University of Brighton Research Ethics Policy

1 Introduction

The University is committed to promoting and upholding high ethical standards, and aims to ensure that research is carried out in a way that respects the safety, wellbeing, rights and dignity of all research participants.

All members of the University involved in carrying out research, including staff, postgraduate and undergraduate students and their supervisors, are expected to act in accordance with the principles set out in this policy, and to comply with the University's processes for ethical review, as well as with government legislation and requirements and standards set out in the ethics guidelines and frameworks of research funders and other relevant professional organisations. A list of useful links, including professional ethics codes and funders' guidelines is set out in **Annex I**.

2 Principles

The following broad principles should be respected to ensure that research undertaken within the University meets high standards of ethics and conforms to good practice:

- Research should be carried out wherever possible to avoid risk of harm to participants, (including the researchers themselves), or where risk of harm is unavoidable it should be minimised by robust precautions. The benefits of the research should outweigh any risks. At all times the safety, wellbeing, rights and dignity of research participants should be respected.

- Research should be designed and carried out to high standards to ensure integrity and transparency. Any potential partiality or conflicts of interest should be made explicit and dealt with appropriately to ensure the independence of the research.

- Research participants should normally be fully informed regarding the aims, purpose and methods of the research, and the potential use and dissemination of its results. In particular they should be given information on what their participation is likely to involve, including any possible risks and benefits.

- Participation in research should be voluntary, and participants should be free from any coercion to take part, or penalty for not taking part. Participants should be free to withdraw from the study at any time without giving a reason.

- The confidentiality of information supplied by participants and their privacy and right to anonymity should be respected.

- The conduct of ethics committees and panels should follow the appropriate Standard Operating Procedures and be carried out in accordance with the University's Research Ethics Policy and Policy on Research Integrity.

It should be noted that these are broad principles underpinning research ethics, and that variations in disciplinary areas and methodological approaches might occasionally necessitate exceptions to some of these principles. Research proposals should be considered individually in order to identify and address specific ethical issues raised by the research. Further guidance on identifying and addressing ethical issues can be found in the University's Guidance on good practice in research ethics.

3 Scope

3.1 Introduction

The University of Brighton's Research Ethics Policy covers the following types of research:

- Human participant research (see section 3.2 below)
- Research that could present a risk of physical or psychological harm to those carrying out the research (beyond standard health and safety procedures and issues identified via the University's risk assessment form)
- Research with potential for significant negative impact on or damage to the natural environment (see section 3.3 below)
- Research with potential for significant negative impact on culture or cultural heritage (see section 3.4 below)

A checklist for determining whether your research project requires ethical review is included as **Annex C.**

3.2 Human participant research

It should be noted that some research may not involve human participants directly, but may still require their consent (eg use of human tissue or data). In order to encompass this type of work, human participant research is therefore defined as:

- Research involving the participation of humans, including observations, photography, audio or video recording, questionnaires, interviews, physical activity or invasive or intrusive procedures;
- Research involving the use of bodily materials derived or obtained from humans, including human tissue
- Research involving the access to, collection of or use of personal human data (including some forms of data collected via the internet) or property including images (for example in relation to health, lifestyle, housing, working environment, attitudes, preferences, perceptions, experiences etc).

3.3 Research with potential for significant negative impact on the natural environment

Significant negative impact on the natural environment includes, but is not limited to:

- the creation of environmental pollution or waste
- damage to, or destruction of plant and animal species or the natural landscape
- intrusion into or damage to habitats or disturbance of eco-systems

3.4 Research with potential for significant negative impact on culture or cultural heritage

Significant negative impact on culture and cultural heritage includes:

- damage to, or deterioration or destruction of, historical or cultural buildings, artefacts, human remains, records or archives
- damage to, or lack of respect towards, cultural protocols, practices, knowledge, languages, beliefs, spirituality or traditions

Research involving communities that engages with or impacts cultural issues should be conducted in partnership with the groups being studied, ensuring that their interests are considered and that their needs and concerns are addressed through the design and implementation of the research.

Researchers should ensure that communities have a stake in the ways that knowledge about them and their traditional cultural expressions are presented, used and interpreted.

3.5 Research involving animals

All research and related activities undertaken by staff and students involving non-human animals should be reviewed by the University Animal Welfare & Ethics Review Board (AWERB), which ensures that all animal research fully complies with the requirements of the Animals (Scientific Procedures) Act 1986 and is carried out in accordance with the 'University's Policy Statement on the Use of Animals in Scientific Procedures'(https://www.brighton.ac.uk/_pdf/research/resource-docs/use-of-animal-in-scientific-procedures.pdf).

3.6 Wider ethical issues

It is recognised that some research may present wider ethical or moral issues, other than those covered in section 3.1 above. This could involve:

- Studies where the research is politically or socially sensitive; or could have a significant impact on the welfare and interests of the wider community or society
- Research where there might be a risk to the reputation of the department, the University and/or academia as a whole
- Involvement of sponsors/participants/associates whose connections or interests might impede or be perceived as impeding the impartiality of the research process from design through to publication/exploitation
- Involvement of external sponsors/associates/organisations with a controversial ethical record (for example which sell products injurious to health or life), or where the source of funding for the research has the potential to compromise the University's position as a publicly funded charitable body.
- Activities conducted in particular countries with/under oppressive political regimes, with a poor human rights record or identified as dangerous by the Foreign & Commonwealth Office.

However, these wider issues do not fall within the scope of this Research Ethics Policy, and consideration of them is not within the remit of committees and panels in the three tier ethical review framework. Any concerns regarding research that might raise such issues should be referred to the Head of School.

3.7 Research presenting no ethical issues that lies outside the scope of the UoB ethics policy

Some types of research do not involve human participant research or other ethical issues outlined in Section 3.1 above, and are therefore considered to be outside the scope of the ethical review framework. These include:

1. Desk studies that involve literature review or access to non-personal archived material, or information about human participants that is publicly and lawfully available (e.g. census data, population statistics published by government departments and personal letters/diaries in public libraries).
2. Theoretical studies where no human participants are involved
3. Experimental or laboratory work in areas where no human participants are involved (although such work may present certain risks with regard to the researchers themselves, or may cause potential risk to the environment, and in those instances may therefore require ethical review).

It should be noted that whilst some types of research using internet sources could be considered to fall within 1 above, this is by no means the case with all internet-based research. Online research can take place in a number of settings, such as email, chat rooms and social media, which can pose specific ethical issues. The University has a guidance document on ethical issues, which includes a section on internet research that sets out and discusses some of the dilemmas that can be encountered, and gives guidance on the kinds of activity that would normally require ethical review.

3.8 Collaborative research and research receiving external review

The University aims to avoid unnecessary duplication of ethical review, whilst ensuring that responsibility has been taken for ethics in the research undertaken by members of the University. Where the University is undertaking collaborative research projects with other institutions and is not the lead partner, it is not expected that ethical review of the project would be taken by both parties. The University would normally expect ethical review to be undertaken by the lead partner institution and no further review at Brighton would be necessary. However, in some cases it may be that comparable ethical review processes or standards are not in place at the lead institution, and in order to ensure compliance with the University's ethics policy, review will need to be undertaken by Brighton, even though they are not the lead partner. In such cases each project should be considered on a case by case basis and advice sought from the relevant School Research Ethics Panel or College Research Ethics Committee to decide whether it is appropriate for the University of Brighton to undertake ethical review of the project as a whole, or the element of work being undertaken by the University of Brighton.

Where external Research Ethics Committee (REC)review is required via the Integrated Research Application System IRAS (eg for research involving NHS patients or work in UK social care or prison settings), initial scrutiny of these proposals by a separate External REC Review Panel (EERP) should be undertaken, rather than full review by a College Research Ethics Committee. Further details of this process are set out in **Annex H**.

From time to time the University receives requests from other institutions to involve students or staff as participants in their research or to access data held by Schools. These projects have normally been through ethical review at the institution submitting the request, and there is therefore no need to duplicate ethical review. However, the University needs to be satisfied that appropriate ethical review has been carried out in order to ensure that the relevant issues have been considered. The University has therefore developed a protocol for dealing with such requests that is set out in **Annex B**.

3.9 Research and other activities

The University of Brighton Research Ethics Policy covers all types of research including projects undertaken by undergraduate and taught postgraduate students. Where undergraduate or taught course postgraduate students are conducting research that is low-risk and of a sufficiently similar nature in terms of the ethical issues involved, generic ethical approval for the module may be given in order to avoid the need for individual students to submit ethics applications.

Activities other than research do not fall within the scope of the Research Ethics Policy, but it is acknowledged that there are certain areas where the boundaries between research and other activities are not always clear cut, such as audit, service evaluation and professional practice. The University has a guidance document on ethical review of projects involving audit or evaluation (see **Annex D**) which should be consulted to determine whether ethical review is needed. All audit, service evaluation or professional practice projects where the results are to be published externally require ethical approval.

Where researchers are also working in professional-based roles, and may be engaging with members of the public in order to inform professional practice, it may be considered that such activity is not research and is therefore not subject to ethical review. However, researchers should be aware of the implications of not seeking ethical review for such activities in terms of possible use of the information for publication or for inclusion as an output in the Research Excellence Framework. It can be particularly difficult to make a distinction between research and practice in the area of the arts, as they often involve similar creative processes and outcomes. Research is normally driven by a question or theory to be explored or tested, whilst practice may be driven by other factors including aesthetics, conversations, ideas or chance encounters. Research generally involves the use of methodologies, and results in new knowledge. Practice involves the expression of ideas in forms of artwork or creative outcomes, whilst research involves the use of creative outcomes to test a theory or to demonstrate originality or contribution to knowledge. In general terms, practice is broader than research. Sometimes there can be an overlap between research and practice: for example, a research enquiry may involve elements of practice, or a piece of work that starts out as practice may subsequently form the basis for a piece of research.

Researchers are advised to consider such activities on a case by case basis, and to seek guidance from their Centre for Research and Development when determining whether ethical review is required for this kind of work. Whether or not ethical approval is required, researchers should be mindful of ethical issues associated with any work involving engagement with the public, should ensure that appropriate risk assessments have been undertaken, and should adhere to the University's Policy on research integrity.

4 University of Brighton ethics review framework

4.1 Overview

The University has a three-tier ethics and governance review system in place, with the type of review required being dependent on the level of ethical risk presented by proposals. Lower risk proposals receive a lighter touch review at Tier 1 within Schools, whilst those presenting a higher level of ethical risk are considered by a College Research Ethics Committee (CREC) at Tier 2. The Tier 3 University Research Ethics Committee (UREC) acts as a top level policy and strategy body, and only reviews proposals in cases where appeals are received against Tier 2 decisions. All proposals falling within the scope of the Research Ethics Policy as outlined within section 3 above should be reviewed through the three-tier system, with the exception of research where external REC review is required (see 4.6 below).

A flowchart outlining the process for determining where proposals are reviewed is set out in **Annex A.**

4.2 Tier 1: initial scrutiny of proposals

Tier 1 review consists of initial scrutiny of research proposals at School level by supervisors or principal investigators, by completing a form and checklist (see **Annex E**) to confirm that ethical issues have been considered and appropriately addressed, and to determine whether or not the proposal raises any issues that might require it to be reviewed at Tier 2 (although if it is clear that the proposal raises significant ethical issues, completion of this form may be bypassed and a full ethics application made to Tier 2 in order to avoid duplication of effort). For staff research the PI should complete the form and send it to the chair of the School Research Ethics Panel (SREP) for checking. For student research, the form should be completed by the student and signed by the supervisor. Where completion of the checklist indicates that more than minimal ethical issues may

be presented, the supervisor will refer the proposal to the SREP to determine whether it can be modified and resubmitted to be approved at Tier 1 within the School, or should be referred up to a Tier 2 College Research Ethics Committee.

For undergraduate or taught postgraduate modules or courses where a cohort or group of students is undertaking research that presents a low level of ethical risk, and where the research is of a sufficiently similar nature, generic ethical approval for the project can be given by the SREP.

SREPs are also responsible for:

- Monitoring and carrying out random sampling test audit of Tier 1 forms signed off by supervisors and Principal Investigators (PIs)
- Producing an annual report on Tier 1 activity, including numbers of Tier 1 forms completed, numbers of forms referred to the SREP, and results of any audits carried out
- Providing ethics guidance to staff and students and promoting ethical awareness within the School

SREPs should meet at least once a year in order to monitor proposals reviewed and audited throughout the year. However, Tier 1 forms received from supervisors and PIs may be considered either electronically or at meetings by the SREPs. A set of operational guidelines for Tier 1 review are set out in **Annex E**, together with a copy of the Tier 1 form and checklist.

4.3 Tier 2: College Research Ethics Committees

Proposals presenting more than minimal ethical risk should receive full review by a College Research Ethics Committee (CREC). Applications may either be submitted directly to CRECs where it is clear that the proposal presents more than minimal risk, or may be referred up by Tier 1 SREPs. CRECs will normally consider proposals at meetings rather than electronically, and each CREC should arrange 4-6 meetings per year, with dates and deadlines to be published in advance. A set of Standard Operating Procedures (SOPs) for CRECs is set out in **Annex F** together with the Terms of reference and constitution, role descriptions for members, and a copy of the CREC application form and end of project report form.

4.4 Tier 3: University Research Ethics Committee

The University Research Ethics and Committee (UREC) acts as a top level body, overseeing the work of the Tier 2 CRECs and dealing with strategy and policy issues, and reviewing research ethics proposals only in cases where appeals are made against decisions of Tier 2 committees.

Activities normally undertaken by the REC include:

- Monitoring of Tier 2 and Tier 1 activity via annual reports and minutes of meetings
- Responding to external developments and publications
- Updating and producing University of Brighton documentation and guidance relating to research ethics and governance
- Disseminating relevant information and good practice to members and Tier 2 RECs
- Providing a response or advice to issues raised by Tier 2 RECs
- Approving protocols submitted by Schools to cover routine activities and situations
- Acting as a forum for debate of policy and strategy issues

The Terms of reference, constitution and membership of the UREC are attached as **Annex G** together with role descriptions for the UREC Chair and Administrator.

4.5 Proposals requiring external ethical review via IRAS

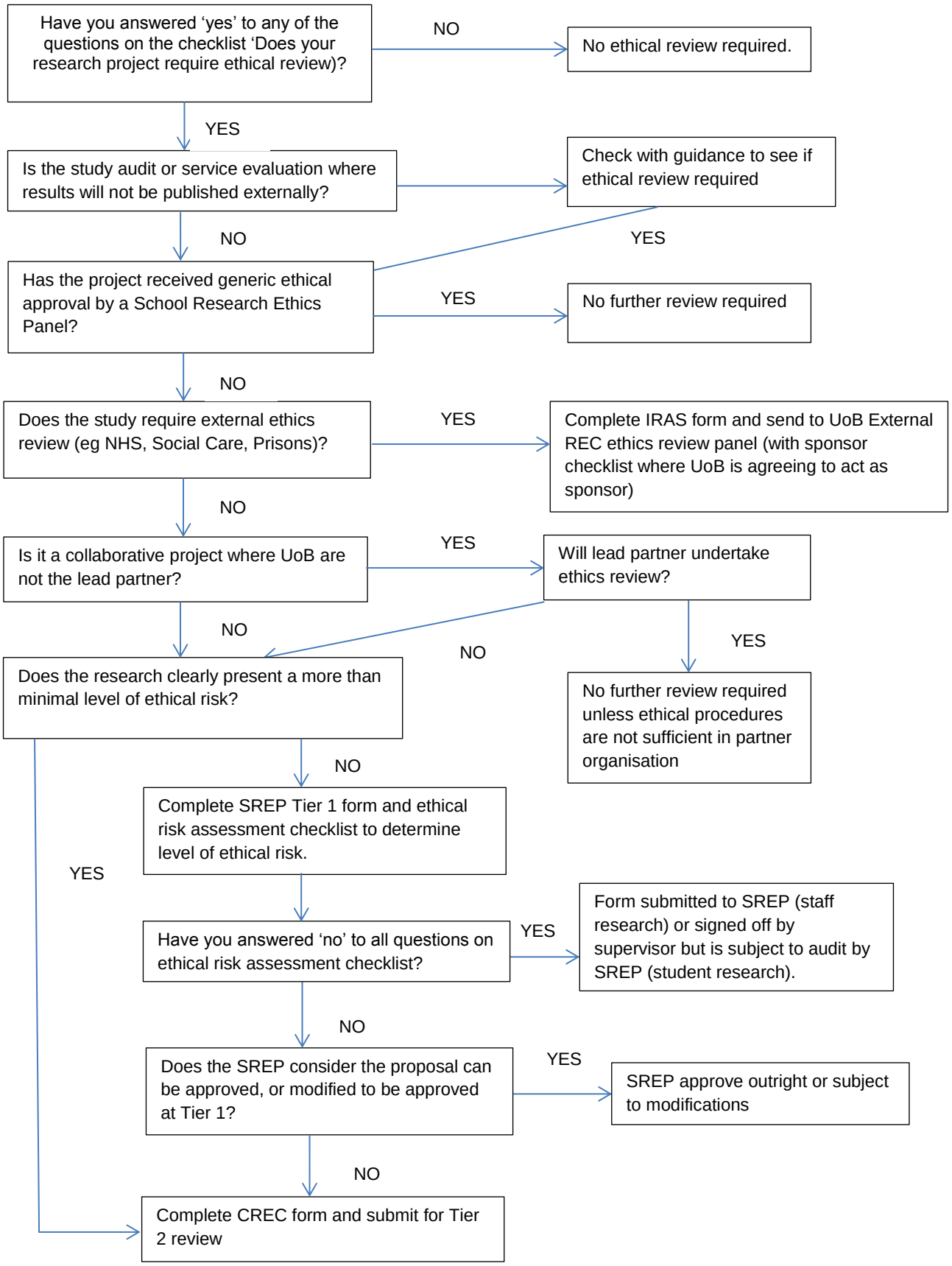
Any proposals that require external ethical review via the Integrated Research Application System (IRAS) are subject to a separate review process at the University prior to submission via IRAS, rather than being considered through the three-tier framework. A guidance document is included at **Annex H** which sets out the types of research that require review by an external REC. These proposals should be completed using the electronic IRAS form, which should then be submitted to the University's External REC Review Panel (ERRP), where it will be sent out by the chair of the panel for review by two appropriately experienced panel members to ensure that the IRAS application is of high quality and (where relevant) the University can agree to act as research sponsor. Further details regarding the types of project that require external review and application process are included in **Annex H**.

AC/HAO April 2015

List of annexes

Annex A	Ethics review process flowchart
Annex B	Protocol for requests to recruit research participants
Annex C	Checklist: Does your research project require ethical review?
Annex D	Audit and service evaluation
Annex E	Tier 1 procedures and documents
Annex F	Tier 2 standard operating procedures, terms of reference and forms
Annex G	Tier 3 terms of reference
Annex H	Guidance on projects requiring external approvals
Annex I	Useful links

Annex A: University of Brighton research ethics review process



Annex B: Protocol for requests from researchers outside the University for participation in research projects

From time to time the University receives requests from other institutions to involve students or staff in particular Schools as participants in their research or to access data held by Schools. These projects have normally been through ethical review at the institution submitting the request, and there is therefore no need to duplicate ethical review. However, the University needs to be satisfied that appropriate ethical review has been carried out in order to ensure that the following issues have been considered:

- Are there any potential risks to participants?
- Have measures been put in place to ensure that participants have been appropriately informed and have given consent, and that issues of anonymity/confidentiality have been addressed?
- If a group of students or staff is to be involved, what are the implications of some members of the group being unwilling to participate/
- If access to data is being sought, what type of data and will this have confidentiality issues?
- Are there likely to be any possible conflicts of interest (for example if a student at another institution is also a member of staff at Brighton)?

The University also needs to ensure that any relevant governance issues have been considered before agreeing to such a request. The following protocol should therefore be followed as a standard way of proceeding when such requests are received.

Institutions requesting to involve staff or students as research participants should be asked to provide a copy of the ethics submission and approval from their institution. No such request will be considered before confirmation of appropriate ethical review is provided.

Once a copy of ethical approval has been received, the institution should then be asked to provide answers to any other questions which might affect the decision whether or not to agree to the request, such as:

- How many students/staff would be involved?
- When and where would their participation take place?
- How long would this take?
- What would be resource implications in terms of staff time?
- Would the involvement of staff/students be likely to cause any disruption to the work of the School?

Subject to satisfactory answers to such questions having been obtained, the request should be passed to the Head of School(s) from which the institution is asking to recruit participants, together with any further information or clarification provided, for them to take a decision as to whether they are happy for their staff or students to be approached as potential participants.

In some cases Schools may wish to attach conditions to any agreement to staff or students being involved. For example, in addition to having access to the outcomes of the research, the School may want to have sight of any material before this is placed in the public domain in order to minimise any risk of reputational damage arising from publication.

Annex C: Does your research project require ethical review?

The following checklist should be used to determine whether your project falls within the scope of the University's Research Ethics Policy, and whether ethical review will be required (see section 3 of the Research Ethics Policy for further information on the types of research that falls within its scope).

	Question	**Yes**	**No**
1	Will the project involve the participation of humans (eg interviews, surveys, focus groups, observations, photography, audio or video recording, physical activity or invasive/intrusive procedures)?		
2	Will the research involve the use of bodily materials derived or obtained from humans?		
3	Will the research require access to, collection of or use of personal human data or property?		
4	Does the research have the potential to expose any person, whether or not participating in the research, to physical or psychological harm?		
5	Does the research have the potential for significant negative impact on or damage to the natural environment?		
6	Does the research have the potential for significant negative impact on culture or cultural heritage?		
7	Will the research involve non-human animal subjects? (Note: animal research should be reviewed by the Animal Welfare and Ethical Review Board, rather than through the three-tier Research Ethics Framework).		
8	Are there are any other ethical issues raised by this research project that in the opinion of the applicant would warrant ethical review?		

If you have answered yes to any of the above questions, then some form of ethical review will be necessary.

If your project is audit or service evaluation rather than research, then it may also require ethical review (for example, if the results are to be published externally). Please see Annex C of the University's Research Ethics Policy for guidance on ethical review of projects involving audit or evaluation.

Annex D: Guidance on ethical review of projects involving audit or evaluation

Cases sometimes arise where a student or member of staff is undertaking work that could be considered as audit or evaluation of services or practice rather than research, either within the University or in a professional context such as within a School or NHS trust. It is not always clear in such cases what counts as audit or service evaluation rather than research and whether ethical approval is required. **However, regardless of whether the work is research, audit or service evaluation, any study where the results are to be published externally falls within the scope of the University's Research Ethics Policy and is therefore subject to ethical review.**

As a general rule it is the University's view that:

- Student projects (undergraduate, taught postgraduate and postgraduate research) involving service evaluation or audit (either within the University or a professional context) should be treated as research training and should therefore be subject to ethical review.
- Projects involving service evaluation or audit by academic staff (including evaluation of University courses, modules, systems or services) where the results are not to be published externally should not normally require ethical approval.

There is no universally agreed definition of 'research'. The staff member responsible for the study must decide whether the study is research requiring ethical approval based on the nature of the study. Unless you can demonstrate that the project is not research ethical approval if required should be sought before the study commences. However, in determining whether a study should be considered as evaluation/audit or research the following guidance may be helpful.

Audit

Audit is defined as assessing the level of service being provided against a set of predetermined standards or benchmarks. This generally involves analysing existing data with results usually being used/distributed locally in order to effect change to improve/change the level of service currently being provided. The results of audit are intended to be seen and used only within the organisation undertaking the audit, and are not intended to be published or to inform people working outside the organisation. Audit does not require ethical approval

Service Evaluation

Service Evaluation is undertaken to benefit those who use a particular service and is designed and conducted solely to define, measure or judge current service. Your participants will normally be those who use the service or deliver it. It involves an intervention where there is **no change** to the standard service being delivered (e.g. no randomisation of service users into different groups). The results of service evaluation are intended to be seen and used only within the organisation undertaking the evaluation, and are not intended to be published or to inform people working outside the organisation. Service evaluation does not require ethical approval.

Other types of Evaluation

Other types of evaluation may involve an active approach which seeks **to change** what is being evaluated. These may involve users of services as direct participants in the evaluation process the aim of which is to develop or improve services and/or policy and to empower service users to make changes to those services. In such cases there is a direct intervention in the service-delivery process. The results may have the potential to be published or to inform others working outside the organisation. These types of evaluation would be considered as research and therefore require ethical approval.

There may still be some grey areas or cases where there are specific concerns regarding ethical issues, in which case advice should be sought from the relevant REC as to whether ethical review is required.

Publication of results

Staff undertaking work that is considered to be evaluation or audit and for which ethical approval has not been obtained should be made aware that the results of the research cannot be published externally. There may be some cases where researchers wish to use the results of previous audits or evaluations for research purposes, and such use would then be subject to ethical review. In particular, if it is proposed to use primary data collected originally for the purposes of an audit or evaluation, it would normally be necessary to ensure that consent had been obtained from the original participants for its subsequent use in a research project.

Annex E: Tier 1 Operational Guidelines

Initial scrutiny of proposals

The checklist 'Does your research project require ethical review?' should be used to determine whether the research falls within the scope of the University's Research Ethics Policy. Where the research falls outside the scope of the Research Ethics Policy ethical review is not required.

Where the research does fall within the scope of the Research Ethics Policy, the applicant should complete the Tier 1 form and checklist to confirm that ethical issues have been considered and appropriately addressed, and to determine whether or not the proposal raises any issues that might require it to be reviewed at Tier 2 (although if it is clear that the proposal raises significant ethical issues a full ethics application made directly to Tier 2 in order to avoid duplication of effort).

For student research, if the applicant has answered 'no' to all questions in Section D of the Tier 1 form or the proposed research is covered by specific School protocols (see below), then the form can be signed off by the supervisor and included when the student project or dissertation outline is submitted for assessment. If the student applicant has answered 'yes' to any of the questions in Section D of the form, then Section E should be completed to provide more details, and the form sent to the SREP.

For staff research, in all cases the completed form should be sent to the SREP. The Chair of the SREP will review the form, and where the applicant has answered 'no' to all questions in Section D of the Tier 1 form, the Chair will sign off the form without the need for further review.

School protocols covering routine activities involving more than minimal ethical risk

Schools may undertake certain types of work on a routine basis that involve activities or situations that would normally be considered as involving more than minimal risk, but where protocols have been established to address and minimise the risks involved. These might include for example:

- Taking samples such as blood or urine from healthy volunteers
- Work involving measuring and recording ranges of physical movement of participants.
- Work involving normally developing children in mainstream educational settings, which focus on routine learning and teaching activities, where researchers have been Disclosure and Barring Service (DBS) checked and are not working alone with children, where permissions to work in such settings have been granted by people in senior roles, and where privacy, confidentiality and anonymity can be assured.
- Laboratory-based work involving healthy adult volunteers in vigorous exercise

For any activities or situations covered by such protocols, Schools need to ensure that processes have been risk assessed, researchers have been appropriately trained, students are being supervised and, where relevant, external requirements are being complied with. Where Schools establish such protocols, they should be submitted to the School Research Ethics Panel Chair, for approval by the College Research Ethics Committee.

Further scrutiny by School Research Ethics Panels

Where completion of the Tier 1 checklist has indicated that a proposed study may present more than a minimal level of ethical risk, the SREP should review the proposal to consider whether:

- The proposal can be signed off at Tier 1 either with or without minor amendments (normally minor amendments recommended by the SREP could be signed off by the supervisor/PI)

- The proposal currently presents ethical risks that would normally require it to go for Tier 2 review, but where modifications could be proposed that would reduce the level of risk and enable it to be approved at Tier 1
- The proposal presents a level of risk that will require it to be referred for Tier 2 review and the proposal is of sufficient standard, all the forms are in place to be assessed at Tier 2

Tier 1 proposals referred to the SREP may be considered at any time, and may be reviewed either electronically or at meetings. Proposals should be reviewed by a minimum of two SREP members, one of whom may be the Chair, and Chairs should ensure that conflicts of interest are avoided as far as possible when allocating proposals to SREP members for review.

Following review, outcome emails to applicants informing them of the SREP's decision should be sent out as soon as possible. The email should include:

- The decision of the SREP
- Any conditions and/or recommendations, including details of revisions, additional information or clarification required for the SREP to give final approval
- Reasons for required resubmission or referral to a CREC and changed (if any) needed before submission to Tier 2.
- An outline of next steps in terms of process to be followed, including mechanisms for providing revisions or resubmitting the application

Generic ethical approval of projects on taught modules or courses

For undergraduate or taught postgraduate modules or courses where a cohort or group of students is undertaking research that falls within the University's research ethics framework but presents a low level of ethical risk, and where the research is of a sufficiently similar nature, generic ethical approval for the project can be given by the Tier 1 School Research Ethics Panel.

For generic approval to be given, the course or module leader will need to demonstrate that projects are sufficiently similar in terms of the following parameters:

- Research topic, or a clearly defined range of research topics
- Range of aims, objectives and research questions
- Research methods and processes
- The types of participant to be recruited
- The types of activities in which participants will be involved
- The means of recruitment and informing participants about the research
- The information sheet, consent form and recruitment materials (where relevant)
- The types of questions for interviews or focus groups (where relevant)

The research should normally be low risk unless it is covered by a protocol for routine work within the School that has already been approved by a Tier 2 CREC. The Tier 1 checklist should be completed in order to determine the level of ethical risk associated with the project.

Course or module leaders wishing to obtain generic ethical approval for a project or set of projects should complete the Tier 1 generic ethical approval form and confirm they have completed any relevant risk assessment procedures.

For all projects where generic ethical approval has been given, module leaders or supervisors responsible for the project should ensure that students have undertaken training in research ethics and have an awareness of the ethical review processes. Module leaders or supervisors may also wish to include an opportunity for students to complete an individual ethics application for training

purposes as part of their coursework, even though the project does not necessarily require individual ethics approval.

Monitoring and auditing of Tier 1 forms

Where Tier 1 forms have been signed off by supervisors, SREP Chairs should monitor the sign-off process, by obtaining lists of project titles that have been signed off. Where titles of project indicate that they may have had the potential to raise more than minimal ethical issues, the SREP can request copies of the Tier 1 forms in order to carry out an audit. The SREP should in addition periodically obtain copies of a proportion of Tier 1 forms (normally 10%) in order to carry out random sample testing.

Additional responsibilities of School Research Ethics Panels

In addition to considering Tier 1 proposals and carrying out audits of forms signed off by supervisors, SREPs are responsible for:

- Producing an annual report on Tier 1 activity (see section on reporting below)
- Producing copies of protocols covering routine activities for approval by the CREC
- Providing ethics guidance to staff and students and promoting ethical awareness within the School (the Chair has a key role in this activity, and a role description for SREP Chairs is set out below)
- Ensuring that courses run by the School include training in ethics for students where this is relevant to the work they will be undertaking

SREPs should meet at least once a year in order to monitor proposals reviewed and audited throughout the year. However, this is a minimum requirement and SREPs may choose to hold more frequent meetings and to consider proposals via meetings rather than electronically if this mode of operation is preferred.

Constitution of School Research Ethics Panels

SREPs should consist of a Chair, nominated by the Head of School in consultation with the relevant College Research Ethics Committee Chair, and at least two other members covering the range of disciplinary areas normally reviewed by the SREP and ensuring a balance of expertise and experience. SREPs may additionally co-opt other staff and include members external to the School or the University if this is felt to be appropriate. Heads of School should seek to avoid conflict of interest in terms of members who may hold other key roles within the School. SREPs should have the option of seeking advice from others with particular expertise where this is deemed appropriate for review of proposals.

Reporting

SREPs are required to produce an annual report to the relevant CREC on their activity to include:

- Numbers of Tier 1 forms signed off by supervisors and PIs, and the results of any audit carried out of these
- Numbers of Tier 1 proposals reviewed by the SREP and the number of these that were referred to the CREC or other committees
- A summary of any issues arising from proposals reviewed
- A summary of any other ethical issues that were discussed or that have arisen in the School over the year
- Any items which the SREP feels should be considered in more detail by the CREC

Role Description: School Research Ethics Panel Chair

Overview of Role

The main purpose of this role is to act as Chair to the School Research Ethics Panel (SREP). The Chair is responsible for the SREP's ethical review function, ensuring that ethical issues are considered thoroughly, and that clear decisions on proposals are made and recorded. The Chair will also take a lead role in promoting a culture of best practice in research ethics within the School and acting as an advocate for research ethics

Key responsibilities

1. Oversee management of proposals submitted to the SREP, ensuring that ethical issues are explored and debated and that proposals are reviewed in a timely manner.

2. Ensure that proposals are dealt with fairly and appropriately, and that any potential conflicts of interest are addressed.

3. Ensure that the SREP operates in accordance with the Tier 1 Operational Guidelines.

4. Ensure that effective monitoring and auditing is undertaking of Tier 1 forms signed off by supervisors and PIs

5. Have an awareness of equality and diversity, and ensure that applicants are treated fairly and equally, regardless of age, gender, sexuality, gender identity, ethnicity, religion or disability.

6. Identify any training needs for SREP members and ensure that arrangements are made to meet these.

7. Provide advice, guidance and information on ethical issues to staff and students within the School, support the development of ethics within teaching and research,and liaise with the CREC, UREC and Research Office where appropriate to promote the embedding of a research ethics culture within the School.

8. Sit as an ex-officio member of the College Research Ethics Committee, attending meetings, and providing an annual report to the CREC summarising the SREP's activities.

Appointment: by Head of School in consultation with the Chair of the College Research Ethics Committee

Tenure: 3 years, renewable for a further term

Tier 1 School Research Ethics form and checklist

Section A: Applicant details

Project title	
Proposed start and end date of project	
Name of researcher	
School	
Level (UG/Taught PG/PGR/Staff)	
Phone	
Email	
Funder (if applicable)	

Section B: Student details (where applicable)

Course/Module/Unit name/number	
Name of supervisor/tutor	

Section C: Description of project

Please provide a brief outline of the proposed project, including the research methods to be used, the types of participants that will be involved, and how they will be recruited.

Section D: Ethical risk assessment checklist

Please tick YES or NO for each question. If you have answered YES to any of questions 1 to 15, please provide a brief outline of how these risks will be addressed in the relevant part of the box in Section E, or give details of any existing protocols within the School that already cover these specific issues.

No	Question	Yes	No
1	Will participants be likely to undergo vigorous physical activity, prolonged or repetitive testing, or to experience physical harm, more than minimal pain or discomfort or exposure to dangerous situations/environments as part of the research?		
2	Does the study involve any physiological or psychological interventions with the potential to be invasive, intrusive or harmful (eg administration of drugs or other substances; taking samples of blood, saliva, urine etc; use of equipment to monitor bodily performance; manual handling of participants; techniques such as hypnotherapy)?		
3	Will the study involve participants who could be considered vulnerable (for example due to age, psychological or medical condition, social inequality), or where possible coercion or feelings of obligation to participate may exist (eg when recruiting ones own students or colleagues)?		
4	Will the study involve the discussion of sensitive topics (for example, painful reflections or traumas, religious or other beliefs, sexual behaviour, experience of violence, abuse or bullying, illness, illegal or political behaviour, people's gender or ethnic status, detailed financial matters, issues relating to body image)?		
5	Could participants experience psychological or emotional stress, anxiety, humiliation or other negative consequences, beyond what would be expected to be encountered in normal life?		
6	Will it be necessary for participants to take part in the study without their knowledge at the time (eg covert observation or recording of people in non-public places), or involve deception or conduct of the research without participants' full and informed consent?		
7	Will the research require the co-operation or permission of an individual or gatekeeper in order to gain access to participants (eg a teacher at a school, a manager of sheltered housing, the organiser of a self-help group etc)?		
8	Will the research involve access to records of a confidential or personal nature, or documents of a sensitive political, moral, medical or religious nature?		
9	Will the research involve collecting visual information of a personal nature, such as taking photographs or making video recordings of participants?		
10	Will the research involve accessing participants or data of a personal nature via an online environment or internet setting (eg chat rooms, social media, instant messaging etc)?		
11	Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?		
12	Does the research have the potential for causing significant negative impact on the environment (including animal or plant populations, or rare or protected species, habitats or sites)?		
13	Might the research raise specific ethical issues regarding cultural/political sensitivities (eg local customs or gatekeepers, political sensitivities)?		
14	Might the research involve the disclosure of confidential information beyond the initial consent given?		
15	Are there any other ethical issues that are not covered in the questions above?		

Section E: Addressing potential risk (to be completed only if one or more questions in section D above have been answered as 'YES')

If you have answered 'YES' to any of the questions in Section D above, please provide an outline of how the potential risks will be addressed against the question number. The School Research Ethics Panel will use this information to assess whether the risks are insignificant enough, or could be mitigated, in order to enable the research to proceed with Tier 1 ethical approval, or whether the proposal needs to be referred to a College Research Ethics Committee.

Q in section D above	**Please outline potential risks and how they will be addressed**
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	

Some Schools may carry out research that involves particular types of risk on a routine basis (eg taking blood, manual handling of participants or working with specific hazardous substances, involving children as participants in a school setting, taking photographs or videos of participants), and may already have specific protocols that cover procedures and guidelines for dealing with these risks. If activities to be undertaken in the proposed project are covered by such a protocol please provide details below. Where the research is covered by such a protocol and does not raise any additional ethical issues it does not need to be considered at Tier 2.

Section F: Checklist for ethical issues relating to research participants

Please use the checklist below to confirm that ethical issues regarding research participants have been identified and addressed appropriately.

		Y	N/A
1	Participants will be fully informed regarding the purpose of the study and their participation in it		
2	It will be made clear to participants that their participation is voluntary and they may withdraw from the study at any time without giving a reason		
3	Consent will be obtained from participants for taking part in the study		
4	Recruitment materials (including posters, leaflets and emails), information sheets, consent forms, questionnaires or letters provide sufficient and accurate information, and have been clearly written and presented in a format suitable for the target audience		
5	Where the research is likely to involve participants who might not understand English, arrangements will be made for translation of materials and/or provision of interpreters as appropriate		
6	Appropriate arrangements have been made to consider anonymity, confidentiality and privacy of participants		
7	Appropriate arrangements have been made for the collection, handling and storage of electronic and/or physical data		

Section G: Supervisor sign-off (for student research only)

I confirm that I have checked the application and that:

- the student has addressed the relevant ethical issues
- the student has the necessary skills and experience to carry out the proposed research and has been trained in ethics as part of their course
- this is a practicable and worthwhile research project, appropriate to the level of study

Supervisor: _____ Date: _____

Section H: Checklist for accompanying documents

Please ensure you have attached copies of any of the following documents where relevant:

- ☐ Information sheets
- ☐ Consent forms
- ☐ Advertising or recruitment materials
- ☐ Sample questionnaires or interview questions (these can be draft prior to piloting)
- ☐ Risk assessment forms
- ☐ Letters of support from external organisations involved in the research
- ☐ List of references

Student applicants: If you have answered 'no' to all the questions in Section D, or the work is covered by an approved School protocol, this form may be submitted with the student dissertation or project outline. If you have answered 'yes' to one or more of the questions in Section D, please return this form and all accompanying documentation to the School Research Ethics Panel .

Staff applicants: Please return this form and all accompanying documentation to the School Research Ethics Panel.

Tier 1 generic ethical approval for projects on taught courses

Section A: Course or Module Information

Course/Module title	
Course or Module leader name	
School	
Level (UG/Taught PG)	
Email address	
Phone	

Section B: Project Details

Title of project	
Project start date	
Project end date	

Project outline
Please provide a brief outline of the project, including an estimate of the number of students who will be involved, the rationale for the project, the aims of the research and the data collection methods to be used.

Information on participants
Please provide details of the types of participants that will be involved, and how they will be recruited.

Section C: Ethical risk assessment checklist

Please tick YES or NO for each question.

No	Question	Yes	No
1	Will participants be likely to undergo vigorous physical activity, prolonged or repetitive testing, or to experience physical harm, more than minimal pain or discomfort or exposure to dangerous situations/environments?		
2	Does the study involve any physiological or psychological interventions with the potential to be invasive, intrusive or harmful (eg administration of drugs or other substances; taking samples of blood, saliva, urine etc; use of equipment to monitor bodily performance; manual handling of participants; techniques such as hypnotherapy)?		
3	Will the study involve participants who could be considered vulnerable (for example due to age, psychological or medical condition, social inequality), or where possible coercion or feelings of obligation to participate may exist (eg when recruiting ones own students or colleagues)?		
4	Will the study involve the discussion of sensitive topics (for example, painful reflections or traumas, religious or other beliefs, sexual behaviour, experience of violence, abuse or bullying, illness, illegal or political behaviour, people's gender or ethnic status, detailed financial matters, issues relating to body image)?		
5	Could participants experience psychological or emotional stress, anxiety, humiliation or other negative consequences, beyond what would be expected to be encountered in normal life?		
6	Will it be necessary for participants to take part in the study without their knowledge at the time (eg covert observation or recording of people in non-public places), or involve deception or conduct of the research without participants' full and informed consent?		
7	Will the research require the co-operation or permission of an individual or gatekeeper in order to gain access to participants (eg a teacher at a school, a manager of sheltered housing, the organiser of a self-help group etc)?		
8	Will the research involve access to records of a confidential or personal nature, or documents of a sensitive political, moral, medical or religious nature?		
9	Will the research involve collecting visual information of a personal nature, such as taking photographs or making video recordings of participants?		
10	Will the research involve accessing participants or data of a personal nature via an online environment or internet setting (eg chat rooms, social media, instant messaging etc)?		
11	Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?		
12	Does the research have the potential for causing significant negative impact on the environment (including animal or plant populations, or rare or protected species, habitats or sites)?		
13	Might the research raise specific ethical issues regarding cultural/political sensitivities (eg local customs or gatekeepers, political sensitivities)?		
14	Might the research involve the disclosure of confidential information beyond the initial consent given?		
15	Are there any other ethical issues that are not covered in the questions above?		

If you have answered NO to all questions, please complete the remainder of the form. If you have ticked YES to one or more questions and they are covered by a Tier 2 approved protocol, please complete section D. If you have answered YES to any questions that are not covered by a Tier 2 protocol, the proposed project is not appropriate for general ethical approval.

Section D: Tier 2 approval protocols

Some Schools may carry out research that involves particular types of risk on a regular basis (eg taking blood, manual handling of participants or working with specific hazardous substances, involving children as participants in a school setting, taking photographs or videos of participants), and may already have specific protocols that cover procedures and guidelines for dealing with these risks. If activities to be undertaken in the proposed project are covered by such a protocol please provide details below.

Section E: Checklist for ethical issues relating to research participants

Please use the checklist below to confirm that ethical issues regarding research participants have been identified and addressed appropriately.

		Y	N/A
1	Participants will be fully informed regarding the purpose of the study and their participation in it		
2	It will be made clear to participants that their participation is voluntary and they may withdraw from the study at any time without giving a reason		
3	Consent will be obtained from participants for taking part in the study		
4	Recruitment materials (including posters, leaflets and emails), information sheets, consent forms, questionnaires or letters provide sufficient and accurate information, and have been clearly written and presented in a format suitable for the target audience		
5	Where the research is likely to involve participants who might not understand English, arrangements will be made for translation of materials and/or provision of interpreters as appropriate		
6	Appropriate arrangements have been made to consider anonymity, confidentiality and privacy of participants		
7	Appropriate arrangements have been made for the collection, handling and storage of electronic and/or physical data		

Section F: Research ethics training for students

Please outline how and where in the course or module research ethics will be taught to students.

Section G: Accompanying documents

Please attach copies of any of the following documents where relevant:

- ☐ Template to be used for information sheets
- ☐ Template to be used for consent forms
- ☐ Examples of advertising or recruitment materials (eg posters, letters, emails)
- ☐ Sample questionnaires or interview questions
- ☐ Risk assessment forms
- ☐ Any other supporting documentation

Annex F: Tier 2 documents

College Research Ethics Committee Standard Operating Procedures

1 Purpose and scope of College Research Ethics Committees

The main purpose of College Research Ethics Committees (CRECs) is to undertake ethical review of research proposals that present more than minimal ethical risk. A more detailed description of the remit of CRECs is set out in the Terms of Reference, Constitution and Membership below. Types of project or work that is outside the scope of ethics committees within the University are set out in section 3 'Scope' of the University's Research Ethics Policy. A description of the types of work that would present more than minimal ethical risk is set out in the Tier 1 checklist that is included in Annex D of the Research Ethics Policy.

2 Constitutional matters

The formal Terms of Reference, Constitution and Membership for CRECs are set out below. The chair of each CREC is appointed by the chair of the University Research Ethics Committee, in consultation with the Dean of College. The chair of each School Research Ethics Panel (SREP) within the College should be represented on the CREC as an ex officio member, and other members of the CREC are nominated by the chair. The chair should ensure that the membership includes sufficient representation from the subject disciplines normally reviewed by the CREC, as well as a lay member and members from outside the College. Where the CREC is likely to be reviewing proposals involving particularly vulnerable people (for example work taking place outside the UK involving patients, prisoners or those in social care where the proposal will not be going for external REC review) membership should include people with relevant expertise in these types of research. The chair should also try to ensure where possible that there is a balance in terms of gender and ethnicity. Chairs should seek to avoid conflict of interest in terms of members who may hold other key roles within the College or University. Nominated members should hold the post for a term of three years, with a third of the membership changing each year. The chair should nominate a deputy chair from within the membership to undertake the role of chair in his or her absence. The membership should include provision for co-opted members, and CRECs should have the option of seeking advice from others with particular expertise where this is deemed appropriate for review of proposals. The quorum of a CREC should be 40% of the total membership minus any vacancies or members occupying more than one position. The key roles and responsibilities of the CREC chair, administrator and members are set out in the role descriptions below.

3 Meetings, application processes and timescales

In order to ensure that review of proposals is robust and thorough, scrutiny of proposals should normally be undertaken by the CREC at meetings rather than electronically. Meetings should be held frequently enough to ensure timely review of proposals, and to avoid delay to research projects. It is expected that this would normally mean scheduling 4-6 meetings per year, with the possibility that some may subsequently be cancelled due to lack of business. Meeting dates for the year should be publicised in advance via the College web site, together with application deadlines of three weeks before each meeting. CRECs should undertake to provide a response to applicants within a week of the meeting.

Applications to CRECs should be submitted electronically to the CREC administrator using the form attached here. Applications should be made by the Principal Investigator of the project. Where the applicant is a student, the form should also be signed by the project supervisor or relevant module leader. Applications should be accompanied by relevant documentation such as participant information sheets, consent forms, recruitment materials, sample questionnaires or interview schedules. A checklist of these is included on the application form.

Applications should be checked by the administrator to ensure that they are complete and adhere to the word counts on the form. Applications that are incomplete or exceed the stated word counts may be returned and not considered by the CREC. The Chair may refer applications to a Tier 1 School Research Ethics Panel or to the External REC Review Panel (ERRP) where it is felt that review by one of these panels is more appropriate than Tier 2 review.

Applications should be circulated electronically to all members prior to the meeting. For each proposal two primary reviewers should be identified to take the lead on introducing and commenting on the proposal at the meeting. The lead reviewers should complete the reviewer form, and where time allows, the forms should be circulated to members in advance of the meeting. The chair should ensure that they have read all applications prior to the meeting, but will not take the lead on introducing any proposals. Proposals should be kept confidential, and members asked to securely dispose of copies following the meeting, with a copy being retained only by the administrator.

4 Conduct of meetings

The Chair should ensure that any potential conflicts of interest where individuals may gain any direct or indirect benefit from the decision are declared and addressed (for example, where one of the members is the supervisor of a student or line manager of a member of staff submitting an application, the member may be asked to leave the room or remain silent while the application is discussed). Members should be made aware that applications and all discussion of them that takes place in the meeting are confidential.

Each application should be introduced by the two lead reviewers, following which other members may comment on the proposal and a discussion of the ethical issues take place. Normally applicants will not be expected to attend the meeting at which their proposal is considered. However, if the lead reviewers feel it is useful, they may recommend that the chair invites the applicant and/or supervisor to join the meeting in order to provide further information or clarification, or to explore how some of the ethical issues might be addressed. Where student applicants are invited to attend the meeting, their supervisor should attend with them.

The focus of the review of proposals should be the ethical issues that they present, and the primary consideration should be the safety, welfare, rights and dignity of research participants. The committee should ensure that they have considered any potential risks and how these might be addressed, how participants will be informed about the research and will give consent to take part, and any issues regarding anonymity, privacy and confidentiality. Recruitment materials, information sheets, consent forms and any other materials should be checked to ensure that they are clear, provide sufficient information and are appropriate to the target audience. The decision of the CREC should be based on a review of the ethical issues rather on other issues such as research design, unless these make a proposal unethical. CRECs may offer supplementary comments regarding other issues such as research methodology or the presentation of the proposal, but these should not form the basis of conditions of approval.

5 Decision-making

Once discussion of a proposal has taken place the committee should make a decision which should be recorded. Normally decision-making should take place by consensus, but in the event of being unable to reach an agreement, a vote may be taken with a decision being made by a simple majority. Decisions available to the committee would normally be:

- Unconditional favourable ethical opinion

- Favourable ethical opinion with conditions (This would normally be approval subject to minor revisions, and the CREC would not need to see a revised version of the proposal. In cases of student research, supervisors would be expected to sign off a revised version)
- Unfavourable ethical opinion requiring resubmission of proposal with revisions (depending on the nature and/or number of revisions, the CREC may either ask for the resubmission to be considered at the next meeting, or to be signed off by the chair and/or lead reviewers). Where revisions are required, the subsequent review of revised proposals should normally focus on the issues identified in the original proposal.
- Unfavourable ethical opinion with no option for resubmission (It is unlikely that proposals will be given an unfavourable ethical opinion without the opportunity to resubmit if they are being scrutinised for the first time. Applicants whose proposals have been given an unfavourable ethical opinion may either submit a new application, or appeal to the UREC against the decision of the CREC)
- Referral to another committee, with or without advice (The Chair may refer applications to the ERRP or a Tier 1 SREP without consideration by the CREC if it is felt that review by one of these panels is more appropriate than Tier 2 review. Proposals may be referred to another CREC if it is felt that they have more relevant expertise in the research area. Advice may be sought from the University Research Ethics Committee (UREC), but proposals should not normally be referred up to the UREC, as it is the body to which appeals against CREC decisions may be made.)

In addition to the decision and any conditions for approval, CRECs may wish to provide recommendations or non-mandatory advice.

6 Follow-up to meetings

Following the meeting, the CREC administrator should draft a set of minutes for approval by the chair and circulation to members. The minutes should include:

- Members present and apologies received
- For each application: a summary of issues discussed; a record of the decision and any conditions or recommendations; a record of voting if the decision was not made by consensus; any follow-up action required
- A record of any other business considered by the CREC
- Dates of next meetings

Outcome emails to applicants informing them of the CREC's decision should be sent out within one week of the meeting using the standard templates provided. For student applicants, supervisors should be copied in on the outcome email and any subsequent correspondence relating to the application. The email should include:

- The decision of the CREC
- Any conditions and/or recommendations, including details of revisions, additional information or clarification required for the CREC to give a favourable ethical opinion
- Reasons for being unable to give a favourable ethical opinion or for required resubmission
- An outline of next steps in terms of process to be followed, including mechanisms for considering further information and deadlines for providing revisions or resubmitting the application
- For proposals that have been given a favourable ethical opinion, a reminder about the need to contact the CREC in the event of any subsequent changes to the planned research, and to complete an end of project form on completion of the research
- For proposals that have been given a favourable ethical opinion, a reminder of the need to flag up any unexpected ethical issues that arise during the project, and to report immediately any serious adverse events that occur during the research

- For proposals that have not been given a favourable ethical opinion, an outline of the options available (submitting a new application or making an appeal to the UREC)

7 Amendments

Occasionally there may be a need to make changes to a research study after ethical approval has been obtained, and these may raise ethical issues. Changes that might raise ethical issues could include:

- Measures to reduce potential harm or distress to people
- Changes to the design of the research and methods used
- Changes to the location or context in which the research is being carried out
- Additional uses to which the data collected might be put

Changes to the study may not necessitate resubmission to the CREC, and in cases where they do not raise significant ethical issues, they may be signed off by the CREC chair (eg where the study is being extended to recruit additional participants of a similar type to those already taking part). Researchers should notify the CREC of any proposed changes using the CREC change notification form below, which should be assessed by the CREC chair to see whether the changes proposed would constitute a substantial amendment in terms of the ethical issues raised.

8 Expedited review

Normally proposals should receive scrutiny by the full committee at a meeting. However, in exceptional cases it may be necessary to undertake expedited review, if it is not feasible to wait until the next main meeting of the CREC. Circumstances in which this might occur are:

- Where funders' requirements necessitate that a project commences by a particular date
- Where student research needs to be carried out within a particular timeframe in order to fit with assessment requirements
- Where a proposal has required resubmission to the CREC more than once, and further consideration at a full meeting would result in an unacceptable delay to the project

Sometimes in order to avoid delays, it may be possible to approve earlier stages of a project for commencement where these don't involve complex ethical issues (for example for a project where interviews were to be carried out with non-vulnerable people, this stage of the work could be approved initially, whilst additional interviews with vulnerable participants may require further ethical consideration). CRECs should explore such options carefully and should only use expedited review when there is no other option.

Applicants requesting expedited review of a proposal should make a case in writing, outlining the reason for the request, to the chair of the CREC via the secretary. Where expedited review is used, a sub-committee should be convened consisting of the chair and at least two other reviews. The chair may additionally wish to send the proposal out electronically for comment by other members.

9 Appeals

If applicants are given an unfavourable ethical opinion or if they think the conditions imposed are unreasonable they may either submit a new application or appeal against the decision. Appeals will be referred up to the UREC for consideration. Any members of the UREC that were involved in the original CREC review of the application will not be involved in the consideration of the appeal other than to provide evidence to the UREC if requested.

10 Monitoring and reporting

Ethical approval by CRECs should normally be valid for the duration of the project, unless stated otherwise when approval is given, or where an amendment has been made to the study and further subsequent approval is required (see section 7 above). For all projects, an end of project report is required, to be submitted using the University's end of project report form below. End of award reports may be considered by the chair, rather than the full committee, but any matters of concern that arise should be referred to the full committee for discussion, and appropriate actions taken.

CRECs are required to produce an annual report to the UREC on their activity to include:

- Statistical information on proposals reviewed, including the total number received, and numbers of those approved outright, those requiring minor revisions, those requiring major revisions and resubmission, and those referred to the University REGC
- A summary of any issues arising from proposals reviewed.
- Reports from School Research Ethics Panels (see below).
- A summary of any other issues which were discussed throughout the year.
- Any items which the CREC feels should be considered in more detail by the UREC
- A statement on how end of project reporting procedures are operating, including how many have been received, and any issues arising from these.

CRECs may also be asked by the UREC periodically to provide lists of proposals reviewed from which the UREC will select a number for random sample testing for audit purposes.

CRECs are responsible for obtaining an annual report from School Research Ethics Panels on their activity including statistical information on proposals reviewed, and any other significant issues arising during the year.

Terms of Reference, Constitution and Membership

College Research Ethics Committee

Committee of: University Research Ethics Committee

Terms of Reference

A Committee of the UREC to:

1. Assess the ethical risk of research involving human participants or raising other ethical issues conducted by individuals employed by or registered as students within the College
   1.1. review research involving human participants or raising other ethical issues conducted by individuals employed by or registered as students within the College;
   1.2. ensure that ethics review is independent, competent and timely;
   1.3. protect the dignity, rights and welfare of research participants;
   1.4. consider the legitimate interests of other individuals, bodies or communities associated with the research;
   1.5. consider the safety of the researcher(s);
2. Advise researchers on addressing ethical risk
   2.1. make informed recommendations to the researcher if a proposal is found to be wanting in some respect;
   2.2. make recommendations directed at improving research design where issues of governance and/or ethical concern arise;
   2.3. review amendments to approved projects;
   2.4. refer issues to the University Research Ethics where it is not possible to resolve them;
   2.5. ensure research proposals comply with the internal and external requirements for the ethical scrutiny of research;
3. Oversee and monitor the work of School Ethics Panels
   3.1. approve the Terms of reference, constitution and membership of School Research Ethics Panels;
   3.2. monitor the operation of School Research Ethics Panels through receipt of annual monitoring reports and periodic dipstick testing of proposals reviewed, ensuring that they operate competently, review proposals in a timely manner, act independently, are free from bias and undue influence and have measures in place to deal with conflicts of interest;
   3.3. review research proposals referred up by School Research Ethics Panels;
   3.4. ensure mechanisms are in place to monitor the conduct of research that has received approval;
   3.5. review protocols covering research carried out on a routine basis that involves particular types of risk;
4. Report to the University Research Ethics Committee
   4.1. produce an annual report for the University Research Ethics Committee, on the discharge of its responsibilities;

4.2. have due regard within its decisions to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between different people, in accordance with the public sector general duty of the Equality Act (2010).

Constitution and membership

Members

Chair, appointed by the Chair of the University Research Ethics Committee, in consultation with the Dean of College

Ex officio members

Chairs of Tier 1 School Research Ethics Panels within the College

Nominated members (Term 3 years, with a third of the nominated membership to change each year)

Deputy Chair, nominated by the Chair

At least one additional member of academic staff from each School within the College nominated by the Chair

One member of academic staff from each of the other two Colleges nominated by the Chair

One external lay member with no affiliation to the University nominated by the Chair

Co-opted members

Up to two co-opted members to ensure appropriate disciplinary and methodological coverage of research across the College

Secretariat

Research Office

Officers

Research Policy Officer (Research Office)

Quorum: 40% of the membership excluding vacancies or members occupying more than one position.

Role Descriptions

Role Description: College REC Chair

Overview of Role

In addition to the key responsibilities set out for REC members, the main purpose of this role is to act as Chair to the College Research Ethics Committee (REC). The Chair is responsible for the REC's ethical review function, ensuring that ethical issues are thoroughly explored and debated, and that clear decisions on proposals are made and recorded. The Chair will also take a lead role in promoting a culture of best practice in research ethics within the College. The Chair will receive support from and work closely with the REC administrator.

Key responsibilities

1. Oversee management of research ethics applications to the REC, ensuring that ethical issues are explored and debated and that proposals are reviewed in a timely manner.

2. Ensure that proposals are dealt with fairly and appropriately, and that any potential conflicts of interest are addressed.

3. Ensure that the REC operates in accordance with the Standard Operating Procedures for research ethics, and that clear decisions are reached and recorded.

4. Have an awareness of equality and diversity, and ensure that applicants are treated fairly and equally, regardless of age, gender, sexuality, ethnicity, religion or disability.

5. Nominate a Deputy Chair and offer support to the person in this role, ensuring they are able to take over the duties of the Chair when required.

6. Identify any training needs for REC members and ensure that arrangements are made to meet these.

7. Provide advice and guidance on ethical issues to staff and students within the College, and liaise with the UREC and Research Office to promote the embedding of a research ethics culture within the College.

8. Support, advise and disseminate information to School Research Ethics Panel Chairs, and receive an annual report from them on School level ethical review.

9. Sit as an ex-officio member of the University Research Ethics Committee, attending meetings, and providing an annual report to the UREC summarising the REC's activities.

Appointment: by Chair of University Research Ethics Committee in consultation with Dean of College.

Tenure: 3 years, renewable for a further term

Role Description: College REC Member

Overview of Role

The main purpose of this role is to act as a member of the College Research Ethics Committee, carrying out ethical review of proposals from Schools within the College, and to bring specific expertise to the review process. The REC member will also take a role in promoting a culture of best practice in research ethics across their School and College.

Key responsibilities

1. Provide independent, competent and timely review of ethics proposals from staff and students within the College.

2. Ensure that proposals are dealt with fairly and appropriately, and that any potential conflicts of interest are addressed.

3. Ensure that the REC operates in accordance with the Standard Operating Procedures for research ethics, and that clear decisions are reached and recorded.

4. Have an awareness of equality and diversity, and ensure that applicants are treated fairly and equally, regardless of age, gender, sexuality, ethnicity, religion or disability.

5. Identify any training needs and alert the Chair to these, and attend any training provision that is made available.

6. Raise with the Chair any ongoing challenges or issues relating to the ethical review of research that may need to be dealt with as a matter of policy by the College REC or UREC.

7. Maintain confidentiality regarding proposals, ethical review discussions and outcomes.

8. Provide ad hoc advice and guidance on ethical issues to staff and students within the member's School, and promote and encourage a culture of best practice in research ethics within the School.

9. Ongoing contribution to development, monitoring and review of research ethics processes.

Appointment: by Head of relevant School in consultation with Chair of University Research Ethics Committee in consultation

Tenure: 3 years

Role Description: College REC Lay Member

Overview of Role

The main purpose of this role is to bring an independent and impartial contribution to the ethical review of proposals by the College REC. They bring a wider perspective to the work of the REC, and are important in increasing public confidence in the integrity of research undertaken at the University.

The Lay Member will not be employed by or affiliated to the University, but will perform the same tasks as members from within the University, including scrutiny of research ethics proposals and discussion of other ethical issues or developments.

Key responsibilities

1. Provide independent, competent and timely review of ethics proposals from staff and students within the College.

2. Ensure that proposals are dealt with fairly and appropriately, and that any potential conflicts of interest are addressed.

3. Ensure that the College REC operates in accordance with the Standard Operating Procedures for research ethics, and that clear decisions are reached and recorded.

4. Have an awareness of equality and diversity, and ensure that applicants are treated fairly and equally, regardless of age, gender, sexuality, ethnicity, religion or disability.

5. Identify any training needs and alert the Chair to these, and attend any training provision that is made available.

6. Raise with the Chair any ongoing challenges or issues relating to the ethical review of research that may need to be dealt with as a matter of policy by the College REC or UREC.

7. Maintain confidentiality regarding proposals, ethical review discussions and outcomes.

8. Ongoing contribution to development, monitoring and review of research ethics processes.

Appointment: by Chair of College REC

Tenure: 3 years

Role Description: Tier 2 REC Administrator

Overview of Role

The main purpose of this role is to act as Secretary to the College REC, providing administrative support to ensure effective operation of systems and procedures to manage the ethical review and approval of research within the College.

It is recognised that role of College REC Administrator will normally account for only part of the job description of the individual who undertakes this role, and that the individual will be accountable to a line manager within their School or College CRD for the performance of their role as a whole. The responsibilities set out in this Role Description relate only to work carried out in support of the College REC.

Key responsibilities

1. Administer applications to the College REC, ensuring application documentation is complete and maintaining appropriate filing systems for applications, correspondence and outcomes to ensure adequate records are kept.

2. Provide advice and guidance to staff and students on processes for ethical review and approval of research.

3. Provide administrative support to meetings of the College REC, including taking and drafting minutes.

4. Work with the Chair of the College REC to support the process of ethical review, including providing applicants with appropriate feedback and outcomes of applications.

5. Liaise with other College REC Administrators, CRDs, Schools and Departments and with the Research Office, to ensure co-ordinated delivery of ethical review across the University as appropriate.

6. Produce data, management information and reports from College REC records on request for reporting, monitoring and audit purposes, including for the annual report to the UREC.

Appointment: To be decided

Tenure: Permanent

Tier 2 College Research Ethics Committee (CREC) Application Form

Please note that review by a Tier 2 CREC is only required for proposals that present more than minimal ethical risk. For lower risk proposals, please complete the Tier 1 form and submit it to your School Research Ethics Panel. The Tier 1 form includes a checklist to help determine the level of review required. If it is unclear whether your proposal requires Tier 1 or Tier 2 review, please complete the Tier 1 form and checklist in the first instance. If your proposal has been referred up to the CREC by your Tier 1 School Research Ethics Panel, please attach a copy of the completed Tier 1 form to this application. Please do not include any other forms or documents with your application, other than those listed in the checklist in section 11.

Please adhere to the indicated word counts on this form. Any application that exceeds the word counts will not be considered by the CREC.

1 Applicant details

Project title	
Proposed start and end date of project	
Name of researcher	
School	
Level (UG/Taught PG/PGR/Staff)	
Address	
Phone	
Email (please use University email address)	
Funder (if applicable)	

2 Student details

Course/Module/Unit name/number	
Name of supervisor/tutor	
Supervisor contact details	

3 Introduction (Maximum 500 words)

Please provide a brief background to the research, including context and rationale and the purpose of the research and aims of the study/hypothesis to be tested.

4 Research approach and methods (Maximum 1,000 words)

Please outline the research approach and methods to be used including:

- How is the research to be conducted – what is the design?
- How, where and when will data be collected (please include copies of any questionnaires to be used, or sample interview questions)?
- What research methods (statistical or qualitative) will be used? Please demonstrate an understanding of procedures to be used and/or training undertaking in research methods.
- How will the results be analysed and by whom?
- How will the analysis achieve the purpose of the study?
- What facilities/resources will be required and who will provide them?

5a Participants and recruitment: general information (Maximum 500 words)

What sort of participants (age range, ethnicity, number, gender) are to be recruited? Will any vulnerable groups of people or individuals be involved? Consider the concept of 'vulnerability' in its broadest sense.

What inclusion/exclusion criteria will be used? Is exclusion from the research likely to deny an individual access from services that would otherwise have been provided?

How will initial contact be made? Include details of gatekeepers and others who are to be approached? Please supply a copy of any means of advertising, such as posters, leaflets, emails, web pages or letters.

A copy of any relevant materials used to recruit participants should be attached to this application

5b Participants and recruitment: payments to participants (Maximum 500 words)

Will participants be reimbursed or paid for their expenses and/or time? If so, please provide details of any payments or vouchers to be offered, or other incentives such as being entered into a prize draw (you should ensure that any payment does not constitute an inappropriate inducement to take part).

6 Potential ethical issues including risks, benefits, outcomes and impacts of the research beyond participant recruitment and vulnerabilities (Minimum 200 words)

Referring to the Tier 1 checklist, please outline the key ethical issues in this research and discuss how potential issues are to be addressed and how any negative impact(s) will be minimised. Please ensure where relevant that you have completed a risk assessment form and (for students) it has been signed by your course leader, and attach it with this application.

Are there any expected benefits or positive impacts of the research on participants or their communities? Possible impacts might include psychological, health, social, economic or political changes or ramifications, either at the time the research is carried out or in the future.

Potential ethical issues	**How ethical issues will be addressed**

7 Participant information and consent (Maximum 500 words)

Please outline how participants will be informed (both orally and in writing) about the research and their participation in the study. How will you ensure that information is provided in a format/language suitable for the target audience? Please describe how written consent will be obtained, or if you are working with participants who cannot give written consent, an explanation of the reason for seeking oral consent and details of the procedure to be adopted.

If consent is not being sought, or will not be sought until after data has been collected (e.g. if it involves covert observation), please say why consent will not be sought or why the delay is necessary, and what steps will be taken (if any) to debrief participants and obtain consent afterwards.

Copies of consent forms, participant information sheets and any other information for participants should be attached to this application

8 Confidentiality and data storage (Maximum 500 words)

Please describe measures that will be taken to ensure anonymity, privacy, confidentiality and data protection. This should include:

- How participants will be identified without breach of the data protection act and to guard against invasion of privacy (e.g. if you plan to access personal information to identify potential participants)?
- What steps will be taken to anonymise data (this may include removing identifying information in addition to names)
- How data (both physical and digital) will be collected, handled, transferred and stored
- Who will have access to the data other than the researcher (eg supervisors, transcribers etc)
- How long data will be retained, and how it will eventually be destroyed
- Where the research data will be published (eg essay, dissertation, academic paper, exhibition, online) and who will have access to the results

9 Other ethical issues

Please outline any other ethical issues that have not already been discussed in the sections above and describe how these will be addressed.

10 Supervisor sign-off (for student research only)

I confirm that I have checked the application and that the student has addressed the relevant ethical issues, has received training in ethics as part of their module or programme and has the necessary skills and experience to carry out the proposed research.

Supervisor: _____ Date: _____

11 Checklist for accompanying documents

Please ensure you have attached copies of any of the following documents where relevant, and please do not include any other forms with your application.

- ☐ Tier 1 form (where proposal has been referred up from School Research Ethics Panel)
- ☐ Information sheets
- ☐ Consent forms
- ☐ Advertising or recruitment materials
- ☐ Sample questionnaires or interview questions
- ☐ Risk assessment forms
- ☐ Letters of support from external organisations involved in the research
- ☐ List of references cited in the application

Please also note that the application must be complete and please ensure that it has been checked for accuracy, grammar and spelling.

Please return this form and all accompanying documentation to the Secretary of the College of x Research Ethics Committee (name and email address).

CREC change notification form (Please complete this form and submit it to the CREC that reviewed the original proposal)
Title of project:
Name of lead researcher: School:
Date CREC approval obtained:
Please outline proposed changes to the project, including changes in methodology, number or types of participants to be recruited, location/context of research or use to which data will be put :
Please say whether the proposed changes present any new ethical issues or changes to ethical issues that were identified in the original ethics review, and provide details of how these will be addressed:

End of project report form to College Research Ethics Committee

Title of project:

Name of lead researcher: School:

Date CREC approval obtained: Dates project undertaken: Date report submitted:

Please state whether the aims of the project were achieved and provide a brief summary of research outcomes :

Were any changes in protocols made during the project:? YES ☐ NO ☐
If yes, please say whether this presented any ethical issues and if so how these were addressed:

Did any unforeseen ethical issues arise during the project? YES ☐ NO ☐
If yes, please say how these were addressed:

Did any adverse events which occur during the project? YES ☐ NO ☐
If yes, please provide details of how these were dealt with:

Please provide any suggestions or recommendations for future ethics guidance or processes:

Annex G

UNIVERSITY RESEARCH ETHICS COMMITTEE

Committee of: Research Strategy Committee (a committee of the Academic Board)

Terms of reference

A Committee of the Research Strategy Committee to:

1. develop and advise on strategy and policy in respect of research ethics

2. approve the Terms of reference, constitution and membership of the College Research Ethics Committees

3. monitor the operation of the College Research Ethics Committees through receipt of annual monitoring reports and periodic review of proposals, ensuring that they operate competently, review proposals in a timely manner, act independently, are free from bias, conflict of interest and undue influence and have measures in place to deal with conflicts of interest

4. approve School protocols covering activities involving more than minimal ethical risk that are undertaken on a regular basis

5. review research proposals where an appeal has been made against the decision of a College Research Ethics Committee

6. ensure effective dissemination to College Research Ethics Committees, School Research Ethics Panels and the wider University community of information relating to research ethics

7. produce an annual report for the Research Strategy Committee on the discharge of its responsibilities

8. have due regard within its decisions to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between different people, in accordance with the public sector general duty of the Equality Act (2010)

Constitution and membership

Constitution	**Member**
Chair, appointed by the Chair of the Research Strategy Committee	
Deputy Chair , appointed annually by the Chair, from the members of the Committee	

Constitution	**Member**
Ex officio members	
Chair of the Research Strategy Committee	
Legal Services Officer	
Chair of each College Research Ethics Committee	
Other members	
An external lay member with no affiliation to the University nominated by the Chair of the Committee	
A member with specific expertise in the area of ethics nominated by the Chair of the Committee	
A research student representative nominated by the Dean of Graduate Studies	
Up to three co-opted members	
The UREC may also appoint advisors on an ad hoc basis to attend meetings where proposals are being reviewed and additional expertise is required	

Officers

Members of the Senior Management Team who are not members of the committee:

Vice-Chancellor	Prof J Crampton
Deputy Vice-Chancellor	Prof C Pole
Registrar and Secretary	Ms C Burns
Director of Finance	Ms S McHugh
Pro-Vice-Chancellor (Learning & Teaching)	Prof S Denyer

Secretariat

Research Office

Quorum

The quorum for meetings of the Research Ethics Committee is one half of the members, excluding vacancies.

At	Total positions	13
	Vacancies	
	Members occupying more than one position	-1
	Total members	12
	Quorum	**6**

Frequency of meetings

Two meetings per year

Amended terms of reference and constitution approved Academic Board:

Membership last updated:

Role Description: University REC Chair

Overview of Role

In addition to the key responsibilities set out for REC members, the main purpose of the Chair is to be responsible for the UREC's operation, ensuring that items relating to ethics strategy and policy are considered appropriately and that issues referred up by College RECs are dealt with fairly, competently and in a timely manner. The Chair will also take a lead role in promoting a culture of best practice in research ethics within the University. The Chair will receive support from and work closely with the UREC administrator.

Key responsibilities

1. Oversee operation of the UREC, ensuring that items relating to ethics strategy or policy and the monitoring of College RECs are considered appropriately.

2. Ensure that appeals arising from decisions made by College RECs are dealt with fairly, appropriately and in a timely manner, that any potential conflicts of interest are addressed and that clear decisions are reached and recorded.

3. Have an awareness of equality and diversity, and ensure that applicants are treated fairly and equally, regardless of age, gender, sexuality, ethnicity, religion or disability.

4. Ensure that the UREC operates in accordance with the University's research ethics policy.

5. Nominate a Deputy Chair and offer support to the person in this role, ensuring they are able to take over the duties of the Chair when required.

6. Identify any training needs for UREC members and ensure that arrangements are made to meet these.

7. Provide advice and guidance on ethical issues to staff within the University, and liaise with the Research Office to promote a research ethics culture within the University.

8. Support, advise and disseminate information to College Research Ethics Committee Chairs, and receive an annual report from them on College level ethical review.

9. Sit as an ex-officio member of the University Research Strategy Committee, attending meetings, and providing an annual report to the RSC summarising the UREC's activities.

Appointment: by Chair of University Research Strategy Committee.

Tenure: 3 years, renewable for a further term

Role Description: University REC Administrator

Overview of Role

The main purpose of this role is to act as Secretary to the University REC, providing administrative support to ensure effective operation of the UREC.

It is recognised that role of UREC Administrator will normally account for only part of the job description of the individual who undertakes this role, and that the individual will be accountable to a line manager within the Research Office for the performance of their role as a whole. The responsibilities set out in this Role Description relate only to work carried out in support of the University REC.

Key responsibilities

1. Provide administrative support to meetings of the University REC, including taking and drafting minutes, and drafting and preparing reports and papers.

2. In consultation with the Chair of the UREC, draft reports and papers relating to research ethics strategy and policy.

3. Work with the Chair of the UREC to support the process of ethical review of appeals against decisions by College RECs, including providing applicants with appropriate feedback and outcomes of applications.

4. In consultation with the Chair of the UREC, produce an annual report to the RSC, and liaise with Chairs of College RECs, to co-ordinate the process of annual monitoring of College RECs and School Research Ethics Panels.

5. Produce data, management information and reports from REC records on request for reporting, monitoring and audit purposes, including for the annual report to the UREC.

6. Ensure effective dissemination of information relating to research ethics strategy, policy, guidance and good practice.

7. Provide advice and guidance to staff and students on processes for ethical review and approval of research.

8. Liaise with Colleges, Schools and other Departments, to ensure co-ordinated delivery of ethical review across the University as appropriate.

Appointment: by Head of Research Office in consultation with Chair of UREC

Tenure: Ongoing

Annex H: Guidance on projects requiring external ethics and/or governance approvals

External REC Review Panel (ERRP) Terms of Reference

A Panel reporting to the UREC to:

- Undertake initial scrutiny of proposals being submitted for external ethics review via the Integrated Research Application System (IRAS)

- Sign off the IRAS form to agree for the University to act as research sponsor in cases where the Head of School has completed the Sponsor Checklist to confirm that the University can act in this capacity

- Provide an annual report to the UREC on proposals reviewed and any issues arising

Constitution and membership

Members

Chair, appointed by the Chair of the University Research Ethics Committee

Deputy Chair, nominated by the Chair of ERRP

Reviewers with relevant disciplinary expertise and experience of reviewing IRAS applications

Additional reviewers may be co-opted as and when specific expertise is required

The Panel will conduct business electronically and it is envisaged that meetings will not normally be required.

Annex H: Guidance on projects requiring external ethics and/or governance approvals

1 Introduction

This document outlines the types of project that require ethics and/or governance approvals from external organisations, and provides information on the processes to be followed, including any internal scrutiny required prior to submission externally.

2 NHS and Health Research Authority (HRA) approvals

For studies being undertaken in the NHS there are three aspects of scrutiny that may be relevant to your project, all of which are undertaken following application through the Integrated Research Application System (IRAS):

- NHS REC review – for research ethics
- HRA approval – for governance and legal compliance
- R&D approval – for local capacity and capability

These approvals apply to proposals submitted by both staff and students, including projects that are for educational purposes only. However, there is considerable variation in terms of the types of approval required, depending on a number of factors. Please read the guidance below and see the flowchart in **Annex 1** below. You may also want to look at the NHS application process Flowchart, which can be found here

2.1 Audit and service evaluation

For projects that the NHS deem to be audit, service evaluation or public health surveillance, or some other type of non-research activity (such as case study, system/equipment testing or satisfaction survey) you do not need to apply via IRAS, but should contact the clinical governance office of your local NHS organisation to check what other review arrangements or sources of advice apply to the project. You should obtain written confirmation from the relevant NHS R&D office that an IRAS application is not required. However, you may still need ethical approval from the University, particularly if you are intending to publish the results of your project, and you should check the University guidance regarding this.

2.2 Projects involving NHS staff or site, but not involving NHS patients or users

For research projects being undertaken by University staff that involve NHS staff or where the research is taking place on NHS sites, but which do not involve NHS patients/users, their relatives/carers, their data or tissue, there is no need for NHS ethics review, but the IRAS form should be completed in order to obtain HRA and R&D approvals. The completed IRAS form should be sent to the University's External REC Review Panel (ERRP) prior to submission to IRAS, for initial scrutiny and ethics review. This also applied to educational projects being undertaken by students where the research is taking place at more than one organization, or student projects where support is being applied for from the NIHR Clinical Research Network.

For projects involving NHS staff or sites that are being undertaken by students for educational purposes only at a **single** NHS site, there is no need for NHS ethics review, and **in some cases** there is also no need for HRA approval. Students should check with the relevant NHS R&D office as to whether HRA approval is required for their specific project, as there does not appear to be any consistency regarding this. See HRA guidance here for further information.

3 Research requiring external ethical approval from the NHS or other UK statutory bodies via IRAS

Ethical review by an NHS REC is required for research projects involving:

- Participants identified from, or because of their past or present use of, services for which the UK Health Departments are responsible (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls
- Research participants identified because of their status as relatives or carers of past or present users of these services
- Collection of tissue (i.e. any material consisting of or including cells) or information from any users of these services, including those who have died within the last 100 years
- Use of previously collected tissue or information from which the research team could identify individual past or present users of these services, either directly from that tissue or information, or from its combination with other tissue or information in or likely to come into their possession.

The relevant services are:

- NHS healthcare (UK-wide)
- Adult social care (England, Wales, NI)
- Children's social care (Wales, NI)

External REC review is also required for the following:

- Xenotransplantation (i.e. putting living cells, tissue or organs from animals into people)
- Health-related research involving prisoners in the custody of the National Offender Management Service, Scottish Prison Service and Northern Ireland Prison Service
- Social care research projects funded by the Department of Health - see more here
- Research involving participants unable to consent for themselves - see more here
- Projects involving research in prisons or the probation service and need approval from the National Offender Management Service (NOMS). Further information can be found here

3.1 Participant Identification Centre (PIC) studies

Research projects that involve NHS patients/users, their relatives/carers, their data or tissue, but where the NHS are being used for recruitment only and the research is being carried out off site, can be flagged as 'PIC only' on the IRAS form by completing the non-NHS SSI section of the form and giving details of the NHS site and University contact in Part C. A REC number will be automatically generated that allows proposals to go straight to HRA and ethics scrutiny. No R&D approval is required, but R&D are given 35 days to object to HRA approval, after which research can proceed.

3.2 Proportionate review

If you consider that your study presents no material ethical issues it may be eligible for proportionate NHS REC review. Further guidance on proportionate review can be found here. You will still need to complete an IRAS form, and will also need to apply for proportionate review. If the proportionate review process is not considered appropriate for your research, your application will automatically be referred for full REC scrutiny

4 Internal scrutiny of research requiring external REC approval via IRAS

In order to avoid duplication of review, proposals that are subject to external REC, HRA and/or R&D approval via IRAS (i.e. those covered by Sections 2 and 3 above) need not be considered by a full Tier

2 College Research Ethics Committee via the University's three tier research ethics framework. However, they should be submitted for scrutiny by the University's External REC Review Panel (ERRP) to ensure that the application is of high quality and (where relevant) the University can agree to act as research sponsor (see section 5 below). These proposals should be completed using the electronic Integrated Research Application System (IRAS) form, which should then be submitted via the ERRP electronic submission system, where it will be sent out by the chair of the panel for scrutiny by two appropriately experienced panel members. In order to ensure that applications meet external REC deadlines, proposals can be sent to the ERRP at any time. The ERRP aims normally to carry out review within three weeks.

5 Agreement for the University to act as research sponsor for NHS projects

In some cases the University may need to agree to act as research 'sponsor' for an NHS project. The sponsor is defined in the Health Research Authority UK policy framework for health and social care research as being 'the organisation responsible for securing the arrangements to set up, start, manage and finance a study'. In this context the 'sponsor' is not necessarily the body funding the research. The sponsor is normally expected to be the employer of the principal investigator in the case of non-commercial research or the funder in the case of commercial research. In some cases the NHS Trust may take on the role of sponsor, and principal investigators or supervisors should consult with the relevant NHS Trust to determine who will take on the sponsorship role.

The responsibilities of the sponsor are outlined in section 8.10 of the Health Research Authority UK policy framework for health and social care research. Where the University is agreeing to act as sponsor for a project the attached sponsor checklist should be completed by the principal investigator or supervisor and submitted to the ERRP (see section 4 above) for internal scrutiny together with the completed IRAS form. The ERRP will review the IRAS application against the sponsor checklist and flag up any concerns to the relevant Head of School. The Head of School should then ensure that any such concerns have been addressed, and that appropriate arrangements are in place within the School for setting up and managing the study, before signing the form.

6 NHS Research Passports

Where researchers are to be involved in an NHS-related project and are to interact with individual patients in a way that directly affects the quality of their care, they may also need an NHS Research Passport, and in some cases additionally an Honorary Contract with the NHS organisation in which they will be working. The NHS Research Passport is a system to ensure that all the necessary pre-engagement checks have been carried out on the researcher. Further information regarding the Research Passport Scheme can be found here. Members of staff requiring an NHS Research Passport should contact their HR officer for details of how to apply, and students (including undergraduate, taught postgraduate and research students) should contact the Research Office (h.a.ougham@brighton.ac.uk).

7 NIHR CRN portfolio applications

The NIHR CRN portfolio is a database of clinical research studies that are supported by the National Institute of Health Research Clinical Research Network (NIHR CRN) in England. Adoption on to the portfolio is dependent on your study meeting eligibility criteria. The Clinical Research Network provides infrastructure support including NHS Service Support costs (SSCs) and access to R&D support. You will need to apply through IRAS using the Portfolio Application Form (PAF). Research studies are reviewed for inclusion in the NIHR CRN Portfolio in parallel with the Ethics review and R&D governance process. Further information can be found here. The process of applying for CRN

portfolio status can be very complex and time-consuming, so students should ensure that they discuss potential applications with their supervisors in advance.

8 Research in prisons

Projects involving research in prisons or the probation service in England and Wales require approval from the National Offender Management Service (NOMS), and applications should be sent for initial scrutiny by the ERRP before submission via IRAS. Further information can be found here.

If you intend to undertake non-health related research in Scotland, you will need to apply to the Scottish Prison Service (SPS) Research Access and Ethics Committee. Further information can be found in the SPS Research Access Guidance information pack.

For research in prisons in Northern Ireland there is no formal application process, and requests to undertake research are considered by the governor of the relevant prison on a case by case basis. The level of authority that is required varies, depending on the scope of the research to be undertaken and the participants to be recruited. Further information can be obtained from the Northern Ireland Prison Service Headquarters (**Tel**: 028 9052 2922 **Email:** info@niprisonservice.gov.uk).

Please note that health related research involving prisoners in Scotland or Northern Ireland requires review by an NHS Research Ethics Committee (via IRAS) as well as compliance with the relevant prison service approval procedures, as detailed in the Governance Arrangements for Research Ethics Committees (GAfREC). Please be careful when determining whether your study requires REC review or not.

For prison based research in the Republic of Ireland, an application should be submitted to the Irish Prison Service. Details of how to apply can be found here.

9 Proposals requiring review from the Ministry of Defence Research Ethics Committee (MODREC)

Research that is undertaken, funded or sponsored by the Ministry of Defence (MOD) and that involves human participants is subject to review by the Ministry of Defence Research Ethics Committee (MODREC). Further information and guidance on the review process can be found here. Proposals requiring MODREC review should be sent to the External REC Review Panel (ERRP) for initial scrutiny, using the MODREC application form, which can be found here.

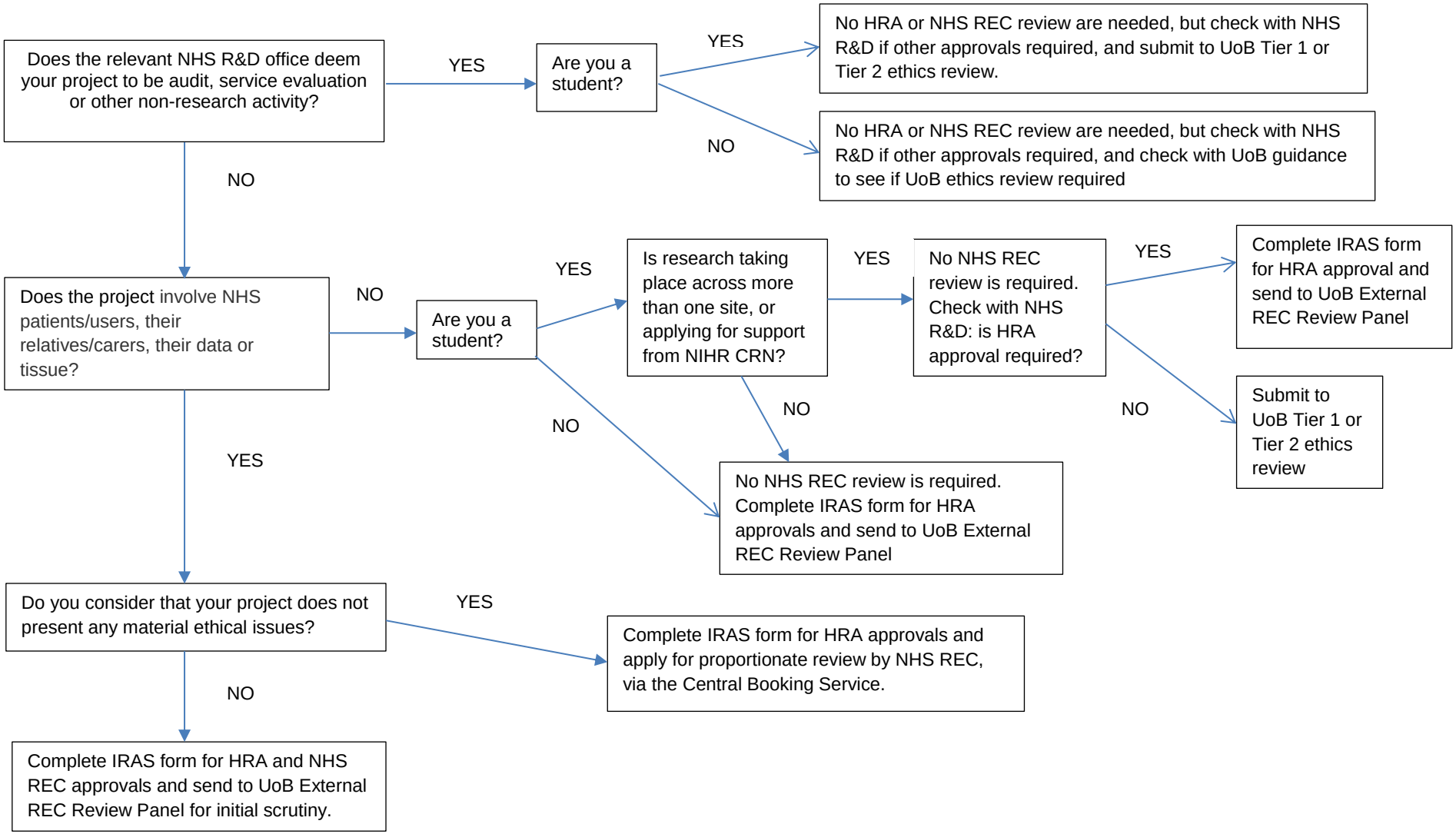
10 Proposals requiring other external approvals (not via IRAS)

Some types of research may not require external ethical approval via IRAS, but may be subject to other external review or approvals, for example:

- Research relating to Local Authority services, staff or users that requires Local Authority governance approval
- Research being carried out abroad that requires local ethics or governance approvals

Proposals of the above types should be sent to the relevant School Research Ethics Panel or College Research Ethics Committee for review, rather than being scrutinised by the External REC Review Panel.

NHS approvals flowchart to determine whether HRA and/or NHS ethics approvals required



Sponsor Checklist

This checklist should be completed in cases where an application to an external REC is being made via IRAS, and where the University is agreeing to act as research sponsor. In the case of student research projects this form should be completed by the Academic Supervisor, and for staff research projects it should be completed by the Principal Investigator. The form should be passed to the External REC Review Panel (ERRP) Chair for consideration with the completed IRAS form. The ERRP Chair should review the IRAS application against the checklist and flag up any concerns to the Head of School. The Head of School should then ensure that any such concerns have been addressed, and that appropriate arrangements are in place within the School for setting up and managing the study, before signing the form.

Name of Student/Principal Investigator …….

Name of Supervisor (if applicable) ……

Course (if applicable) …….

Title of project ……

Project start date …….. Project end date ……

The Supervisor or Principal Investigator should work through the following list to determine whether the University can act as research sponsor. Can you:

		Yes	No
1	Confirm that the study has been assessed as worthwhile, necessary, feasible, of high academic quality and represents value for money?		
2	Be confident that where research is to be carried out on University premises, the research sites are suitable and that the quality of the research environment is sufficient?		
3	Confirm that the arrangements and resources needed to conduct the research successfully are in place, and that funding and resources are being used appropriately?		
4	Confirm that the researcher(s) have an appropriate level of experience and expertise to carry out the research?		
5	Confirm that appropriate and effective arrangements are in place for the management and monitoring of research, including assessing and managing risk?		
6	Confirm that the research complies with the guidelines and policies of the University, the NHS and any other funding bodies?		
7	Confirm that roles and responsibilities of all parties involved in the research are agreed and appropriately documented?		
8	Confirm that there are appropriate procedures for the collection, handling and storage of data?		
9	Confirm that appropriate arrangement have been made for making information about the study available, and for making finding and data accessible after it has finished as appropriate?		

Signature of ERRP Chair: ……. Date: ……

Signature of Head of School: …… Date: ……

Annex I: Useful links

University of Brighton guidance and codes of practice

- Guidance on issues in research ethics https://staff.brighton.ac.uk/ease/ro/docs/Guidance%20on%20issues%20in%20research%20ethics.pdf
- Code of good practice in research https://staff.brighton.ac.uk/ease/ro/docs/Code%20of%20Good%20Practice%20in%20Research.pdf
- Procedures for investigating and resolving allegations of misconduct in research https://staff.brighton.ac.uk/ease/ro/docs/Procedures%20for%20investigating%20and%20resolving%20allegations%20of%20misconduct%20in%20research.pdf
- Data protection policy https://staff.brighton.ac.uk/reg/legal/policies/Data_Protection_Policy.pdf
- Guidelines on health and safety whilst working overseas http://staffcentral.brighton.ac.uk/safety/codes/overseas.shtm
- Policy on safeguarding children and young people http://staffcentral.brighton.ac.uk/xpedio/groups/public/documents/staffcentral/doc012805.pdf
- Policy statement on use of animals in scientific procedures https://www.brighton.ac.uk/_pdf/research/resource-docs/use-of-animal-in-scientific-procedures.pdf

Professional and funders' ethics codes and guidelines

- Academy of Social Sciences (2014). Developing Generic Ethics Principles in Social Science Research - http://acss.org.uk/developing-generic-ethics-principles-social-science/
- AREC (2013). A Framework of Policies and Procedures for University Research Ethics Committees http://s3.spanglefish.com/s/21217/documents/independent-membership/12-11-13-framework-complete.pdf
- Association of Internet Researchers (2012). Ethical decision-making and internet research 2.0 http://aoir.org/ethics/
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