



SCHOOL OF HEALTHCARE STUDIES
Ysgol Astudiaethau Gofal Iechyd

RESEARCH ETHICS HANDBOOK

ACADEMIC YEAR 2011/12



BUDDSODDWR MEWN POBL
INVESTOR IN PEOPLE

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The Scope of the Handbook

Who does it apply to?

This guidance applies to all staff and students in the School of Healthcare Studies 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. However, it does not cover work carried out as part of the teaching of the programme, for example, students conducting established experiments as part of their learning.

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.

If you require clarification or further information please do not hesitate to contact Paul Brown, School Ethics Officer, or Liz Harmer, Research Administrator, or see the School website at:

<http://www.cardiff.ac.uk/sohcs/research/ethics/index.html>

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School Ethics Officer
Room 4.9
Ty Dewi Sant
Ext: 87764
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Liz Harmer
Research Administrator
Room 2F08A
Second Floor
Cardigan House
Ext 87552
Email: harmerl@cf.ac.uk

The School Ethics Officer

At the request of the University the Head of School has appointed a School Ethics Officer responsible for the management of ethical issues in research in the School. The responsibilities of the Officer are as follows:

- ensuring that there are effective mechanisms to bring any policy, guidelines or procedures developed with or through the University Research Ethics Committee (UREC) 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:
- to Chair the School Research Ethics Committee;
- keeping under review School ethical issues in research;
- to advise school staff with regard to research ethics issues (students should primarily be advised by their supervisor/s);
- in conjunction with the Research Administrator managing and monitoring the procedures established within the School;
- in conjunction with the Research Administrator ensuring that appropriate records of applications, practices and decisions are retained within the School;
- to ensure that the School's established procedures for the ethical review of research are consistent with the best practice in the subject domain and conform with the requirements of the relevant professional bodies;
- reporting to the Head of School as appropriate;
- reporting to the School via School Board;
- reporting, on an annual basis, on behalf of the School to the University Research Ethics Committee (UREC);
- conducting a three yearly review of School ethical procedures and reporting the outcome to UREC.

The 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.

Terms of Reference

There shall be a Research Ethics Committee of the School of Healthcare Studies which will be sub-committee of the School Board and shall consider matters relating to the ethics of research conducted by members of staff and students of the School and grant ethical approvals where deemed to be appropriate, and, where additional external approval is required, refer proposals to the relevant external ethics committee. Where deemed appropriate it shall make recommendations to the School Board on any of the issues involved as appropriate. Without prejudice to the generality of the foregoing, the Research Ethics Committee shall:-

1. Review research proposals from staff and post graduate students the ethical requirements of the research and where appropriate grant written approval for such proposals in the form of Minutes and written communication to the proposer(s) that approval has been granted or to provide written information as to why approval has not been given;
2. To consider revised submissions from members of staff or post graduate students in the event that an original proposal had been declined and to deal with the revised submission in the same way as an initial proposal;
3. To refer to the School Board cases which cannot be satisfactory resolved or about which there is uncertainty;
4. To receive reports from departmental Undergraduate and Pre registration Ethics Groups;
5. To advise the School Board on the development and sustainability of School wide awareness of ethical issues;
6. To submit an annual report to University Research Ethics Committee.

Composition

The School Ethics Officer who shall be Chair

The Dean (ex officio)

The Director of the Department of Post Graduate and Continuing Education

The Chair of the School's Research Committee

The Chairs of the 4 Departmental Pre-registration Undergraduate Ethics Groups or their nominees

1 Representative from another School

1 lay member, not being an employee of the University

Secretarial Support – The School's Research Administrator

The Procedures

Undergraduate and Pre Registration Student Procedure

Application Process

All dissertation proposals need to be subjected to scrutiny and approval by the School. In order to manage this process the School had agreed that each Department will establish a Departmental Undergraduate and Pre Registration Ethics Group. These Groups are responsible for reviewing the scientific validity and ethical requirements of all Undergraduate dissertation proposals within a Department. All undergraduate students are therefore required to complete a research proposal form (see [appendix I](#)). This completed proposal form must be submitted to the relevant Departmental Undergraduate and Pre Registration Ethics Group, four weeks prior to the date of the departmental meeting.

Timings of Meetings

Meeting dates will be publicised to undergraduate students at the appropriate stage during their programme of study.

Membership

Chair

Vice Chair

A minimum of 3 representatives from within the department

Terms of Reference

1. To review the scientific validity of the proposed research in relation to the School's Research Strategy;
2. To review the ethical requirements of the proposed research;
3. To give written approval for research proposals in the form of minutes or to provide written information as to why approval has not been given;
4. To consider revised submissions;
5. To consider referred submissions;
6. To report to the School Research Ethics Committee on the outcome of applications;
7. To refer to the School Research Ethics Committee cases which cannot be satisfactorily resolved or about which there is uncertainty;
8. Meetings will be deemed quorate if three members are present, including the Chair, or the Vice Chair in the Chair's absence;
9. To monitor the progress of undergraduate and pre registration research within the School.

Outcomes

- 1 Pass and proceed with research
- 2 Pass and inform trust R & D
- 3 Pass and inform trust R & D and seek ethical approval from an NHS REC
- 4 Proceed with amendments, to be approved by Chair and one other
- 5 Project deferred subject to amendments, to be resubmitted to Group
- 6 Proposal rejected

Reporting procedure

A brief report of the applications considered and the outcome is sent to the Research Administrator within two weeks of the meeting and will be presented to the Research Ethics Committee at its next meeting.

Postgraduate Taught Students, Postgraduate Research Students and Staff Procedure Application Process

Postgraduate Taught Students

All dissertation proposals need to be subjected to scrutiny and approval by the School. All postgraduate taught students are required to complete the research proposal form (see [appendix I](#)); this research proposal is considered at a meeting of the School Research Ethics Committee, which is a sub-Committee of School Board. All proposal forms should be submitted to the Research Administrator no later than three weeks prior to the date of the meeting to which the proposal form is to be submitted.

Postgraduate Research Students

Scrutiny of the scientific validity of all postgraduate research students proposed research is an integral part of the admissions process and is carried out by individuals both within and external to the School. However, there is a need for the School to undertake a review of the ethical requirements of the project. All postgraduate research students are required to complete the research proposal form (see [appendix I](#)). This proposal is considered by the School Research Ethics Committee, which is a sub-Committee of School Board. All proposal forms should be submitted to the Research Administrator no later than three weeks prior to the date of the meeting to which the proposal form is to be submitted.

Staff

There is a need for the School to scrutinise the scientific validity of, and the ethical requirements of research being proposed within the School. All staff proposing to undertake research projects, that will not ultimately require the approval of a Trust R&D and/or a NHS REC, are required to complete the research proposal form (see [appendix I](#)). This proposal is considered by the School Research Ethics Committee, which is a sub-Committee of School Board.

Proposal forms should be submitted to the Research Administrator no later than three weeks prior to the date of the meeting to which the proposal form is to be submitted.

Those staff intending to carry out research using students of the School as the participants are required to complete an abridged proposal form (see [appendix IX](#))

In the cases of staff applications that will ultimately require approval by the appropriate Trust/s R&D offices and/or a NHS REC copies of the correspondence confirming the approval of the project should be sent to the Research Administrator along with a copy of the finalised project outline. An application does not need to be submitted to the School Research Ethics Committee.

For **all** applications a lead reviewer will be appointed to review the application and will be required to submit a brief written report ([appendix V](#)) to the School Research Ethics Committee.

Timings of Meetings

The School Research Ethics Committee will meet, on average, every 2 months, the meeting dates will be publicised on the School website (attached as [appendix VII](#)).

Membership

The School Ethics Officer who shall be Chair

The Dean (ex officio)

The Chair of the School's Research Committee

The Chairs of the 4 Departmental Pre-registration Undergraduate Ethics Groups or their nominees

1 Representative from another School

1 lay member, not being an employee of the University

Lead Reviewers (the expectation is that lead reviewers will attend meetings on an ad hoc basis)

Secretarial Support – The School's Research Administrator

Terms of Reference

There shall be a Research Ethics Committee of the School of Healthcare Studies which will be sub-committee of The School Board and shall consider matters relating to the ethics of research conducted by members of staff and students of the School and grant ethical approvals where deemed to be appropriate, and, where additional external approval is required, refer proposals to the relevant external ethics committee. Where deemed appropriate it shall make recommendations to the School Board on any of the issues involved as appropriate. Without prejudice to the generality of the foregoing, the Research Ethics Committee shall:-

1. Review research proposals from staff and post graduate students the ethical requirements of the research and where appropriate grant written approval for such proposals in the form of Minutes and written communication to the proposer(s) that approval has been granted or to provide written information as to why approval has not been given;
2. To consider revised submissions from members of staff or post graduate students in the event that an original proposal had been declined and to deal with the revised submission in the same way as an initial proposal;
3. To refer to the School Board cases which cannot be satisfactory resolved or about which there is uncertainty;
4. To receive reports from departmental under graduate and pre registration Ethics Groups;
5. To advise the School Board on the development and sustainability of School wide awareness of ethical issues;
6. To submit an annual report to University Research Ethics Committee.

Outcomes

1. Pass and proceed with research
2. Pass and inform trust R & D
3. Pass and inform trust R & D and seek ethical approval from an NHS REC
4. Proceed with amendments, to be approved by Chair and one other
5. Project deferred subject to amendments, to be resubmitted to sub-Committee
6. Proposal rejected

Reporting Procedure

The minutes of the meetings are presented to School Board

Amendment Procedure

In certain circumstances amendments will occur to your research proposal. Only when amendments are classed as substantial are you required to submit a revised research proposal for consideration by the Departmental Undergraduate and Pre Registration Ethics Group or the School Research Ethics Committee, where appropriate. The following outlines where amendments are classed as substantial or minor, however, if you have any questions please contact the School Ethics Officer or the Research Administrator (contact details are to be found on page 3 of this document).

Substantial Amendments

Examples of substantial amendments may be as follows:

- changes to the design or methodology of the study, or to background information affecting its scientific value;
- changes to the procedures undertaken by participants;
- any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
- changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers;
- appointment of a new chief investigator or key collaborator;
- inclusion of a new research site;
- appointment of a new principal investigator at a research site;
- any other significant changes to the protocol.

Minor Amendments.

Examples of non-substantial amendments may be as follows:

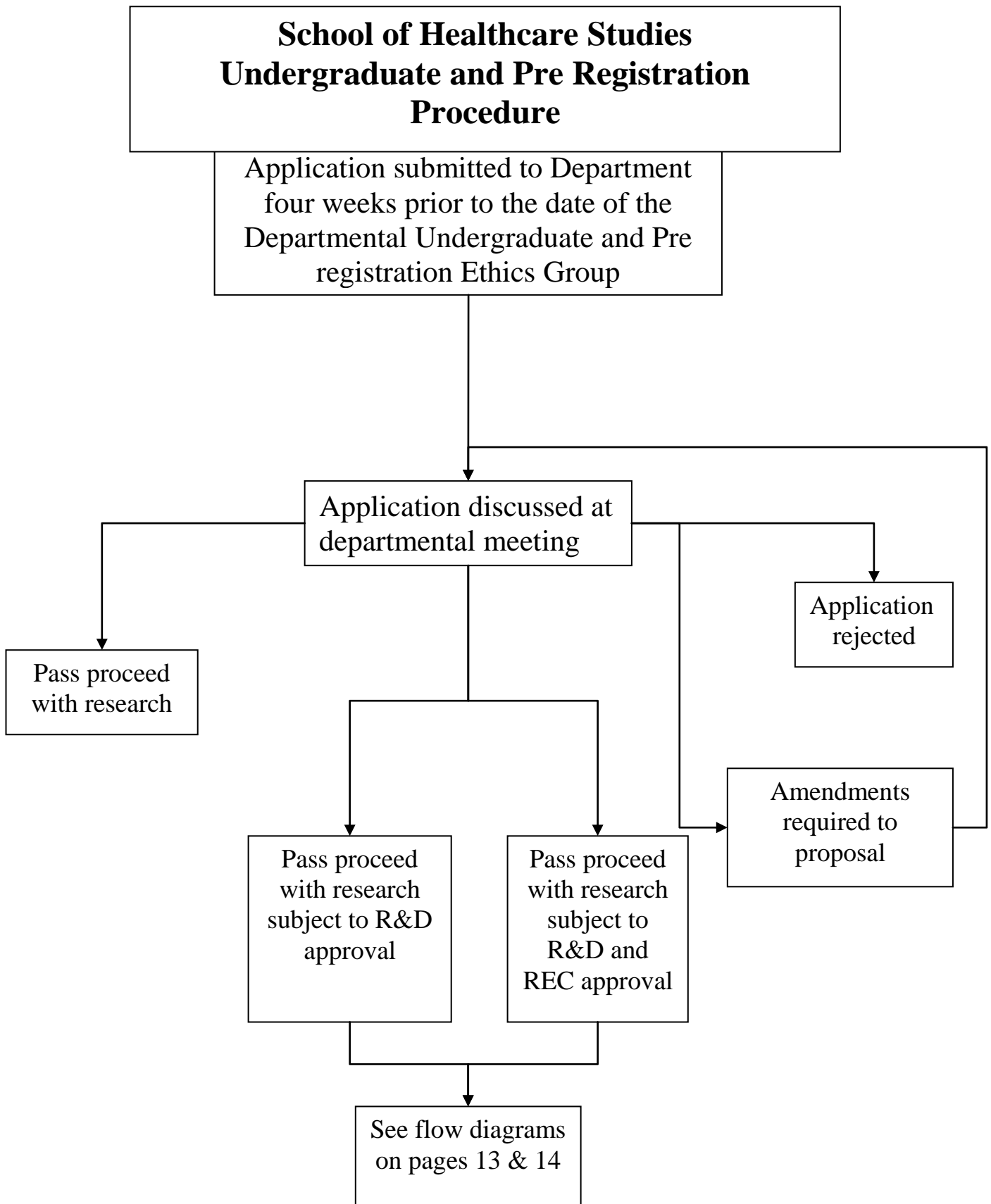
- correction of typographical errors in the protocol or other study documentation;
- other minor clarifications of the protocol;
- changes to the chief investigator's research team (other than appointment of key collaborators);
- changes in funding arrangements;
- changes in the documentation used by the research team for recording study data;
- changes in the logistical arrangements for storing or transporting samples;
- extension of the study beyond the period specified in the application form.

Appeals Procedure

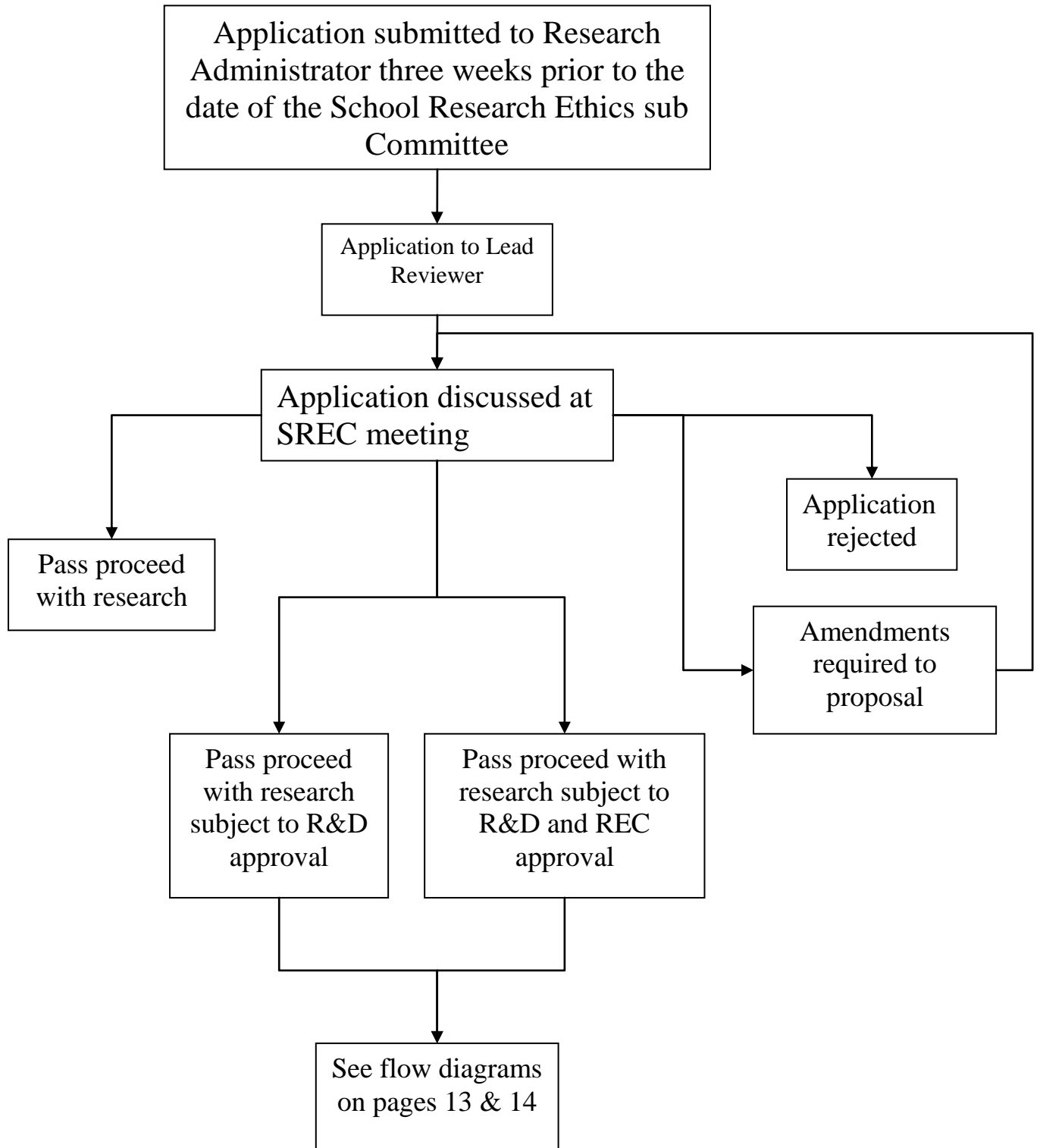
If you are dissatisfied with the decision made by the School Research Ethics Committee you should in the first instance discuss this with the School Ethics Officer. If discussion is unable to resolve the issue satisfactorily an appeal against the decision of the School Research Ethics Committee may be made to the University Research Ethics Committee via the School Research 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.

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.

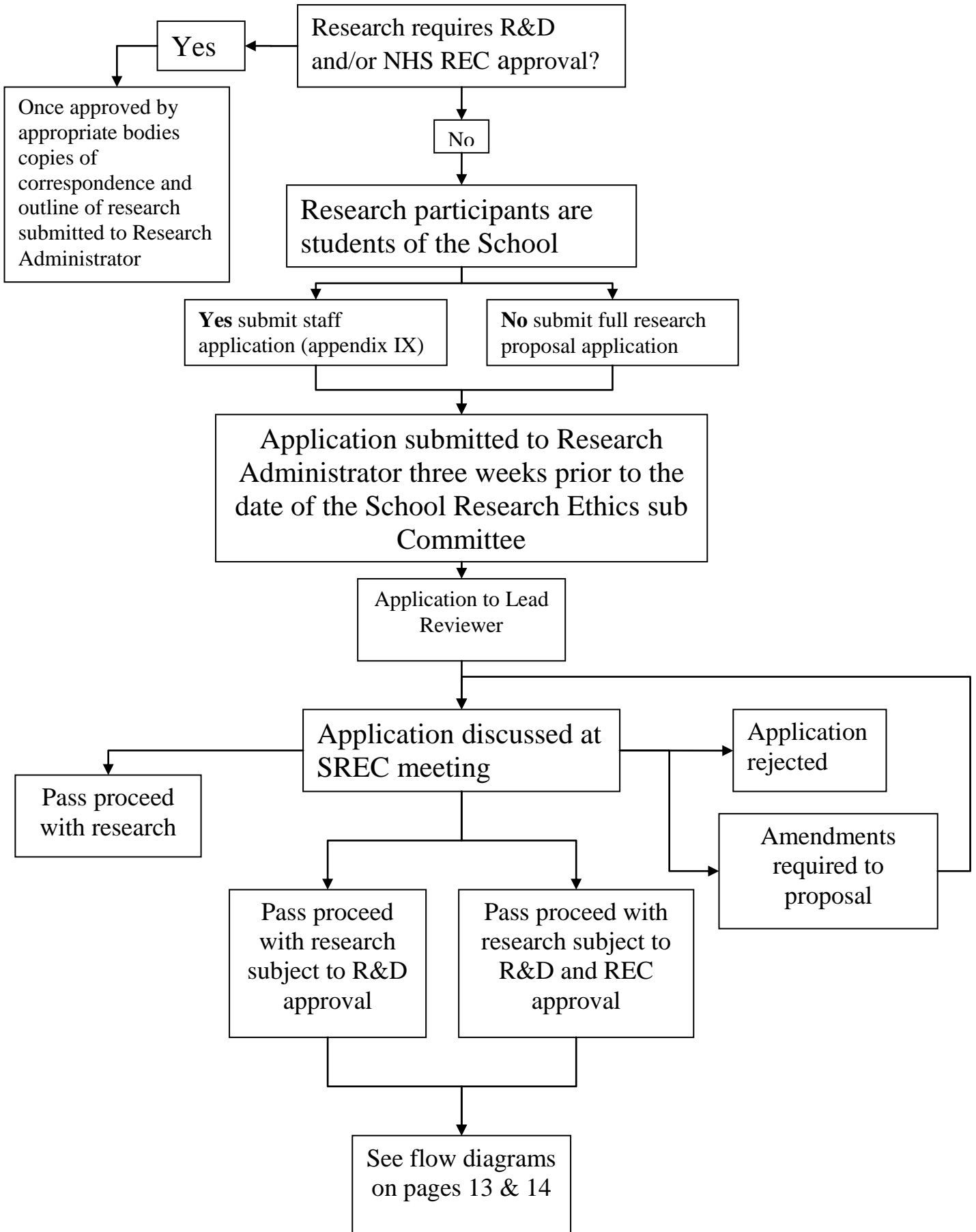
Application procedures flow charts



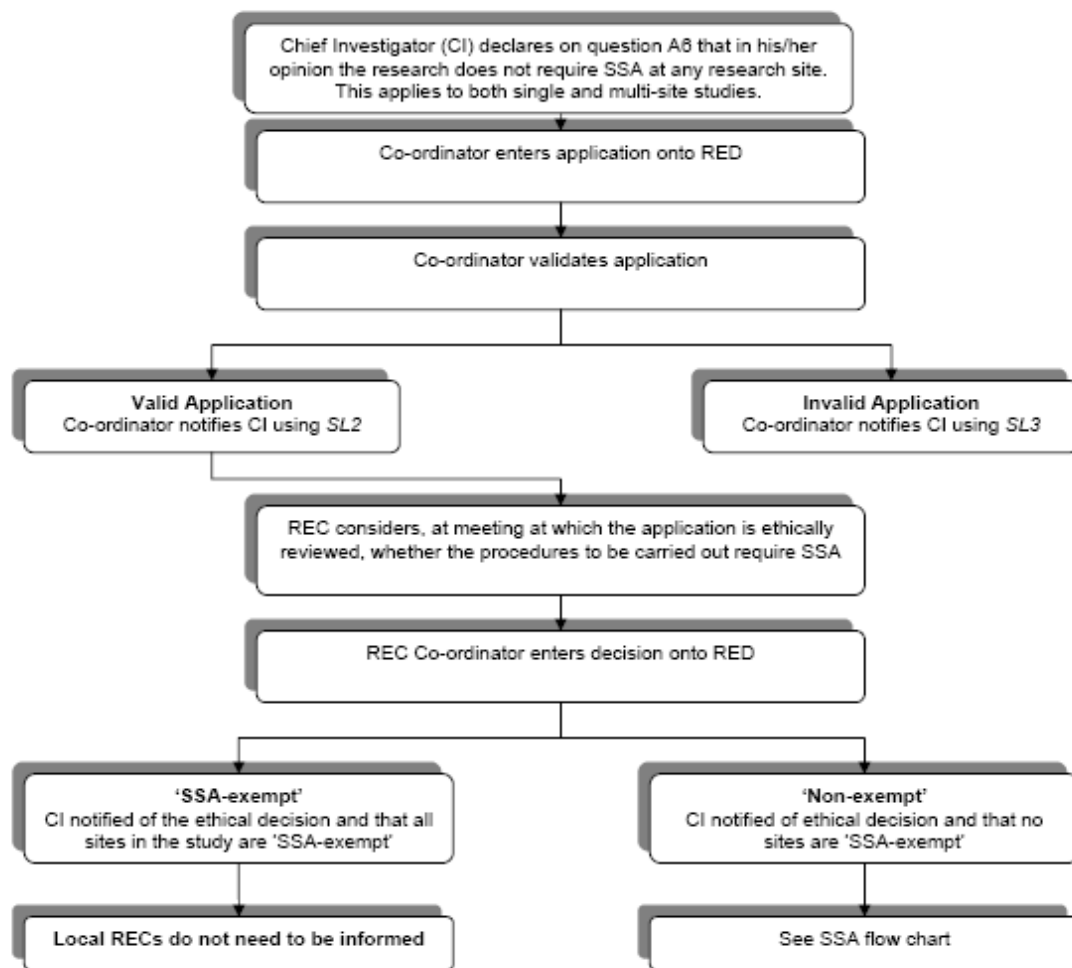
School of Healthcare Studies Postgraduate Procedure



School of Healthcare Studies Staff Procedure



'SITE-SPECIFIC ASSESSMENT-EXEMPT' STUDIES



Research procedures not requiring SSA

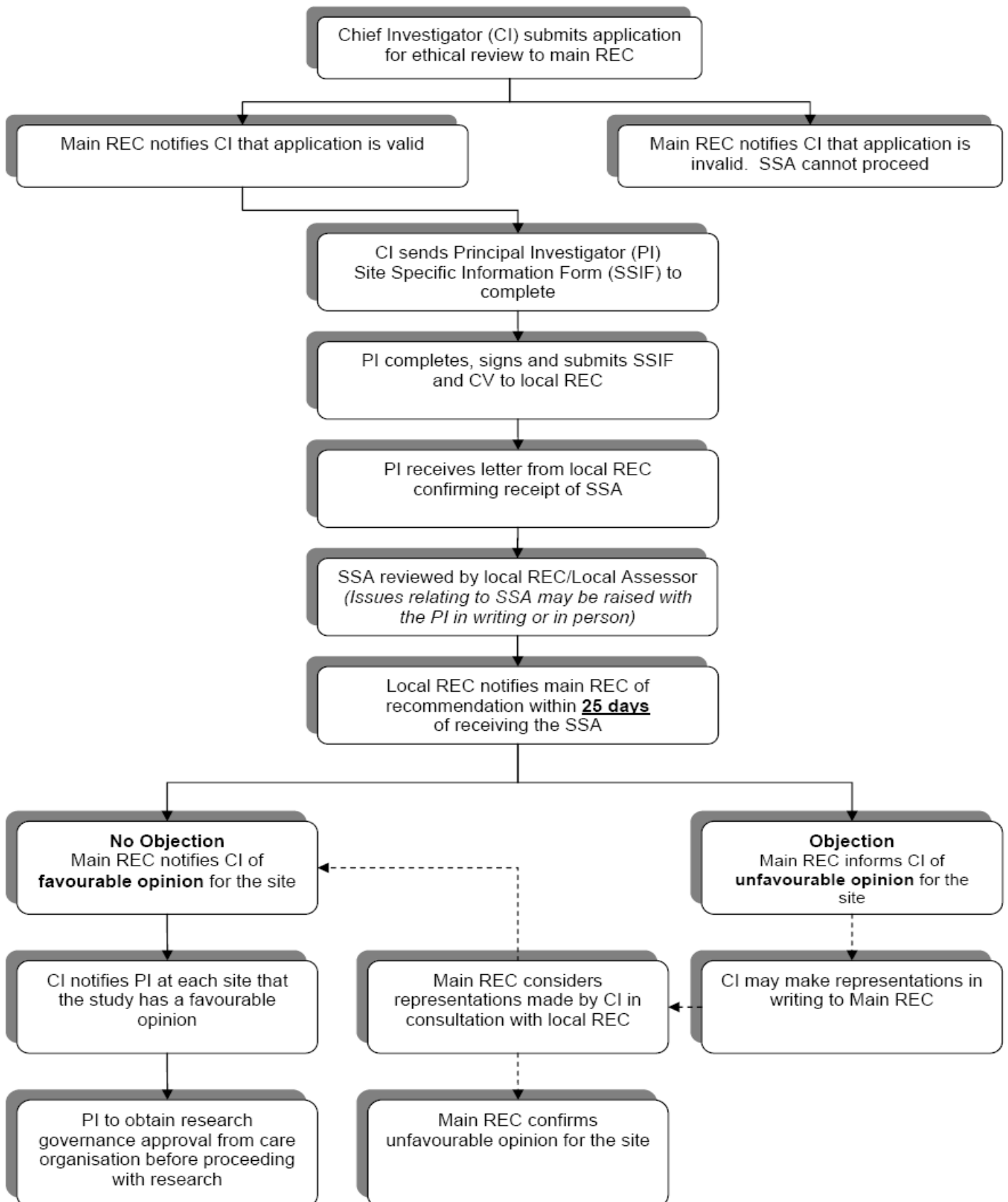
- (a) Routine investigations or assessments e.g. taking blood or urine sample
- (b) Questionnaire and surveys
- (c) Qualitative research methods
- (d) Collection of data or human tissue
- (e) Routine clinical monitoring
- (f) Laboratory tests and analysis
- (g) Facilitating the recruitment of participants

Research procedures requiring SSA

- (a) Novel Clinical Interventions
- (b) Novel Clinical Assessments
- (c) Medical Devices
- (d) Additional Clinical Monitoring
- (e) Taking of informed consent by local collaborators (see SOPs 4.29-4.31)

- The main REC may review SSA exemption at any time by the CI completing and submitting the NRES Substantial Amendment Form
- There may be cases in which the procedures to be carried out vary between sites according to their level of involvement in the research. The main REC may designate individual sites as not requiring SSA and give immediate approval in a study which normally requires SSA (see SOPs 4.32).

SITE-SPECIFIC ASSESSMENT (SSA)



PI should not contact local REC for decision. Notification is by main REC only.

Monitoring Procedures

Cardiff University requires that all applications approved by the School Research Ethics Committee are subject to annual monitoring. With regards to undergraduate and pre registration research proposals the School Research Ethics Committee will require a written report from the Chair of the appropriate Departmental Undergraduate and Pre Registration Ethics Group confirming that a project has been completed by 1 November in the year following approval of the research proposal. In other words if a research proposal was approved in June 2006 the dissertation submitted in April 2007 then in November 2007 the Chair of the Departmental Undergraduate and Pre Registration Ethics sub-Group will be required to confirm in writing that the research project has been completed and that the details of the study have substantially followed the proposal as initially presented.

With regards to postgraduate taught students, postgraduate research students and staff, annual monitoring will be required. An annual monitoring form will be despatched, by the Research Administrator, to the principal investigator, in the case of postgraduate students it will be despatched to the student. Monitoring will continue on an annual basis until the principle investigator/supervisor has confirmed that the study has been completed. The monitoring form should be returned to the Research Administrator within two weeks of its receipt by the principal investigator/student.

A written report on the progress of all research projects will be made to the School's Research Ethics Committee.

The annual monitoring form is attached as [appendix VIII](#)

Research V Audit

The distinction between research, audit and service/therapy evaluation can be nebulous. Research projects involving patients, volunteers or health/social care staff normally requires ethical approval from a NHS REC. Audit projects and service /therapy evaluations must comply with NHS Trust R & D arrangements. Staff and students of the School who had had approval, by the School's Research Ethics Committee, to carry out an audit /service evaluation within a Trust will be provided with a statement confirming that their project has been ethically reviewed. Undergraduate students will be able to obtain a statement from the Chair of the Departmental Undergraduate and Pre Registration Ethics Group. Staff and Postgraduate students will be able to obtain a statement from the Research Administrator.

The following table provides a useful distinction between the three activities.

| RESEARCH | CLINICAL AUDIT | SERVICE EVALUATION |
|---|---|---|
| The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them. | Designed and conducted to produce information to inform delivery of best care. | Designed and conducted solely to define or judge current care. |
| Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology. | Designed to answer the question: “Does this service reach a predetermined standard?” | Designed to answer the question: “What standard does this service achieve?” |
| Addresses clearly defined questions, aims and objectives. | Measures against a standard. | Measures current service without reference to a standard. |
| Quantitative research -may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced. | Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.) | Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.) |
| Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. | Usually involves analysis of existing data but may include administration of simple interview or questionnaire. | Usually involves analysis of existing data but may include administration of simple interview or questionnaire. |
| Quantitative research - study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications. | No allocation to intervention groups: the health care professional and patient have chosen intervention before clinical audit. | No allocation to intervention groups: the health care professional and patient have chosen intervention before service evaluation. |
| May involve randomisation | No randomisation | No randomisation |
| ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:- | | |
| RESEARCH REQUIRES REC REVIEW | AUDIT DOES NOT REQUIRE REC REVIEW | SERVICE EVALUATION DOES NOT REQUIRE REC |

The Role of NHS Trust R&D Offices

Each Trust within Wales will have a NHS Office of Research and Development, in England the situation is currently changing and you would be advised to contact the appropriate Trust to ascertain the situation with regards to their procedures for R&D approval.

Basically, if you intend carrying out research on any NHS patient, member of staff or using any NHS resources then you are required to submit a proposal to the relevant Trust R&D office for consideration and approval.

Application forms can be obtained from the appropriate Trust R&D office. It is advised that, if you require ethics approval from a NHS REC, you submit your research proposal to the Trust R&D office first. The REC may require proof of sponsorship from the appropriate Trust and this will only be provided once the Trust R&D office has approved the research proposal. Normally if the lead researcher is employed by the University then the University will act as sponsor and if the lead researcher is employed by a Trust then the Trust will act as sponsor. In addition, the Trust R&D office may require some changes to the proposed research so any REC application that has been submitted may no longer be relevant.

Most R&D offices will have regular meetings so you are advised to contact them to establish the timetable for the submission of applications and R&D Meetings.

One of the requirements of the Research Governance Framework for Health and Social Care (2005) is that active studies are monitored/audited. This can happen in two ways. One way is that routine information is requested for every study by the relevant R&D Office at registration, throughout and at the end of the study.

The second way is that a more detailed check is made to make sure that all aspects of the Framework are in place, including any legal obligations. The R&D offices are required to carry out this more detailed check on at least 10% of active studies. This may involve a visit, the purpose of which is to look over the information that is held about the study and to ask some questions about how the study is going and how it is being managed.

The Role of the National Research Ethics Service

Research Ethics Committees (RECs) safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical.

RECs are entirely independent of research sponsors (that is, the organisations funding and hosting the research) and investigators. This enables them to put participants at the centre of their research.

Each year, RECs review around 6,000 research applications. On average, they give an opinion after 35 days: well within the maximum allowance of 60 days.

The National Research Ethics Service (NRES) was launched on 1 April 2007 and comprises the former Central Office of Research Ethics Committees (COREC) and Research Ethics Committees (RECs) in England.

NRES Head Office, working on behalf of the Department of Health in England:

- co-ordinates the development of operational systems for RECs, on behalf of the National Health Service (NHS) in England;
- maintains an overview of the operation of the National Research Ethics Service in England, and alerts the Department of Health and other responsible authorities if the need arises for them to review policy and operational guidance relating to the National Research Ethics Service;

- develops and manages a national training programme for REC members and Co-ordinators in England;
- maintains close contact with officials in the Department of Health with policy responsibility for wider issues of research ethics and with colleagues from Northern Ireland, Scotland and Wales;
- with appropriate advice, develops, implements and maintains operating procedures and standards for RECs that will be consistent across the UK;
- establishes and manages regional centres to oversee the activity of RECs;
- provides advice to the Department of Health on the implications and practicalities of transposing the European Clinical Trials Directive in the UK.

NRES in England works closely with colleagues with similar responsibilities in Northern Ireland, Scotland and Wales to ensure a UK-wide framework for ethical review.

Research Governance/Sponsorship

What is the Research Governance Framework (RGF)?

The RGF was published in 2001 by the Welsh Assembly Government, Wales Office of Research and Development for Health and Social Care (WORD). The equivalent RGF for England was published by the Department of Health (DoH) in 2004. The RGF:

- sets out national standards in ethics, science, information, health, safety and employment, finance and intellectual property;
- defines mechanisms to deliver those standards;
- identifies the responsibilities of each party; and
- describes monitoring and assessment arrangements to ensure that the defined standards are met.

The main aim of the RGF is to ensure that *“the dignity, rights, safety and well being of participants must be the primary consideration in any research study”* (RGF, 2.2.1).

The RGF governs all research conducted by the NHS or using NHS resources. This includes both clinical and non-clinical research, and both commercial and non-commercial research.

NHS resources include additional NHS staff time, the use of an NHS Trust location (including recruitment or consent in an NHS Trust clinic/ward or research participants recruited via their association with the NHS), patient samples or data (including medical records or NHS Trust databases). All such projects require that a Sponsor be declared.

Any research project governed by the RGF cannot commence without:

- a declared **Sponsor**;
- independent **peer review**;
- **ethical review** by an appropriate body, e.g. an NHS Research Ethics Committee;
- **monitoring systems** to demonstrate adherence to the WORD/DoH RGF and Good Clinical Practice (GCP) (as laid down by the International Conference on Harmonisation of Good Clinical Practice).

What are the responsibilities of the key people involved?

The RGF defines the responsibilities of key people and organisations involved in a research project. These should be understood by all researchers involved in the project and can be viewed at <http://wales.gov.uk/docs/dhss/publications/governance/090929researchen.pdf>. The roles and responsibilities can be summarised as detailed in *Fig.1*.

Chief/Principal Investigator

A senior individual must be designated as the Chief/Principal Investigator for any research undertaken under the RGF.

A Chief/Principal Investigator is the person designated as taking overall responsibility within a team of researchers for the design, conduct and reporting of the study. The CI/PI must have suitable experience and expertise to enable him/her to ensure the research is carried out to the standards set out in the RGF.

If you are a Chief/Principal Investigator you must ensure that your responsibilities, as set out in the RGF, are fully understood.

Fig.1

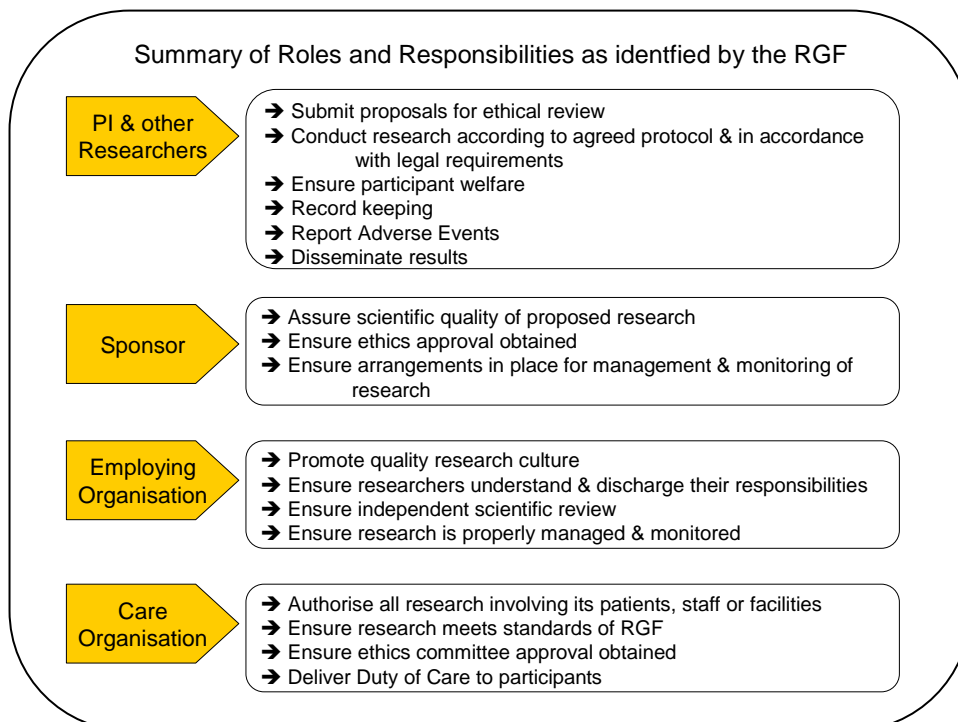
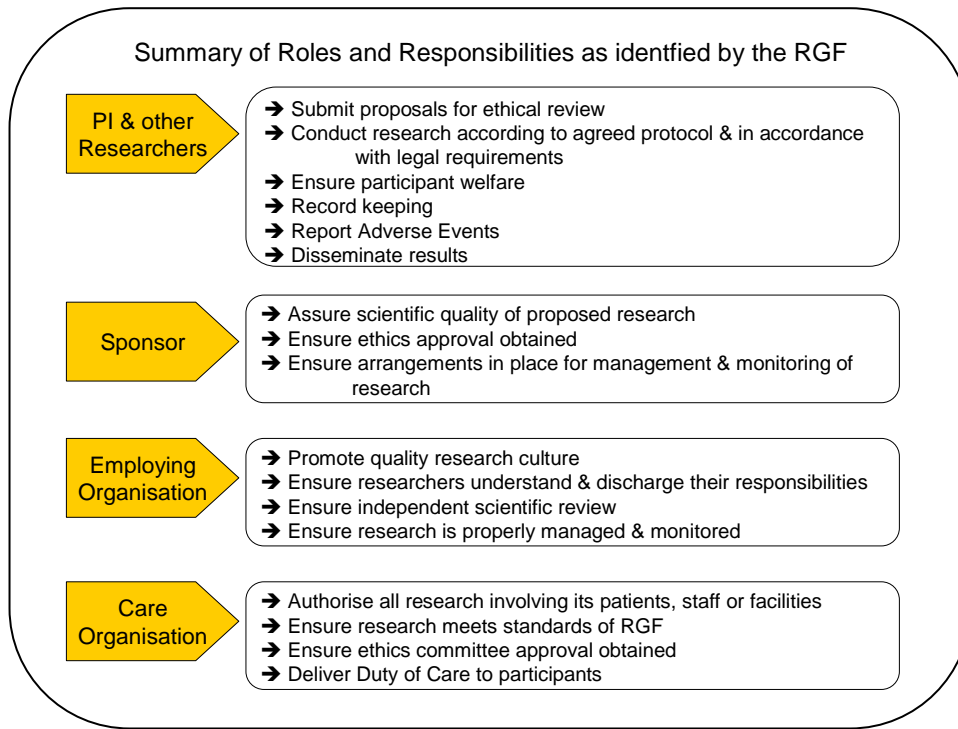
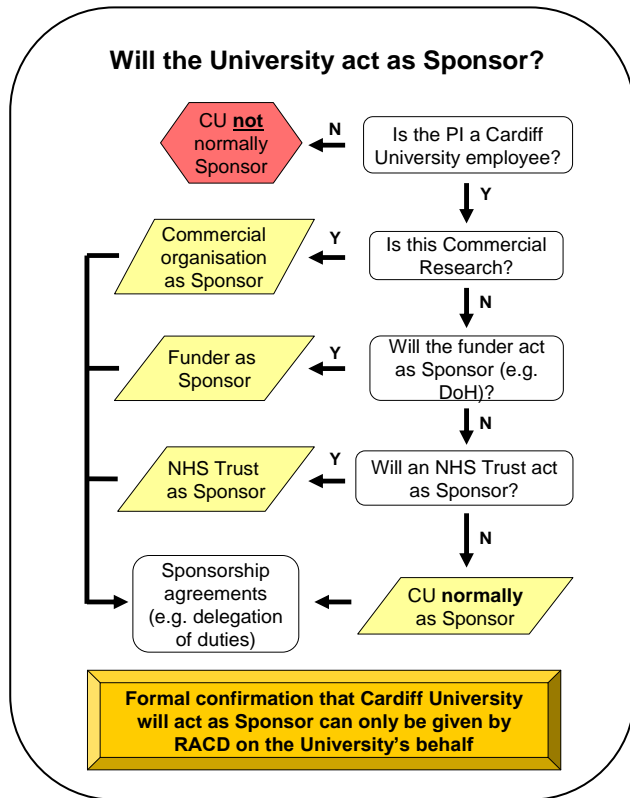


Fig 2



What is a Sponsor?

All research requiring the collaboration of the NHS must have an organisation willing and able to take on the responsibilities of research Sponsor.

The Sponsor is the organisation that takes the lead in confirming there are proper arrangements for the initiation, management and monitoring, and financing of a research project. A Sponsor is not the same as the funding body.

Who will act as Sponsor?

Fig.2 can be used as a guide to identify who might be the Sponsor for a particular research project. Confirmation that the University will act as Sponsor for a project can only be given in writing by the Research and Commercial Division (RACD) on behalf of the University.

The University schools, departments or individual employees shall not act as Sponsor for any projects.

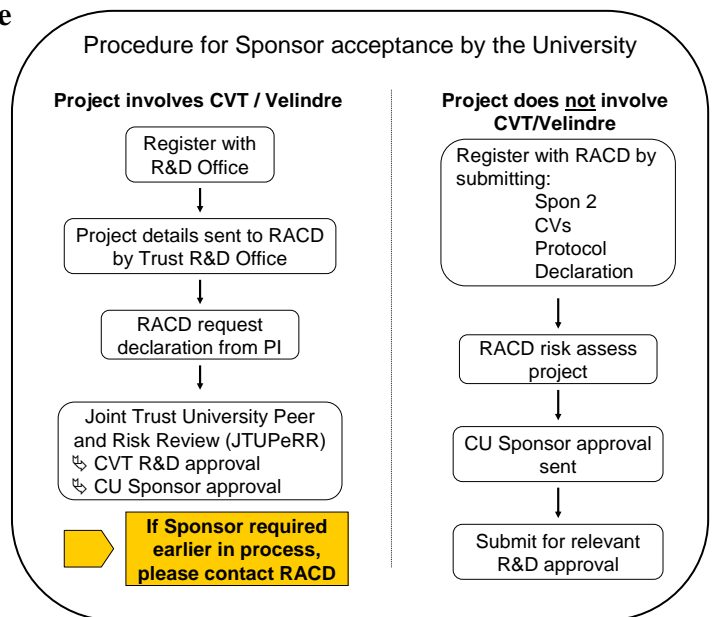
In order to enable the University to consider if it will ‘declare’ it will act as Sponsor for a research project, the principal investigator will first need to complete Spon 2 form and return it to RACD along with other requested information.

What is the University Sponsor Acceptance process?

Fig 3

In order to accept sponsorship of a research project, RACD must request specific information about the research project. The procedure for requesting that the University acts as Sponsor and the information to be provided to RACD is detailed in Fig 3

The University’s Spon 2 form, declaration and this guidance note can be found at <http://www.cardiff.ac.uk/racdv/resgov/index.html>



The Research Passport

The Research Passport is the mechanism for non-NHS staff to obtain an Honorary Research Contract (HRC) when the research they propose to carry out is likely to impact on patient care .e.g. researchers with substantive university employment contracts. The benefits of the new system are that there is the consistent use of HRCs by the NHS; clear guidance on the use of HRCs, no need to repeat checks for every HRC; research staff will be able to start research in the NHS faster. The scheme was rolled out across the UK from September 2007. For further information see:

http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

Data Protection

All staff and students who process personal data must comply with the Data Protection Act. Section 4(4) of the Act states that:

‘it shall be the duty of the data controller to comply with the data protection principles in relation to all personal data with respect to which he/she is the data controller’.

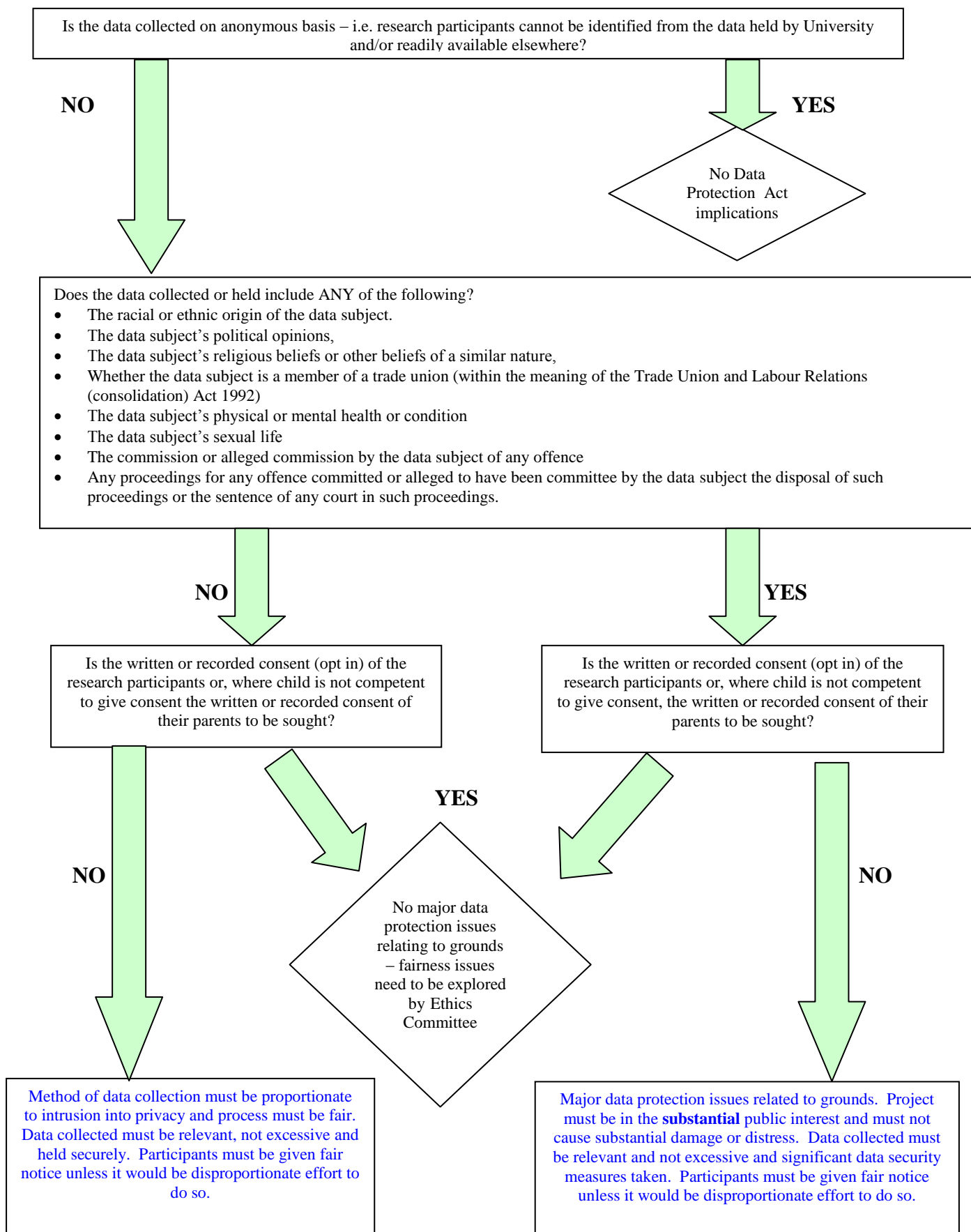
The University has established a Data Protection Policy the purpose of which is to ensure that the University and the University’s staff and students comply with the requirements of the Act when processing personal data. This Policy can be found on the University’s website at:

<http://www.cf.ac.uk/cocom/accinf/dataprotection/index.html>

and at

<http://www.cardiff.ac.uk/govrn/cocom/accinf/dataprotection/datap/data-protection-for-researchers.html>

DATA PROTECTION FLOWCHART – RESEARCH PROJECTS



PLEASE NOTE THAT EVEN WHERE THE PROVISIONS OF THE DATA PROTECTION ACT PERMIT COLLECTION OF DATA WITHOUT CONSENT, THE PROVISIONS OF THE

MENTAL CAPACITY ACT AND/OR THE HUMAN TISSUE ACT MAY STILL REQUIRE YOU TO GET **EXPLICIT CONSENT. PLEASE SEEK ADVICE FROM UREC OR GOVRN.**

Data Storage/Records Retention

The University recognises that the efficient management of its records is necessary to support its core functions, to comply with its legal and regulatory obligations and to contribute to the effective management of the institution. The University has developed a Records Management Policy (see: <http://www.cf.ac.uk/cocom/recordsmanagement/records-management.html>) that provides the policy framework through which this effective management can be achieved and audited.

This policy applies to all records created, received or maintained by staff or students of the University in the course of carrying out their work. Records are defined as all those documents that facilitate the business carried out by the University and which are thereafter retained (for a set period) to provide evidence of its transactions or activities. These records may be created, received or maintained in any format or medium, including electronic media. Records Management is defined as a field of management responsible for the efficient and systematic control of the creation, receipt, maintenance, use and disposition of records, including process for capturing and maintaining evidence of and information about business activities and transactions in the form of records.

School Heads are responsible for ensuring that records management within their School is in line with established policy, guidelines and procedures and that individuals receive guidance as appropriate.

Individual schools and directorates must ensure that records for which they are responsible are accurate, and are maintained and disposed of in accordance with the University's records management guidelines. All records within a School should have an identified 'owner' responsible for their management and use.

The Records Retention Schedule provides some basic guidance about broad records retention see: <http://www.cf.ac.uk/cocom/recordsmanagement/recordsretention/recordreten.html>

Risk Assessment of Research Projects

Introduction

Under the provision of the Management of Health and Safety at Work regulations (1999) a suitable and sufficient risk assessment must be carried out for any work activity or procedure at work. Other safety regulations also contain requirements for risk assessment. These include: The Control of Substances Hazardous to Health (COSHH), Display Screen Equipment (DSE), the Personal Protective Equipment at Work and the Manual Handling Regulations.

Responsibility

The Head of School is responsible for ensuring that arrangements are put in place for ensuring risk assessments are carried out and any required control measures are put in place. All groups of people who might be affected must be considered. These include:

- Research and Academic Staff
- Students
- Research Participants, including children
- Lone Workers

What is a Hazard?

A Hazard is anything that can cause harm (e.g. machinery, working on ladders, paper clips) The harm may range in severity from minor, say a cut to the finger to major – death. However, a hazard only becomes a risk if you have any chance of it affecting you or the research participants. Therefore, risk is the severity of the hazard, together with the chance or likelihood that someone will be harmed by it.

Undertaking a Risk Assessment

A Risk Assessment attempts to estimate the combined effect of both components:

$$\text{Risk} = \text{Severity} \times \text{Likelihood}$$

The practical significance of this is that even with high hazards, proper control measures can sufficiently reduce the likelihood of harm to adequately control the risk. Conversely, a relatively low hazard can become a substantial risk if not properly controlled.

Risk assessment can initially be a simple consideration of the activity/procedure in order to identify potential hazards. Should none be identified, no further action is required. In this respect, trivial risks can be ignored, as can those associated with life in general, unless the work activity compounds these risks or they are of significant relevance to the work activity.

Risk should be calculated for an existing activity taking into account any control measures in place. This is estimated by considering both the likelihood of exposure risk and the severity of the consequences of such an exposure. The calculation of risk should be done as follows:

Select an appropriate number for both Likelihood and Severity from the table

| Likelihood | Severity |
|---------------------------|--|
| 0 Zero to very low | 0 No injury or illness |
| 1 Very unlikely | 1 First aid injury or illness |
| 2 Unlikely | 2 Minor injury or illness |
| 3 Likely | 3 “Three day” injury or illness |
| 4 Very Likely | 4 Major injury or illness |
| 5 Almost certain | 5 Fatality, disabling injury |

Apply the formula: Likelihood x severity = Risk

Group the level of risk and determine the required action using the table:

| Score | Action to be taken |
|--------------|---|
| 0-5 | No further action needed. |
| 6-10 | Appropriate additional control measures should be implemented |
| 12-25 | Work should not be started or should cease until appropriate additional control measures are implemented. |

If any potential hazards are detected, then you must carry out a full assessment using the Risk Assessment Form, with assistance from the Risk Assessment Guidance. Both the form and guidance can be found on the University website at; http://www.cf.ac.uk/osheu/complete_risk_assessment/index.html

Lone Workers

Lone working is a catchall phrase that describes some quite distinct occupational arrangements. Yet, strict definitions of what constitutes lone working do not necessarily serve a useful purpose. It is important, therefore, to provide a suitable method of work, related to the task itself, and to provide a back-up system appropriate to the circumstances in which the task is undertaken.

An employer should carry out an assessment of the risks of lone working which encompasses: remoteness or isolation, the environmental conditions, communications, vulnerability to criminal intent, emergency procedures, information and training, medical fitness and safe work equipment. Lone working could be

defined as any situation where a worker is engaged in a solo activity out of others' sight and hearing range. Unfortunately, this definition is broad to be and it covers so many scenarios that ultimately almost everyone will be a lone worker at some point in their normal work activity.

Some examples of lone working defined by place are:

- working in a fixed establishment with no other persons on site, or when others may be elsewhere on site
- working in a remote location, including outdoors
- work on other employers' premises or working from home
- travelling in the course of work.

Solitary workers should not be exposed to significantly more risks. The purpose of assessing the risks of working alone or unsupervised for significant periods of time is to establish two main facts:

1. Whether the work can be done safely by an unaccompanied person;
2. What arrangements will ensure that an individual is not exposed to greater risks than employees who work together.

The starting point of the assessment should be the recognition that a lone person is more vulnerable when the unexpected happens. Therefore, before anyone is asked to work by themselves, certain issues should be considered.

Employers should consider whether communication is adequate, and in particular:

- what level of supervision is intended and how is it to be carried out?
- has the lone worker been equipped with a system for maintaining contact, such as two-way means of communication, a pager or a personal alarm?

Workers who are thought to be carrying cash, or who can be seen in possession of valuables such as laptop computers, mobile phones, etc. may be at risk from robbery or attack. Women can face increased risks from violence when working alone, such as sexual harassment and assault, although men can also be victims of this type of violence.

In case of emergency, consideration must be given to:

- whether sufficient preparation has been made to cope with the emergency, e.g. fire, illness or accident, and have appropriate procedures been established?
- what provisions are in place to make the workplace secure if it must be left unattended.

Solitary workers should be capable of responding correctly in emergency situations.

Emergency procedures should be established and workers trained to implement them.

Suitable systems should be devised to monitor the condition of solitary workers, and include at least a check at the end of the working period. In addition it is desirable to consider:

- Procedures where supervisors contact, periodically visit and visually monitor people working alone.
- Procedures where regular contact between the solitary worker and supervision is maintained using either a telephone or radio.
- Automatic warning devices which operate if specific signals are not received periodically from the solitary worker, e.g. systems to include security staff.
- Other devices to raise the alarm in the event of an emergency operated manually or activated automatically by the absence of activity.

The Department should establish clear procedures to see the limits to what can and cannot be done while working alone. They should specify how to behave in circumstances which are new, unusual or beyond the scope of training, e.g. when to stop work and seek advice from a supervisor.

Useful contacts

School of Healthcare Studies Ethics Website

<http://www.cardiff.ac.uk/sohcs/research/ethics/index.html>

Cardiff University Research and Commercial Division

<http://www.cf.ac.uk/racdv/index.html>

Dr Kathy Pittard- Davies

Deputy Director and Head of Research Policy and Management

Telephone: 029 2087 9274

Email: davieskp2@cardiff.ac.uk

Chris Shaw

Research Governance Framework, NHS Commercial Activity, Clinical Trials

Telephone: 029 208 79130

Email: ShawC3@cardiff.ac.uk

The University's Occupational, Health and Safety Unit

<http://www.cf.ac.uk/osheu/index.html>

The University's Corporate Compliance Unit

<http://www.cf.ac.uk/govrn/cocom/index.html>

National Research Ethics Service

<http://www.nres.npsa.nhs.uk/>

Wales Office of Research and Development Research Governance Framework

<http://wales.gov.uk/docs/dhss/publications/governance/090929researchen.pdf>

The network for R&D management in health and social care

<http://www.rdforum.nhs.uk/>

UK Clinical Research Collaboration (UKCRC)

<http://www.ukcrc.org/>

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School of Healthcare Studies

Research Proposal Form

2010/11

All applications must be completed in line with the guidance notes attached as Appendix II. Applications must be submitted no later than the deadlines stipulated. Contact the Research Administrator for dates. Late applications will not be considered.

1, Personal Details

Name of applicant:

Please tick where appropriate;

Student: **Full time:** **Part Time:**

Title of Course:

Student Number:

Contact Address:

Email address:

Contact telephone number:

Staff:

Department:

Email address:

Proposed start date of Study (m/y):

Proposed end date of study (m/y):

Title of Project:

2, Additional Information

Where the project is part of an undergraduate or postgraduate course

Full name of academic supervisor:

Address:

Where the research is being carried out by a member of staff please provide details of co-investigators

Full Name/s:

Department/School/Institution:

3, Project Details

3.1 Lay Summary

(250 words maximum)

3.2 Background and Objectives of Study

(300 words maximum)

3.3 Principal Research Question

3.4 Methodology

(500 words maximum)

3.5 Location of study and access arrangements

Has informal consent been obtained to access these facilities/participants?
Yes No (Please tick where appropriate)

3.6 Resource Implications

(Staff should also stipulate the source of funding for the research)

3.7 Ethical Considerations

Outline the potential ethical issues of the proposed research and how you intend addressing these issues.

Is NHS R & D approval required? Yes No

If so which Trusts will be required to give approval?

Is NHS Research Ethics Service approval required? Yes No

Does your research involves children and young people? Yes No

If yes, please indicate whether, or not, you have read and understood the University's Safeguarding Children and Vulnerable Adults Policy

A copy of which can be found at:

<http://www.cardiff.ac.uk/racdv/ethics/guidelines/FINAL%20Safeguarding%20Children%20&%20VAs%20Policy%202010.doc>

Yes- I have read and understand the Policy

No – I have not read or understood the Policy

(tick where appropriate)

3.8 Project Milestones and Timescales

| Activity | Start Date | Completion Date |
|----------|------------|-----------------|
| | | |

3.9 References

4, Signatures

In signing this form the applicant confirms that the relevant health and safety measures, in accordance with University Policy and School requirements, have been taken into account for the proposed research.

Applicant:

Name:

Date:

Signature:

Academic Supervisor:

Name:

Date:

Signature:

Clinical Supervisor:

Name:

Date:

Signature:

For completion by staff applicants only

Project Mentor

(where applicable)

Name:

Date:

Signature

Head of Department

Name:

Date:

Signature:



School of Healthcare Studies

Research Proposal Form Guidance Notes

2010/11

General

These guidance notes should be used when completing the Research Proposal form. Word lengths are the maximum accepted, if you are over the lengths stipulated then your form will be returned to you for revision. Please note that all sections of the form should be completed even though you may find that some of the information is duplicated.

1. Personal Details

Please provide your full name underlining your surname/family name.

ALL students must provide their student number. This can be found on your student id card.

Clearly state the full title of the course of study that you are currently pursuing.

ALL students should provide details of their contact address, email address and contact telephone number.

Staff applicants are asked to provide their work email address and stipulate the department in which they are based.

For the proposed start and end dates of the proposed research the month and year will suffice.

The full title of the proposed research project should also be provided.

2. Additional Information

In certain cases the Supervisor may be appointed after your research proposal has been submitted and approved. If this is the case with your application then please insert “Not applicable”.

For staff applications details of the co investigator/s must be included

3. Project Details

Lay Summary

This section must be comprehensive to a general audience without any specific knowledge of the topic. It must be no more than 250 words in length.

Background and Objectives of Study

You should outline the background to the problem to be investigated. Make a case for your research question, identifying an area of concern, discussing the work carried to date and therefore establishing a gap in knowledge, you should then lead

into the aims/objectives of the research, and hypotheses where appropriate. It should be no more than 300 words.

Principal Research Question

This information should be as specific as the research design permits. You should stipulate the principal question or hypothesis being addressed by the piece of research. When a hypothesis is being tested, enter the hypothesis.

If possible, this should be a single sentence.

Methodology

In this section you should include a description of the methodology to be used, it should be no more than 500 words. You should include details of the participants e.g. numbers, from where they are to be recruited, the sample size, the data analysis process you will be using e.g. statistical packages, qualitative analysis. You should also detail how the research will be carried out e.g. protocols, data gathering such as interviews, questionnaire etc. Attached as appendices to the methodology you should include examples of, where appropriate, any questionnaires and participant information sheets and consent forms to be used.

Location of Study and Access Arrangements

Please state where the study will take place. If it is the intention that the study will take place off University property please indicate if informal consent has been provided to access the off site facilities and participants. Once the research proposal has been approved by the School you will be required to provide the School with a letter indicating formal consent has been given by the off site facilities to utilise these facilities and the participants before the research can officially commence.

Resource Implications

You should include where possible estimates of costs. Will you need help? Who will you recruit? How will you recruit? What equipment will be used and where?

Ethical Considerations

You should outline what you perceive to be the potential ethical issues with the proposed research and how you propose addressing these issues.

Have you undertaken a risk analysis of the proposed research? Are there external approval requirements that need to be sought?

Research on minors and vulnerable adults e.g. those with mental health problems or learning disabilities, should be undertaken with great care. You should satisfy yourself that there is a real need to involve these groups in the research and be able to justify this to the relevant ethics committee. Researchers should also check and comply with legal obligations before proceeding with the research (such as obtaining clearance from the Criminal Records Bureau prior to commencing research involving minors). In any study protocol, the role and responsibilities of individuals on whom the research participant is dependent (e.g. parents, carers, and supporters) must be clearly explained. Where consent is given by a legal representative it is important to also try and obtain 'real' consent from the research participant.

Where applicable copies of consent forms, confidentiality information, participant information and the risk assessment for both participants and researcher should be attached as an appendix to the proposal application.

Project Milestones and Timescales

In this section please provide a timetable for the project some of the key milestones could be the literature review, the pilot study, data collection, data processing, data analysis, the discussion, for students compilation and binding of resultant dissertation/thesis, submission, and dissemination of results.

References

You should list those references cited throughout the application.

4. Signatures

For postgraduate students and staff **ALL** forms should be signed and must be submitted in hard copy to the Research Administrator by the dates indicated below. This may not be necessary for undergraduate students when submitting the form electronically. You will be informed by your Departmental Ethics Officer of the dates for the submission of your proposal and the means of submission.

5. Accompanying Documentation

Your research proposal should, where appropriate, be submitted with the participation information sheet, consent form, and a copy of any questionnaire/s.

6. Dates for submission for Postgraduate Students and Staff

| Submission Date | School Research Ethics Committee Meeting Date |
|----------------------------|--|
| Thursday 23 September 2010 | Thursday 14 October 2010 |
| Thursday 11 November 2010 | Thursday 2 December 2010 |
| Thursday 3 February 2011 | Thursday 24 February 2011 |
| Monday 18 April 2011 | Thursday 5 May 2011 |
| Thursday 2 June 2011 | Thursday 23 June 2011 |
| Thursday 7 July 2011 | Thursday 28 July 2011 |

7. Contact Details

Miss Liz Harmer, Research Administrator
School of Healthcare Studies
Room 2F08A 2nd Floor Cardigan House
Cardiff University
Heath Park
Cardiff CF14 4XN

Email: harmerl@cf.ac.uk

Tel: (029) 20 687552



School of Healthcare Studies

Research Proposal Form

Accompanying Documentation

2010/11

When submitting your research proposal you should ensure that all the relevant documentation accompanies it. What follows is a comprehensive list of the documentation that could be submitted with your research proposal. Please note that in certain circumstances it may not be appropriate to submit some of the documentation listed.

Participant Information Sheet

Participant consent forms

Letters of invitation to participants

Questionnaire

Trial Protocol

Risk Assessment

Letter to GP

All accompanying documentation must bear version numbers and dates.

Guidelines for Preparing a Participant Information Sheet

Before asking for written consent, prospective participants must be given written information on the study and time to read and assimilate. If they then agree they should sign the consent form.

Studies with little or no intervention, and hence less than minimal risk are likely to need a shorter information sheet. You may not need to complete all sections.

Where appropriate the information sheet should be divided into 2 parts;

- Part 1 should provide briefer and clear information on the essential elements of the study.
- Part 2 should contain additional information on factors such as confidentiality and data protection, indemnity and compensation, publication etc.

But if appropriate it is entirely acceptable to produce a single section information sheet.

The Information Sheet should be written in simple, non-technical terms that a lay person will easily understand and, if children are to be involved, it should be written at a level that reflects the appropriate age range of the potential participants.

For the first page use the headed paper of the University. All consent forms and information sheets should have version dates in the header/footer to ensure the most recent is used, and pages numbered, e.g. page 2 of 5.

For your information the publication “Guidance for Researchers and Reviewers on the production of Information Sheets and Consent Forms” can be found on the National Research Ethics Service at; <http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId=4757>

Guidance for the Design of Information Sheets

Part 1

Study Title

- this should be consistent across all documentation.

Invitation Paragraph

- why are you asking the participant to take part in the research.

What is the purpose of the study?

Why have I been invited to participate?

- Explain briefly why and how the participant was chosen and how many others will be in the study.

Do I have to take part?

- Explain that taking part is purely voluntary.

What will happen to me if I take part?

- Should include details on;
 1. how long the participant will be involved in the research;
 2. how long the research will last (if different to 1 above)
 3. how often they need to attend
 4. how long these visits will be
 5. what exactly will happen.

Expenses and Payment

- should explain if expenses are available.

What will I have to do?

- Set down briefly what you will expect of your research subjects.

What is the device/procedure being tested?

- Include a short description and give the stage of development.

What are the alternatives for diagnosis or treatment?

- What other managements are available with important comparative risks and benefits.

What are the possible disadvantages and risks of taking part?

- Any risks, discomfort or inconvenience should be briefly outlined.

What are the side effects of any treatment received when taking part?

- You should explain the possible side effects.

What are the possible benefits of taking part?

- Explain, but where there is no intended clinical benefit, this should be stated clearly.

What happens when the research stops?

What if there is a problem?

Will my taking part in the study remain confidential?

Part 2

What if relevant new information becomes available?

What will happen if I don't want to carry on with the study?

- Explain what the subject can and can't expect if they withdraw.

What if there is a problem?

- You should inform subjects how complaints will be handled and what redress may be available.

Will my taking part in this study be kept confidential?

- Outline how their confidentiality will be safeguarded during and after the study
- The procedures for the collection, handling, processing, storage and destruction of their data.

Involvement of GP/Family Doctor

What will happen to the results of the research study?

- Whether you intend to publish and how the results will be made available to participants.
- You should add that they will not be identified in any report/publication unless they have given their consent

Who is organizing and funding the research?

Who has reviewed the study?

Further information and contact details

(Headed notepaper)

SUBJECT CONSENT FORM – Sample

Title of study:

Name of Researcher:

Please Initial Box

I confirm I have read and understood the information sheet, dated ,(version) for the above study and have had the opportunity to consider the information to ask questions and to have had these answered.

I understand that my participation is voluntary and that I am free to withdraw at anytime without giving any reason, without my medical care or legal rights being affected.

I give permission for the researcher to access my medical notes. *

I give permission for the researcher to inform my GP of my participation in the study. *

I give permission for the researcher to video the procedure for training purposes. *

I understand that all information about me will be kept in a confidential way and destroyed once the study is completed.

Or

I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [*company name*], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

I agree to take part in this study

Name of subject.....

Signature Date

Name of Witness (Researcher)

Signature Date

When completed, 1 for patient, 1 for researcher site file

* this statement should only be included on the consent form when appropriate

School of Healthcare Studies

Research Ethics Committee

Lead Reviewers Comments Form

| LEAD REVIEWERS COMMENTS FORM |
|--|
| Application Number & Title of proposed research : |
| Applicant Name: |
| Name of Lead Reviewer: |
| Date of Meeting at which proposal is to be considered: |
| 1. The scientific value and validity of the proposal: |
| 2. Justification of the benefit of the study: |
| 3. Welfare, hazards, discomfort and distress to the participants: |
| 4. Consent of the participants: |
| 5. Participant information sheet: |
| 6. Confidentiality: |
| 7. Welfare of Investigator: |
| 8. Trust R & D approval required? : |
| 9. NRES Ethics approval required? : |
| 10. General comments: |
| 11. Outcome: (Please delete accordingly) Pass/ Pass subject to a amendments/ Amend and resubmit to sub-Committee/ Reject |
| |

| LEAD REVIEWERS GUIDELINES |
|---|
| Application Number & Title: <i>(As on application)</i> |
| Name of Lead Reviewer: |
| Date of Meeting at which proposal is to be considered: |
| 1. The scientific value and validity of the proposal: <i>Does the application give sufficient detail to determine whether the study is justified, appropriately designed to answer the research question(s), using robust methods and a sufficient number of subjects/measurements and capable of being completed? Are the aims and objectives achievable?</i> |
| 2. The welfare of the research subject: <i>Has the applicant considered any issues that may affect the research subject? E.g. time requirements, travel etc. Have any factors been put into place to address these?</i> |
| 3. Hazards, discomfort and distress to the research subject: <i>Application should identify any issues that may harm/affect research subjects, the level of any harm etc. and methods that will be employed to minimise/remove these.</i> |
| 4. Consent of the research subject: <i>What consent is being undertaken and how is it being obtained? E.g. written/oral, implied, etc. Is the consent form appropriate and in the recommended format?</i> |
| 5. Patient information sheet: <i>This should be written in understandable English for a lay person. It should include all explanations of the study and what is required of the research subject as well as contact details for the researcher.</i> |
| 6. Confidentiality: <i>Has the applicant considered issues of confidentiality, anonymity, data protection etc. and storage of data – both electronic and physical. Have timescales been indicated and are these realistic?</i> |
| 7. Welfare of Investigator: <i>Has the applicant considered any potential risks/hazards to themselves whilst carrying out the research?</i> |
| 8. R & D approval required? : <i>Indicate whether you feel the application requires R&D approval</i> |
| 9. Ethics approval required? : <i>Indicate whether you feel the application requires NRES approval</i> |
| 10. General comments: <i>Please give any additional comments not covered in previous sections.</i> |
| 11. Outcomes: <ul style="list-style-type: none"> • Pass = The research proposal is satisfactory • Pass subject to amendments = The research proposal requires minor amendments, the applicant is required to revise and resubmit their proposal for approval by the lead reviewer and Chair of the Committee • Amend and resubmit to sub-Committee = The research proposal requires major amendments and will need to be resubmitted to the Research Committee for consideration • Reject = The research proposal is rejected outright |

If you have any issues with the application, please identify these in appropriate sections and comment upon what action you feel is required to improve/enable the application to be passed. These comments will form the basis of the information passed onto the applicant to enable them to amend their research proposal accordingly.

School of Healthcare Studies

School Research Ethics sub-Committee

Dates for 2010/11

| Submission Date | School Research Ethics Committee Meeting Date |
|----------------------------|--|
| Thursday 23 September 2010 | Thursday 14 October 2010 |
| Thursday 11 November 2010 | Thursday 2 December 2010 |
| Thursday 3 February 2011 | Thursday 24 February 2011 |
| Monday 18 April 2011 | Thursday 5 May 2011 |
| Thursday 2 June 2011 | Thursday 23 June 2011 |
| Thursday 7 July 2011 | Thursday 28 July 2011 |

For Undergraduate and Pre registration students you will be advised of the date for the submission of your research proposal by your department.

All meetings start at 2.00pm.

CARDIFF UNIVERSITY

SCHOOL OF HEALTHCARE STUDIES RESEARCH ETHICS SUB-COMMITTEE

Annual Monitoring Form

Cardiff University requires that all applications approved by School Research Ethics Committees are subject to annual monitoring. Please complete the attached form and return to:

Liz Harmer
Research Administrator
Room 2F08A, Second Floor
Cardigan House
School of Healthcare Studies
Heath Park Cardiff. CF14 4XN
harmerl@cardiff.ac.uk

1. Details of Principal Investigator / Supervisor

| | |
|------------|--|
| Name: | |
| Address: | |
| Telephone: | |
| E-mail: | |

2. Details of study

| | |
|---|--|
| Full title of study: | |
| SOHCS reference number: | |
| Date of favourable ethical opinion from School: | |

3. Commencement and termination dates

| | |
|---|----------|
| Has the study started? (Note studies not started within 24 months of approval require reapproval from SOHCS) | Yes / No |
| If Yes, give start date. | |
| If No, what are the reasons for the study not commencing? | |
| Has the study finished? | Yes / No |

| | |
|---|--|
| If yes, on what date did the study finish. | |
| If no, what is the expected completion date? | |
| If you do not expect the study to be completed, give reason(s) | |

4. Safety of participants

| | |
|---|----------|
| Have any concerns arisen about the safety of participants in this study? <i>If yes, give details and say how the concerns have been addressed.</i> | Yes / No |
|---|----------|

5. Amendments

| | |
|---|----------|
| Have any substantial amendments been made to the study? If yes please give details on a separate sheet | Yes / No |
|---|----------|

6. Unforeseen ethical issues

| | |
|---|----------|
| Are there any other developments in the study that you wish to report to the Committee? | Yes / No |
| Are there any ethical issues on which further advice is required? | Yes / No |
| <i>If yes to either, please attach separate statement with details.</i> | |

7. Declaration

| | |
|--------------------------------------|--|
| Signature of Principal Investigator: | |
| Print name: | |
| Date: | |

| |
|---|
| <p>School of Healthcare Studies</p> <p>Ethical Approval Form</p> <p>For Staff Research Projects using the School's students as the participants</p> |
|---|

PLEASE NOTE BEFORE COMPLETING YOUR APPLICATION:

- 1. Please attach the following – without which your application decision will be delayed:**
- Full project proposal
 - Participant information form and Consent form
 - Details concerning external funding (if applicable)

| | |
|---|---------------------------------|
| <p>Title of Project:</p> <p>↑Project Start Date:</p> | <p>Application Date:</p> |
| <p>Name of researcher(s):</p> | <p>Application Date:</p> |
| <p>Signature of researcher:</p> | |
| <p>Signature of Course Leader</p> | |
| <p>Signature of Head of Department/Head of School</p> | |

Recruitment Procedures

| | | Yes | No | N/A |
|---|--|-----|----|-----|
| 1 | Has the course leader been approached to confirm access to the participating student cohort? | | | |
| 2 | Has the Head of Department approved access to the participating student cohort? | | | |

Consent Procedures

| | | Yes | No | N/A |
|----|---|-----|----|-----|
| 8 | Will you tell participants that their participation is voluntary? | | | |
| 9 | If not why not? | | | |
| 10 | Will you obtain written consent for participation? | | | |

| | | | | |
|----|--|--|--|--|
| 11 | If the research is observational, will you ask participants for their consent to being observed? | | | |
| 12 | Will you tell participants that they may withdraw from the research at any time and for any reasons? | | | |
| 13 | Will you give potential participants a significant period of time to consider participation? | | | |

Possible Harm to Participants

| | | Yes | No | N/A |
|----|---|-----|----|-----|
| 14 | Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort? | | | |
| 15 | Is there any realistic risk of any participants experiencing a detriment to their interests as a result of participation? | | | |

If there are any risks to the participants you must explain in your proposal how you intend to minimise these risks

Data Protection

| | | Yes | No | N/A |
|----|--|-----|----|-----|
| 16 | Will any non-anonymised and/or personalised data be generated and/or stored? | | | |
| 17 | Will you have access to documents containing sensitive ¹ data about living individuals? | | | |
| | If "Yes" will you gain the consent of the individuals concerned? | | | |

If there are any other potential ethical issues that you think the Committee should consider please explain them on a separate sheet. It is your obligation to bring to the attention of the Committee any ethical issues not covered on this form.

¹ Sensitive data are *inter alia* data that relates to racial or ethnic origin, political opinions, religious beliefs, trade union membership, physical or mental health, sexual life, actual and alleged offences