones
Secretary, Dental School Research Ethics Committee
Room 128, 1st Floor
Undergraduate Student Centre
School of Dentistry,
Heath Park, Cardiff. CF14 4XY.

To seek further information/advice contact:

Dr V. Sivarajasingam
School Research Ethics Officer / Chair School Research Ethics Committee
Tel: 029 2074 2441
E mail: sivarajasingam@cardiff.ac.uk

TIMING OF THE SCHOOL RESEARCH ETHICS COMMITTEE MEETINGS

The committee will usually meet on the second Tuesday of the Month, at 12.30 pm. Dates of future meetings and the deadline for applications will be posted on the dental school web site.

TIMING OF APPLICATION OF SUBMISSIONS TO THE SCHOOL RESEARCH ETHICS COMMITTEE

Applicants are required to submit three copies of the application form and their research protocol.

In order to be considered at the next meeting, applications should be received **ten** working days before the date of the committee meeting.

Links to School specific guidance

Specific guidance is contained in Appendix A of this document.

Links to general guidance on research ethics

Although clinical research falls outside the remit of the school research ethics committee, the general principles outlined in Good Clinical Practice (GCP) should be followed. Further details on GCP can be found using the links below:

Cardiff University GCP Training

<http://www.cf.ac.uk/racdv/resgov/training/>

Declaration of Helsinki

<http://www.wma.net/en/30publications/10policies/b3/>

Research Governance

<http://www.cardiff.ac.uk/racdv/resgov/>

Research Governance Training via the Graduate College

<http://www.cardiff.ac.uk/ugc/training/university-graduate-college-programme>

Human Tissue Act compliance

<https://intranet.cardiff.ac.uk/staff/research-support/integrity-and-governance/human-tissue-research>

**SCHOOL OF DENTISTRY
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. This is a group of people within the School who meet at regular intervals to discuss research submissions and to 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.

We 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 we have decided and (if relevant) why we have made the decision and what you now have to do. Please note, if your project is approved subject to specified alterations, you may NOT proceed to start the research until the Convenor/Chair of the School Research Ethics Committee has approved these changes.

In all cases (whether your submission is approved immediately or following revisions), **please make sure you retain your Ethical approval letter.**

What types of research does the Committee review?

The School Research Ethics Committee deals only with **non-clinical research**, i.e. research conducted on healthy volunteers, outside an NHS setting. If your research falls into any of the following categories, then separate arrangements exist for the ethical review of **clinical research**. Committee can approve research using previously collected samples from expired NRES approved studies, provided all material was collected prior to 1 September 2006 and all samples are anonymised.

Research that involves:

1. patients and users of the NHS. This is intended to mean all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.
2. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
3. access to data, organs or other bodily material of past and present NHS patients;
4. fetal material and IVF involving NHS patients;
5. the recently dead in NHS premises;
6. the use of, or potential access to, NHS premises or facilities;

If you are unclear whether your research falls within the remit of MDSREC then you should seek advice from the Chairman before submitting your proposal

The Committee

The Committee consists of a Convenor and twelve members. We meet monthly. The Committee will post a notice at the beginning of the year, detailing the last dates for submission for consideration. All undergraduates and postgraduate students must get formal

approval before starting any relevant research work. Staff must also submit their own research plans for ethical consideration, whether the work is funded or unfunded, if the research is being carried out in their capacity as members of University staff or using University facilities. The University policy of review of non-clinical research applies to everyone carrying out research for the University including all University employees, whether their current place of work is within or outside University premises. It also applies to all visiting researchers of the University whether or not they are employed by the University, including persons with honorary positions, conducting research within, or on behalf of, the University.

How the Committee decides

We are guided by the general principles outlined in the Declaration of Helsinki (<http://www.wma.net/e/policy/b3.htm>).

Working with people

We want to know that the safety and wellbeing 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 (such as the use of double-blind techniques).

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 Committee. You should ensure that you have familiarised yourself with the relevant legal position when it is intended to conduct research with children.

Those applicants who intend to work with children in schools must obtain written approval from the Head teacher of the school, from the Local Education Authority or any other person who is *in loco parentis*. The method of informing and, where appropriate, obtaining consent from parents to their child's participation must be clearly explained and agreed with the Head teacher of the school and must follow best practice in this regard. 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.

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.

Projects that fall within the remit of the Mental Capacity Act 2005 require review by the NHS REC.

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.

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.

Be aware that when using student volunteers in research, approval for access to the students may be required from the School as mechanisms may be in place to ensure students are not overburdened with requests to volunteer for participation in research projects.

Electronic Recruiting

On the question of recruiting participants via e-mail and the Web ('electronic recruiting') we have decided that (a) in principle we see no reason to veto this method; (b) we anticipate potential problems where the computer network would be overloaded; (c) the number of electronic recruiting proposals should be carefully monitored.

Electronic recruiting is acceptable within the following limitations:

- 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 and that the reader, if not interested, should 'hit the delete button'.
- 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 post in the University and, where relevant, your experience in conducting research of this kind
- 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)
- if the research project is part of a student's coursework
- 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
- what, if any, arrangements are in place for compensation in the event of something going wrong
- 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.)
- who the research participant can contact if they are concerned about any aspect of how the research was conducted. This would normally be the Convenor/Chair of the School Research Ethics Committee

If participation in a research project is likely to be of no direct benefit to the participants, you should explain this in the information sheet

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 School Research Ethics Committee will wish to receive copies 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. Participant's 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 School Research Ethics Committee. 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.

In most cases however, you will have to supply the Committee with a consent form.

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.

Exceptionally, small tokens of appreciation for taking part in research or the chance to win a small prize may be given, provided they are not deemed to amount to an inappropriate inducement to take part.

What happens if I want to publish the research?

There are ethical issues involved in respect of publishing research.

You must tell the proposed research participant in advance if you have any intention of publishing the results of the project. You must also explain the extent to which, if at all, any identifying information about the research participant will appear in the publication. If identifying information about the research participant is intended to be published, you must obtain and keep specific written agreement to this from the research participant. Preferably these issues should be addressed in the information sheet and consent form that are given out before the research starts. This will prevent any disappointment if the individual, when asked later, chooses not to agree and therefore reduces the value of the information that can be published.

In most cases you will not be the only person with an interest in publishing the results. Research is a collaborative activity and, in the case of student work, supervisors may expect to claim some contribution.

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

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 co-investigator(s) and/or supervisor(s).
2. Prepare your submission. Use the proforma provided at <http://www.cardiff.ac.uk/dentistry/research/ethics>
3. Cross-check your submission with the 'Minimum requirement for consideration by DSREC' (**see end of document, p14**).
4. Append ALL required documents.
5. Sign and date the form and ask any co-investigator/supervisor to sign. Unsigned submissions will not be considered.
6. Submit ten copies of your application in time for the deadline for the next meeting of the School Research Ethics Committee.

Late submissions

Please note that submissions that are received late will NOT be considered until the next meeting of the Committee, save in the most exceptional circumstances. Delay in starting research will not normally be accepted as an exceptional circumstance.

It is the applicant's responsibility to submit applications in good time and in the proper format. It is the responsibility of a student's first named supervisor to draw the student's attention to these procedures.

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. Members of the Committee must withdraw from consideration of any submission in which they are researchers or supervisors.

Powers of the School Research Ethics Committee

The Committee may:

- authorise the research to proceed without requiring any amendment. Any such authorisation is granted on the basis of the project proceeding exactly as stated on the research submission. Any subsequent changes must be notified to the Committee (see below) and renewed approval obtained before proceeding;
- require clarification or modification of parts of the research submission. The Convenor/Chair will generally be granted the authority to approve the amendments without requiring to call a further meeting of the full Committee;
- defer consideration of a proposal to a subsequent meeting if substantial modifications are required or where significant additional information is required;
- reject the research proposal in whole or in part;
- revoke approval of the research if dissatisfied with the conduct of the research or of the researcher(s);

- 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 and its contribution to knowledge.

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.

Consideration of the application by the University Research Ethics Committee

The University Research Ethics Committee will provide general advice to the School Research Ethics Committee and will refer the matter back to them with that advice for them to make a decision. In such cases, to avoid additional delay to the applicant, the School Research Ethics Committee may consider the application between meetings if necessary.

Minimum requirement for consideration by DSREC

Following this guidance will help you to avoid unnecessary delays in ethical approval.

1. Completed and signed Dental School Ethical Approval Form
2. Study Protocol to include
 - Title of project
 - Purpose of project and its academic rationale
 - Background
 - Aims
 - Objectives
 - Methods (including number of participants, age, gender, exclusion/inclusion criteria)
 - Data management including data security and archiving
 - Plan for data analyses and dissemination
 - Concise statement of the ethical considerations raised by the project and how you intend to deal with them.
 - References
3. Participant Information sheet
4. Consent Form (if required)
5. Questionnaires (if required)
6. Debrief

In addition to the above please make sure that you have:

1. Proof read for typographical errors
2. Included page number/version number/date

An example of a good submission for ethical approval can be found below: