

RESEARCH ETHICS COMMITTEES: POLICY AND PROCEDURES FOR RESEARCH ETHICAL APPROVAL

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POLICY - Summary

This document sets out the policy and procedures for the establishment of ethics review processes at UWE. The University embraces and encourages the wide range of research activity with which staff and students engage. Research integrity is at the core of high quality research and good science. All research at UWE should adhere to the highest ethical standards and **any research which has the potential to raise significant ethical concerns may be submitted for independent ethical review.** In any research study involving people, their data or tissue, the dignity, rights, safety and wellbeing of participants must be a significant consideration. The University is required by the Concordat to Support Research Integrity (2012) to have appropriate procedures for ensuring the integrity of research and compliance is a condition of receiving HEFCE funding. Researchers are also expected to carry out research in accordance with the UWE [Code of Good Research Conduct](http://www1.uwe.ac.uk/research/researchgovernance.aspx) (2015). (See <http://www1.uwe.ac.uk/research/researchgovernance.aspx>)

Ethical scrutiny is intended to assist in protecting research participants from harm but a further important consideration is that the researcher is facilitated and supported to carry out research which has the potential to be of benefit for society. In other words the scrutiny must be appropriate, proportionate and efficiently carried out.

As outlined in the ESRC Research Ethics Framework *“It is important for researchers to think ethically when conducting research and consider ethical issues throughout the research lifecycle. The research lifecycle includes the planning stage, the period of funding for the project and all activities that relate to the project once funding has ended. The research lifecycle also includes knowledge exchange and impact realisation activities, the dissemination process and the archiving, future use, sharing and linking of data.”* The same principles apply to internally funded or unfunded research.

For staff and PhD students the UWE approach is based upon the ethical scrutiny of individual research projects by the Faculty Research Ethics Committees (FREC) which have been established in each of the Faculties of the University. These operate to standard terms of reference, composition and procedures as described below.

It is the researcher’s responsibility to identify the potential risks their research may pose for participants and to address these in both the ethics application and the health and safety risk assessment. Separate guidance on risk assessment can be found on the University’s [Health and Safety Webpages](#).

The procedures apply to all staff and student members of the University conducting or contributing to research activities which take place within or outside of the University. They also apply to individuals who are not members of the University but who are engaged in such research activities involving University premises, facilities, students or staff.

UWE staff on secondment to other institutions conducting research should always have, where necessary, ethical approval from UWE or an appropriately constituted Research Ethics Committee. Visiting scholars conducting research at UWE should have appropriate ethical approval for their research from their home institution. UWE researchers collaborating with others should ensure that the research has been approved by properly a constituted external Research Ethics Committee or UWE FREC.

Types of research and ethical review

Ethical scrutiny of **ALL research involving human participants their tissue or their data, conducted by staff or students, is formally required by the University**. Externally funded research must meet the standards expected of funding agencies.

Evaluation studies involving human participants also **require** ethical review. See

<http://www1.uwe.ac.uk/research/researchethics>

Research using human tissue requires ethical review. For guidance on this see separate [Operating Procedures](http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx) at <http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx>

Researchers conducting research which does not involve human participants but which is high risk or has potential for negative impacts on the environment or society should consider submitting an application for review by a Research Ethics Committee: where the research is involved with endangered, vulnerable or threatened species or populations; introduces material into an environment of a species or type not previously present; constitutes significant intrusion or destruction into an environment; disturbance to an ecosystem; causes deliberate damage or harm; pollution; removes plants or animals from an environment; is culturally or socially controversial or potentially infringes the rights of others.

Research which has potential for 'dual use' where significant harm could occur should also be submitted for ethical review. Dual use is a term that is applied to the tangible and intangible features of a technology that enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications. Researchers should carefully consider the ethical implications of any research which may involve dual use technology. If in doubt please seek advice from the appropriate Faculty Research Ethics Committee.

Animal research

Research on 'protected animals' is strictly regulated by the Home Office under the Animal Scientific Procedures Act 1986 see

<https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986>

"A protected animal" for the purposes of this Act means any living vertebrate other than man and any living cephalopod. **Research with live (or the killing of) such animals is only permitted under licence**. UWE does not hold a licence and therefore research with protected animals is not currently permitted.

Researchers using tissues from protected animals obtained from a third party must ensure that the material was obtained legally and ethically before transferring any materials to UWE. **They should notify the designated lead person for animal research** in the Department of Biological, Biomedical and Analytical Sciences of their research plans.

Other research involving animals which falls outside the Act is permitted at UWE - for example

- Work with nematode worms
- Field work where animals may be minimally disturbed
- Ecological work including trapping and counting insects
- Collecting lower animals from water sources.

Researchers conducting such research **need to formally request permission from the designated lead for animal research** based in the Department of Biological, Biomedical and Analytical Sciences in the Faculty of Health and Applied Sciences before commencing their research. The designated lead

for animal research is responsible for ensuring that any ethical issues have been appropriately addressed by the researchers and advise whether a full ethics application to the relevant Faculty Research Ethics Committee should be submitted for review. The designated lead for animal research will keep an auditable record of all research involving animals and produce an annual report for the University Research Ethics Committee detailing such research activity across the University. To obtain the contact details of the designated lead on animal research please contact the Research Governance Officer or Chair of FREC.

Data re-use (secondary data)

In accordance with the ESRC Research Ethics Framework, research that involves **anonymised** records and datasets that exist in the public domain may require only 'light touch review'. This includes, for example, datasets available through the Office of National Statistics or ESRC's data service providers where appropriate permissions have already been obtained and where the risk of identifying individuals from the information provided is negligible. A data producer such as the Office of National Statistics or other government departments may have restrictions relating to access and re-use which must be complied with. The fact that an original piece of research has gone through ethics review for its collection does not rule out ethics issues arising from its re-use. **Re-use of personal data from which individuals may be identified will usually require full review by a Research Ethics Committee.** If in doubt please seek advice from the appropriate Faculty Research Ethics Committee.

See <http://www.esrc.ac.uk/about-esrc/information/framework-for-research-ethics/>

Student research

Student research is expected to meet the same ethical standards as research conducted by staff but is proportionate to the level of risk of the project.

Operating Procedures for ethical review of research conducted by Undergraduate and Masters level Students are set out separately at:

<http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx>

Those procedures recognise that research may be high or low risk. It cannot be assumed that all student research is low risk.

PROCEDURES

1 Establishment of the University Research Ethics Committee and Faculty Research Ethics Committees

The University Research Ethics Committee (UREC) reports via the University Research and Knowledge Exchange Committee (URKEC) to Academic Board which is chaired by the Vice-Chancellor of the University.

Each Faculty has a Faculty Research Ethics Committee (FREC) whose composition, terms of reference and procedures have to be approved by the University Research Ethics Committee (UREC). The FRECs are sub-committees of UREC.

The Terms of Reference of the UREC and FRECs are provided at Appendix 1.

2 Composition and membership

Research ethics committees should provide independent, competent and timely review of the ethics of proposed research studies. In their decision-making, research ethics committees need to have independence from political, institutional, profession-related or market influences. They need similarly to demonstrate competence and efficiency in their work. Research ethics committees are constituted therefore to ensure the competent review and evaluation of all ethical aspects of the research projects they receive, and to ensure that their tasks can be executed free from bias and influence that could affect their independence in reaching decisions. There is provision for representation on committees from qualified people from outside the University. The University will expect the membership of committees to be inclusive, recognising the diversity of the research community in terms of the gender, age, ethnicity and background of members.

Membership requirements

2.1 An appointed member must be prepared to have published his/her full name, profession and affiliation. When making appointments, potential conflicts of interest should be declared. There should be transparency with regard to such interests, and they should be recorded and published with the above personal details. The Chair will make a decision as to whether a conflict of interest is relevant based on the matter at hand.

2.2 An appointed member is expected to maintain confidentiality regarding applications, meeting deliberations, information on research participants, and related matters.

2.3 For University staff, the time required for undertaking such service and the necessary training must be protected. This is part of collegiate professional activity, and it must be recognised as a fundamentally important activity on behalf of the University, without which research could not take place. In line with its commitment to the Concordat to Support Research Integrity, the University will ensure appropriate resourcing of FREC membership, including the time of members to properly discharge their duties as scrutineers and as part of collegial decision making.

2.4 A Committee member is normally required to attend in full at least two-thirds of all scheduled Committee meetings in each academic year. Attendance at scheduled meetings

should be of sufficient frequency to ensure a member's effective contribution to the work of the Committee. Committee members will normally be required to scrutinise at least two-thirds of the applications they are asked to review in each academic year.

Training

2.5 UREC and FREC members will need initial and continuing education and training regarding research ethics, research methodology and research governance. As a condition of appointment, a member should agree to take part in initial and continuing education appropriate to his or her role as a research ethics committee member. It is particularly important that Chairs and Deputy Chairs are fully aware of and up to date with ethical considerations, and are therefore expected to undergo any additional training identified for them.

2.6 In addition to the training of research ethics committee members, UREC will audit the training made available centrally and through faculties in order to appraise staff and students of aspects of ethics and research governance within the University.

2.7 The role and responsibilities of REC members are set out in Appendix 2.

3 Basis of approval by the UREC and FRECs

3.1 The primary task of the Research Ethics Committees lies in the ethical review of research proposals and their supporting documents, with special attention given to the nature of any intervention and its safety and protection for participants and researchers, to the informed consent process, documentation, and to the suitability and feasibility of the proposal.

3.2 A decision by the UREC or a FREC to give ethical approval to a research project does not imply an expert assessment of all possible ethical issues or of all possible dangers or risks involved, nor does it detract in any way from the ultimate responsibility which researchers must themselves have for all research which they carry out and for its effects on human participants. The Committees address themselves to ethical matters and are dependent upon information supplied by the researcher. This information is expected to be properly researched, full, truthful and accurate. **Failure to follow the University's policy and procedures on ethical review of research may be regarded as research misconduct.**

See <http://www1.uwe.ac.uk/research/researchgovernance.aspx>

3.3 In order to give ethical approval for human participant research, the UREC or FREC shall be adequately reassured about such issues as:

- the design and conduct of the study
- the recruitment of research participants
- the consent process
- the care and protection of research participants and others affected by the research
- the right of research participants to withdraw
- the protection of research participants' confidentiality
- research data management plans and data security
- research data sharing arrangements or data disposal, including Data Protection Act requirements

- storage arrangements for human tissue (relevant material) or other human tissue derived materials (acellular materials)
- any community considerations both within and externally to the University

3.4 A decision by the UREC or a FREC to give ethical approval on a research project does not constitute a precedent and each application will be judged on its own merits and in the light of present circumstances.

3.5 A decision to change the University's policies or procedures for ethical review of research does not imply that previous policies or procedures were inappropriate and any such changes do not invalidate ethical approval that has been given.

3.6 The location or nature of the proposed research may require that the researcher approaches partner organisations for approval, for example this might be through an NHS Research Ethics Committee or the Research Ethics Committee of a collaborating University. This will always be in addition to the UWE ethics approval process. However, when ethical approval has been obtained from an **appropriately constituted** external ethics committee, the UREC or a FREC, may accept that opinion with further review only of the 'locality issues'. 'Locality issues' are particularly concerned with:

- the suitability of the researcher
- the appropriateness of the local research environment and facilities
- UWE's reputation and the level of risk of the project.

The researcher will be expected to provide evidence of any ethics approval given by an external REC to the appropriate FREC Chair or Officer for ratification by that FREC. **The research data collection phase cannot begin until internal ratification has been granted.**

Applications requiring scrutiny by an external NHS Research Ethics Committee, through the National Research Ethics Service, for which UWE is the sponsor also require internal review by the appropriate FREC Chair before authorisation by the sponsor representative. See 5.1 below and for further guidance see <http://www1.uwe.ac.uk/research/researchethics>

The appropriate UWE Research Ethics Committee dealing with an application for review must always be informed by the researcher of an external research ethics committee decision. (See Appendix 3 for pathways to approval).

Legal Issues

3.7 It is the researcher's responsibility to ensure that the research conforms to relevant legal or regulatory requirements and to seek appropriate guidance through the University Research Governance team (researchgovernance@uwe.ac.uk) if needed.

Research Ethics Committees have a responsibility to take into account legal matters directly related to the ethical consideration of the way in which research to be conducted, as research which does not comply with legal and regulatory requirements cannot be considered to be ethical. It is not the responsibility of the Research Ethics Committee to consider and give advice on wider legal issues which might affect whether and how the research should be permitted to go ahead but they may request additional information on legal aspects of the research to assist in their deliberation if needed.

4 Processing ethics applications

4.1 The UREC and FRECs shall make decisions at scheduled meetings at which a quorum is present (see 4.5 and 4.6). The regularly scheduled meeting dates shall be announced in advance.

4.2 In order to respond to applications within 6 weeks, applications can be considered between meetings and the Chair is responsible for ensuring that an appropriate level of scrutiny informs the decision.

4.3 Where a decision is made by Chair's Action, this should be on the basis of detailed scrutiny by **at least two members** of the Committee. The decision will be reported to the next available meeting of the Committee for ratification.

4.4 In certain circumstances a 'light touch review' of ethics applications may be appropriate and this means that the FREC or UREC Chair may approve the project without sending the application for further scrutiny. The Chair's decision will require ratification by the REC at its next meeting.

4.5 For UREC meetings, a quorum of one-third of the membership is required, including the Chair and/or Deputy Chair.

4.6 For FREC meetings, a quorum of one-third of the membership is required. This should include the Chair and/or Deputy Chair, and at least one member who is independent of the Faculty where the research is to take place.

4.7 In respect of a proposal being put forward by a member of the reviewing Committee, those involved in the research submission should withdraw from the meeting while the submission is considered.

4.8 Observers, who should play no part in the Committee's deliberations, may be invited subject to the prior agreement of members. Observers should be allowed only if they accept in writing the same duty of confidentiality as Committee members.

4.9 Meetings shall be minuted and there shall be an approval procedure for the minutes.

4.10 The Officers of the UREC and FRECs shall be from Research Administration in RBI.

4.11 The UREC and FRECs shall keep a register of all proposals that come before them. The registers shall form the basis of the UREC's and FRECs' annual reports. These registers will be available for audit and may be shared with relevant partner bodies, such as NHS Trusts hosting the research, for the purposes of governance and management as deemed appropriate by the Chair of UREC.

4.12 The UREC and FRECs shall retain all relevant records for a period of at least six years or longer if required for legal, regulatory or insurance purposes, after completion of a research project. Advice should be taken from the University officer responsible for record retention and management before records are destroyed. Records shall be made available upon request to any member of the Vice-Chancellor's Senior Management Team and where appropriate regulatory authorities.

4.13 The UREC and FRECs should always be able to demonstrate that they have acted responsibly in reaching a particular decision. When the UREC or a FREC rejects research

proposals, the reasons for that decision shall be made available to the applicant and, where appropriate, opportunities for resubmission provided. Where approved, the basis for that decision should be recorded.

4.14 The UREC and FRECs shall consider valid applications in a timely manner. A decision should be reached and communicated to the applicant, wherever possible, within 6 weeks of the submission of a valid application.

4.15 Where significant amendments are made to the research protocol the researcher is responsible for notifying the REC of these for approval. Amendments submitted once ethical scrutiny has been completed shall normally be dealt with through Chair's Action.

4.16 Any adverse events which occur as a result of the research should be notified to the UREC/FREC which approved the research.

4.17 Where the research is terminated prematurely, a report shall be provided to the relevant committee within 14 days, indicating the reasons for early termination.

Confidentiality

4.18 Research Ethics Committee members do not sit on the Committee in any representative capacity (they are not elected) and need to be able to discuss freely the proposals that come before them. For these reasons, all Research Ethics Committee meetings will maintain confidentiality (though see 4.7 above).

4.19 All Research Ethics Committee members will be bound by the duty of confidentiality, and will not disclose to any other third party the research particulars or detailed discussions of applications for ethical approval held during committee meetings.

Complaints

4.20 There is no appeal against the decision of a Research Ethics Committee. Complaints on procedural grounds should be sent to the Chair of the UREC in the case of FRECs or to the Chair of URKEC in the case of the UREC.

5 Research in diverse settings

5.1 Research in the NHS

Where research is being carried in the NHS with patients (or their data or their tissue) application must be made for research ethics approval to a NHS Research Ethics Committee (REC) of the Health Research Authority's National Research Ethics Service (NRES) via the Integrated Research Application System (IRAS). The FREC (Faculty staff and students) or UREC (other applicants) should be notified and advice sought before submitting to a NHS REC. Student applications must be approved by a supervisor before submission. Following submission to and consideration by an NHS REC the applicant must send a copy of their final IRAS application and NHS REC decision letter to the FREC/UREC Secretary for review by the Chair (or nominee) in the context of UWE concerns. This approach has been designed to retain the right of ultimate 'sign off' by the University without asking all researchers requiring NHS REC approval also to have to go through a separate university process.

NHS RECs and NRES now fall within the national Health Research Authority (HRA) who take responsibility for health research. See <http://www.hra.nhs.uk/>

If the research is with NHS staff or on NHS premises then an application may be submitted to a FREC. Researchers will, in addition, require permission from the relevant NHS Research & Development Office before access to these are approved. Applicants should familiarise themselves with the NHS definitions of audit and evaluation in order to determine the necessary approval route. Evaluations in the NHS will require UWE REC approval unless being conducted by a student on a taught programme and assessed as low risk by their supervisor. In these cases the project may be approved by the supervisor who will be responsible for ensuring that NHS R&D approval is obtained as appropriate.

The HRA has provided a decision tool to help researchers decide whether or not their study is research. See <http://www.hra-decisiontools.org.uk/research>

5.2 **Research in Social Care Organisations**

The National Social Care REC reviews applications involving the social care sector (e.g. in local authority, private and voluntary care settings) not suitable for review by other NRES RECs or which cross sector boundaries. See <http://www.hra.nhs.uk/national-social-care-research-ethics-committee/>.

All social care research that is funded by the Department of Health will be reviewed by the National Social Care REC. As with NHS REC applications, if an application is to be made to the Social Care REC via the Integrated research administration system (IRAS) the FREC or UREC should be notified and advice sought before submission. Following submission the applicant must send a copy of their final application and Social Care REC decision letter to the FREC/UREC Secretary for review by the Chair (or nominee) in the context of UWE concerns. This approach has been designed to retain the right of ultimate 'sign off' by the University without asking all researchers requiring external REC approval also to have to go through a separate university process.

Undergraduate and Masters level student projects in social care will need to comply with the UWE Operating procedures for ethical review of student research. See <http://www1.uwe.ac.uk/research/researchethics>

PhD student projects in social care will need the approval of the supervisor before submission to the Social Care REC.

5.3 **Research involving people who lack mental capacity**

Under the Mental Capacity Act (2005) all 'intrusive' research involving people who lack capacity to consent, however funded and of whatever type must by law be approved by a body recognised under the MCA. Some Committees operating under the NRES are so recognised and the National Social Care REC is approved for this purpose. See <http://www.hra.nhs.uk/national-social-care-research-ethics-committee/>

5.4 **Research involving children**

Please refer to the separate guidance on research involving children at <http://www1.uwe.ac.uk/research/researchethics>

All research with children is regarded as potentially high risk. Usually approval by a FREC will be required except in those cases where a student (at U/G or M level) is able to demonstrate to their supervisor, who has the skills and competencies to decide, that the research is low risk. If there is any uncertainty about the risk status of a project involving children the supervisor should refer the project and an ethics application should be made to the relevant FREC.

5.5 **Research using human tissue**

The University's policies and procedures relating to the use of human tissue in research are set out in a separate document [Human Tissue Research at UWE: Operating procedures. Guidance for Staff and Students](http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx) at <http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx>.

All research using human tissue requires ethical approval in accordance with the requirements both of the Human Tissue Act 2004 and the University's own policies as set out in the Operating Procedures. This may require application to a NHS Research Ethics Committee or, in certain circumstances if the material is acellular, or is being immediately rendered acellular, to a FREC. Requests to transfer human materials to UWE from collaborating institutions for use in research will require approval by the Chair of FREC who will need evidence of the relevant NHS REC approval or Tissue Bank licence. For more detailed guidance please consult the Operating procedures for human tissue research at

<http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx>

All research using human tissue must be registered on the **UWE Register of Research using Human Tissue** administered by the Research Governance team in RBI together with supporting documentation. Guidance on research governance issues relating to human tissue research may be sought from the RBI Officer to the Human Tissue Sub-Committee as detailed in the Operating Procedures (researchgovernance@uwe.ac.uk).

5.6 **Research contracted to third parties**

Where a UWE researcher is commissioning the use of tools or services generated and operated by a third party contractor (for example the use of national survey instruments) for data collection and processing, it is the responsibility of the UWE researcher to ensure that the conduct of the survey is ethical and meets the standards expected for research at UWE. UWE ethical review will not normally be necessary for the conduct of the survey, but may be necessary for the overall project of which the survey is a part, if the survey is only a part of a study. The UWE Project Manager is always responsible for ensuring the ethical integrity of the survey including the appropriateness of questions, the adequacy of participant information, and the preservation of participant confidentiality. The UWE Project Manager must also ensure compliance with University Data Protection policies, assure themselves that the survey questions and confidentiality provisions in relation to the survey are appropriate, and that the data security arrangements of external contractors are apposite in this respect. The key principle here is that that survey participants must be afforded appropriate ethical and legal protection. **Project Managers are advised, if in any doubt, to seek advice from the Chair of the relevant FREC or UREC.**

6 Monitoring, auditing and reporting

6.1 The UREC and FRECs recognise that the definition and perceived significance of ethical problems may be subject to change and difference of opinion. In this light, the UREC will conduct an annual review of its work reporting annually to URKE on the management of the Committees, indicating in particular any suggested or agreed change in policy or procedures. The UREC will also report on any outstanding or anticipated difficulties. Each FREC will provide a report to the UREC for these purposes. A list of all submissions and the decision taken in respect of them together with any major issues arising and a record of applications considered outside formal meetings will be required as part of the annual report. Each FREC annual report will also be presented to the appropriate Faculty Research and Knowledge Exchange Committee for information.

6.2 The UREC will carry out an annual audit on selected aspects of UREC's and FRECs' work, including reviewing procedures, record keeping of the RECs, reviewing a sample of ethics applications and monitoring and auditing of research activities to ensure compliance with the decisions of the Research Ethics Committees. UREC will present an Annual Audit Report to URKEC.

7 UREC review process

7.1 In the event that a FREC finds itself unable to make a decision regarding a particular research proposal, it may at any time, forward the research proposal to the UREC for its consideration. This could be due, for example, to the complexity of the proposed research, or due to a split decision within the FREC.

7.2 The FREC can refer cases to the UREC that require advice or opinion. Referral to the UREC for a review will be in exceptional circumstances only. The UREC will not normally challenge FREC decisions.

7.3 Once a FREC has declined to give a favourable opinion on the application and opportunities for resubmission have been exhausted no further application using the same proposal may be made to any other FREC.

APPENDIX 1

University Research Ethics Committee (UREC)

Purpose

To be responsible to the Academic Board for the protection of research participants and the promotion of and continuation of ethical research practice and standards across the University. It is responsible for the development and review of policy, procedures and guidelines for ethical review of all research involving human participants, their data or tissue, conducted by staff and students. The Committee has oversight of Faculty Research Ethics Committees and considers an annual report from these committees.

Terms of reference

1. To develop, review and evaluate procedures, policy and guidelines for the UREC and FRECs for the ethical review of all research conducted by academic staff and students, and to provide appropriate research ethics support for associate faculties.
2. To approve, with advice from the University's Executive, the formation of FRECs where appropriate and in line with this scheme, including the membership, terms of reference and procedures, to conduct business on behalf of the UREC.
3. To advise researchers, faculties (and associate faculties) on the ethical conduct of research, disseminate information on the proper ethical conduct of research and to provide an avenue for the spread of good ethical practice.
3. To receive, consider and give ethical approval for research where
 - it is not appropriate for the application to be delegated to a FREC;
 - the applicant does not have a home faculty;
 - a FREC refers the application to UREC for additional advice;
 - the applicant is proposing research that is university wide;
 - requested by the research ethics committee of an associate faculty (AFREC);
 - the applicant is external to UWE but seeks access to UWE students, staff or premises.
4. To ensure that people taking part in research conducted by staff and students of the University are afforded appropriate ethical protection.
5. To monitor and audit the ethical conduct of research conducted by staff, students and researchers.
6. To seek clarification from external expert bodies, as necessary, on matters of ethical review policy and practice, and advise on and where necessary comply with external regulations and/or guidance on the ethical conduct of research.
7. To provide support to the researcher where circumstances might otherwise challenge their academic freedom, or intellectual property rights, or put the researcher in emotional, psychological or physical danger.
8. To receive and comment on annual reports of each FREC and AFREC, and to consider and advise on difficult or controversial ethical issues raised with FRECs and AFRECs and subsequently referred to UREC.
9. To identify and where appropriate assist with the provision of training on ethical review for members of UREC, FRECs and AFRECs.
10. To make an annual report to the University Research and Knowledge Exchange Committee and advise on matters relating to the ethical protection of human participants in research.
11. To liaise with the Human Tissue Sub-Committee on matters relating to the use of human tissue in research.

Composition

The UREC must have sufficient members to guarantee the presence of a core group at each meeting and to allow for a sufficiently broad range of experience and expertise. Membership should contain at least one person who has been trained in safeguarding children.

As a minimum, the UREC shall comprise the following:
Chair, nominated by the Vice Chancellor
Deputy Chair
Two members from each Faculty Research Ethics Committee, to include the Chair, as designated officer
One member from Hartpury College
Two people not employed by UWE, preferably one of whom should be medically qualified
Research Governance Manager
A member of the Graduate School
A PGR Student

In attendance

Committee Officer

Quorum

One third of the members eligible to attend.

Frequency of meetings

Four per year.

Appointment criteria

1. The appointees should have had at least one year's experience of the work of the UREC or equivalent research ethics committee.
2. Those appointed should have received training in research ethics reviewing and possess the relevant chairing skills. Potential candidates should be offered any appropriate supplementary training.
3. Appointments of any member of the UREC will normally be for a maximum period of five years. Appointments will be staggered to ensure staged turnover of membership. In exceptional circumstances a member may be invited to continue beyond this five year period.

Faculty Research Ethics Committees

Purpose

To act under the authority and guidance of the University Research Ethics Committee (UREC) and provide feedback to the UREC concerning matters and procedures for the ethical protection of human participants.

Terms of reference

1. To disseminate guidelines produced by the UREC on the proper conduct of research investigations in order to promote good ethical practice.
2. To review and approve, where appropriate, applications from members of the Faculty to carry out research involving human participants.
3. To review and approve applications from members of the Faculty (staff and students) to carry out research which may not directly involve human participants but which raises significant ethical issues relating to the impact on the environment or society.
4. For multi-faculty research projects ethical approval is to be sought from the FREC of the lead investigator/project manager (or where the lead investigator does not sit within a UWE faculty from UREC).
5. To monitor and audit research investigations carried out by undergraduate and postgraduate students and staff within the Faculty with respect to ethical practice.
6. To encourage a culture within the Faculty which recognises the central importance of ethical considerations in the design and performance of research.
7. To identify and advise UREC of appropriate training on ethical review for members of FREC.
8. To advise on and, where necessary, comply with external regulations and/or guidance on the ethical conduct of research with particular reference to the research culture within the Faculty.
9. To report to the UREC annually or more frequently if required, and to make the report available for discussion at Faculty Research and Knowledge Exchange Committees.
10. Each FREC will appoint a named member of staff, normally the Chair of the Committee, to act as the designated officer with responsibility for reporting to the UREC. This designated officer will also be a member of the UREC.
11. The FREC designated officer will conduct an annual review of the FREC operations, and report to the UREC on the findings.
12. The FREC will refer cases to the UREC that require advice or opinion. Referral to the UREC for a review will be in exceptional circumstances only.

Composition

The FREC must have sufficient members to guarantee the presence of a core group at each meeting and to allow for a sufficiently broad range of experience and expertise. Membership should contain at least one person who has been trained in safeguarding children.

As a minimum, all FRECs shall comprise the following:

Chair
Deputy Chair
Associate Dean (Research and Knowledge Exchange) (optional member)
Members of the Faculty
Each Department will have at least two representatives to include the appropriate Associate Head of Department (RKE) or a Research Centre Director with a research remit
Two members from other Faculties or Services
At least one person not employed by UWE

Appointment criteria

1. The Chair and Deputy Chair of FRECs shall be appointed as such by the Associate Dean (Research and Knowledge Exchange) in the Faculty in consultation with the Chair of the UREC.
2. The appointees should normally have at least one year's experience of the work of the FREC or equivalent research ethics committee.
3. Those appointed should have received training in research ethics reviewing, and possess the relevant chairing skills. Potential candidates should be offered any necessary supplementary training prior to appointment.
4. Appointments of any member of a FREC will normally be for a maximum period of five years. Appointments will be staggered to ensure staged turnover of membership. In exceptional circumstances a member may be invited to continue beyond this five year period.

In attendance

Committee Officer

Quorum

One third of the members eligible to attend.

Frequency of meetings

Four per year.

APPENDIX 2

ROLES AND RESPONSIBILITIES OF REC MEMBERS

- 1 Attend FREC meetings.
- 2 Receive ethics applications for scrutiny and complete and submit scrutineer report within agreed timescales.
- 3 Promote research ethics culture within the faculty
- 4 Act as a contact person for staff and students seeking advice on research ethics
- 5 Assist in disseminating good practice around research ethics
- 6 Assist in raising awareness and understanding of UWE Ethics policy and procedures.
- 7 Contribute to research ethics policy development.
- 8 Attend training on research ethics – both internal and external events
- 9 Assist in delivering training around research ethics to staff and students.
- 10 Contribute expertise on specialist areas of research – for example research involving children, research with human tissue, research in the National Health Service.
- 11 Deputise for the Chair of FREC.
- 12 Represent the faculty at UREC when appropriate.
- 13 Work closely with staff in Research Administration to ensure effective communication around ethics approvals.
- 14 Report on departmental concerns relating to research ethics policy and procedures.
- 15 Keep updated on research governance policies at UWE.
- 16 Be aware of related policies on data protection, safeguarding, disclosure and barring, health and safety as they apply to research.
- 17 Provide advice on research ethics to module leaders delivering research training.
- 18 Support PGR research supervisors as appropriate.
- 19 Assist in the monitoring and audit of research activity within the Faculty.
- 20 Lead by example of good research practice.

APPENDIX 3

RESEARCH ETHICS PROCESS FLOWCHARTS

UREC/FREC review process

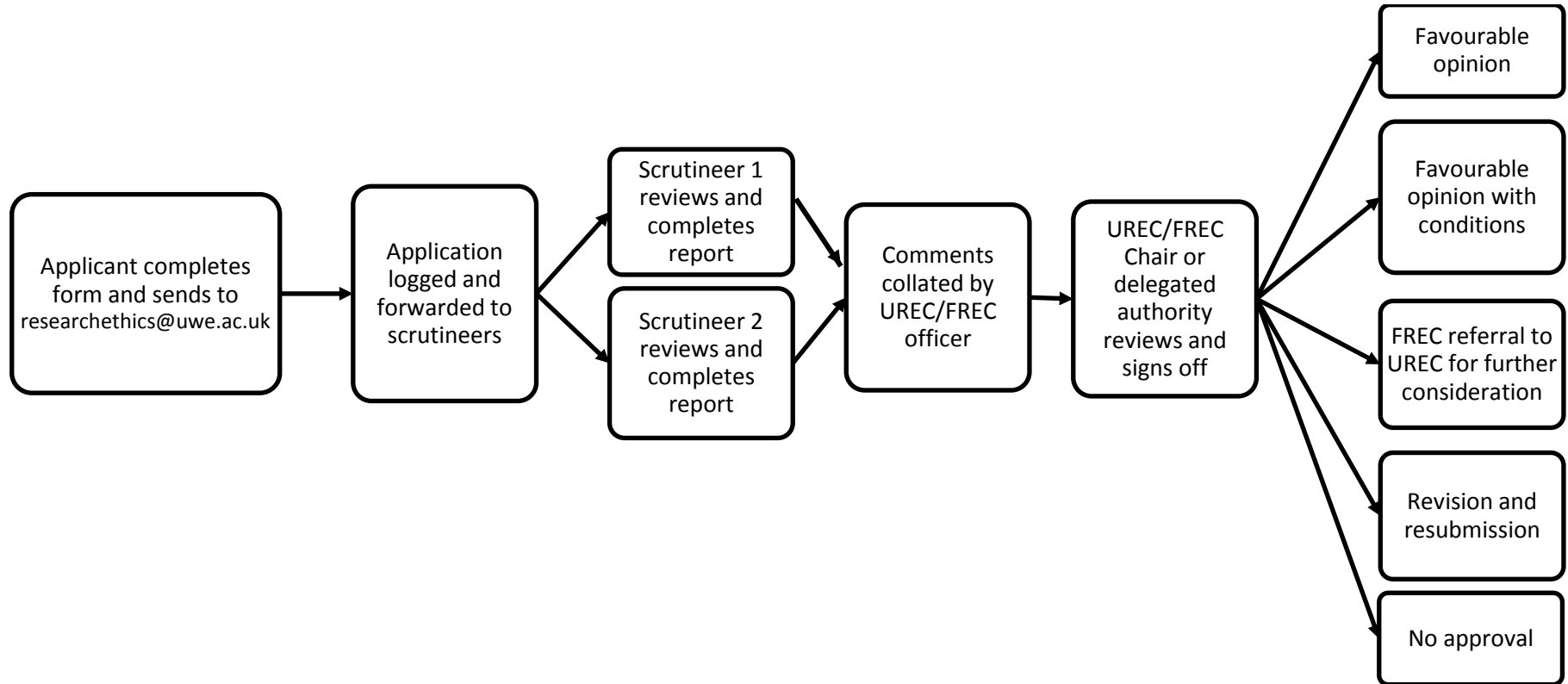
Category A project - EXTERNALLY funded project involving HUMAN PARTICIPANTS (NOT NHS PATIENTS)

Category B project - EXTERNALLY/INTERNALLY funded project involving HUMAN PARTICIPANTS (NHS PATIENTS)

Category C project - EXTERNALLY/INTERNALLY funded project using HUMAN TISSUE as defined by the Human Tissue Act

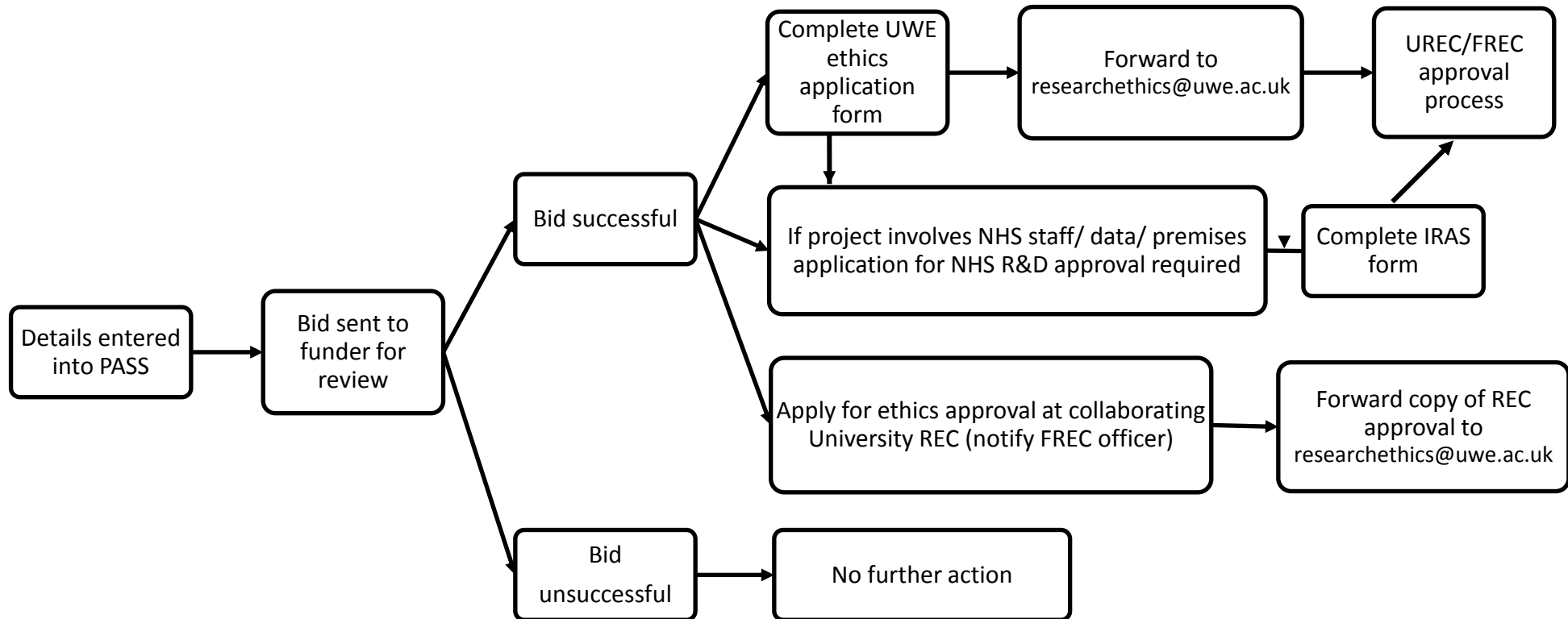
Category D Project - INTERNALLY funded projects involving HUMAN PARTICIPANTS (NOT NHS PATIENTS)

UREC/FREC review process



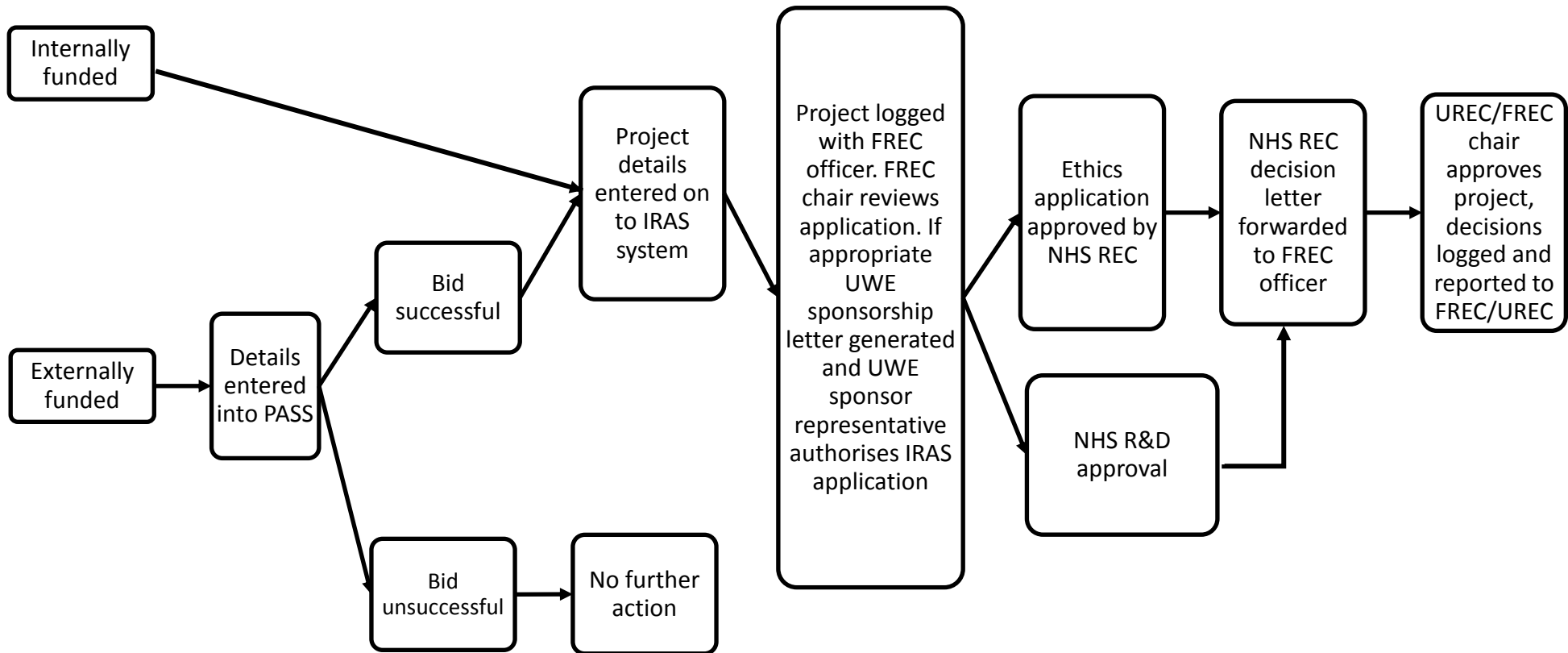
Category A project

Externally funded project involving human participants (not NHS patients) – staff and all student projects



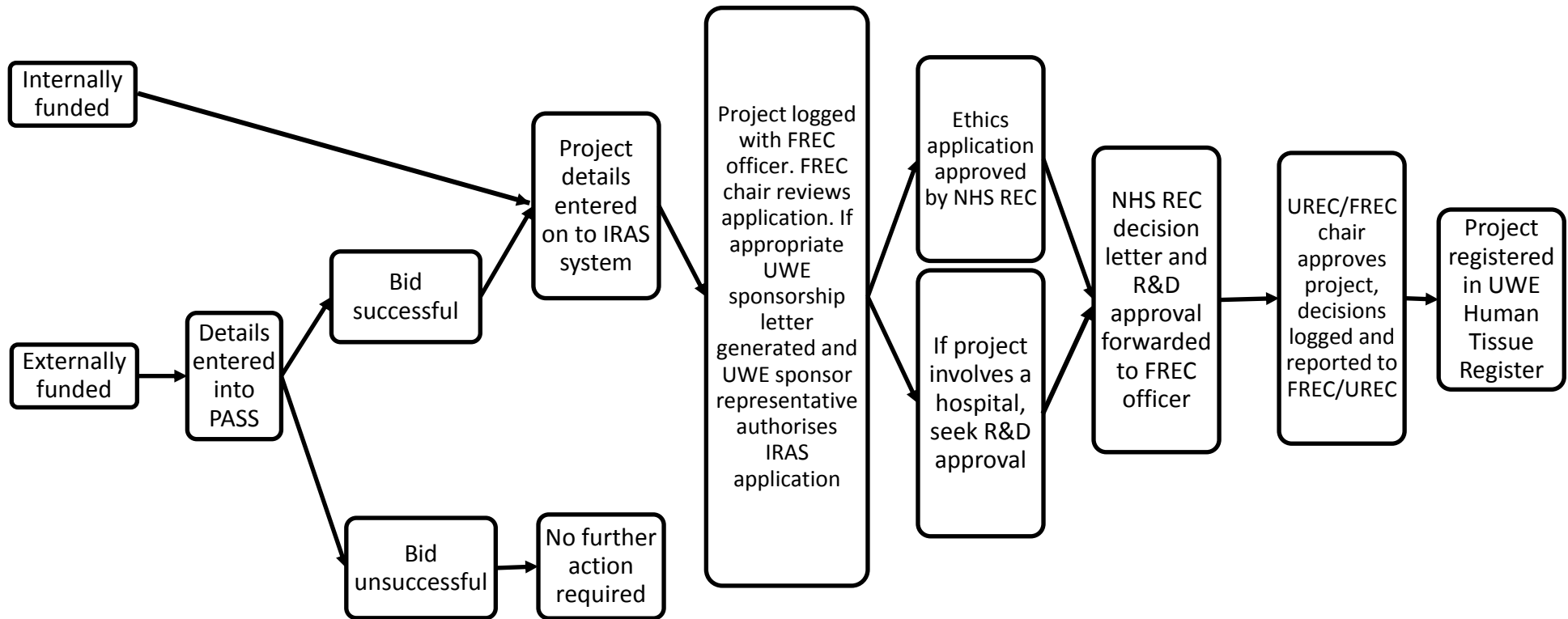
Category B project

Externally/internally funded project involving human participants (NHS patients) - staff and all student projects



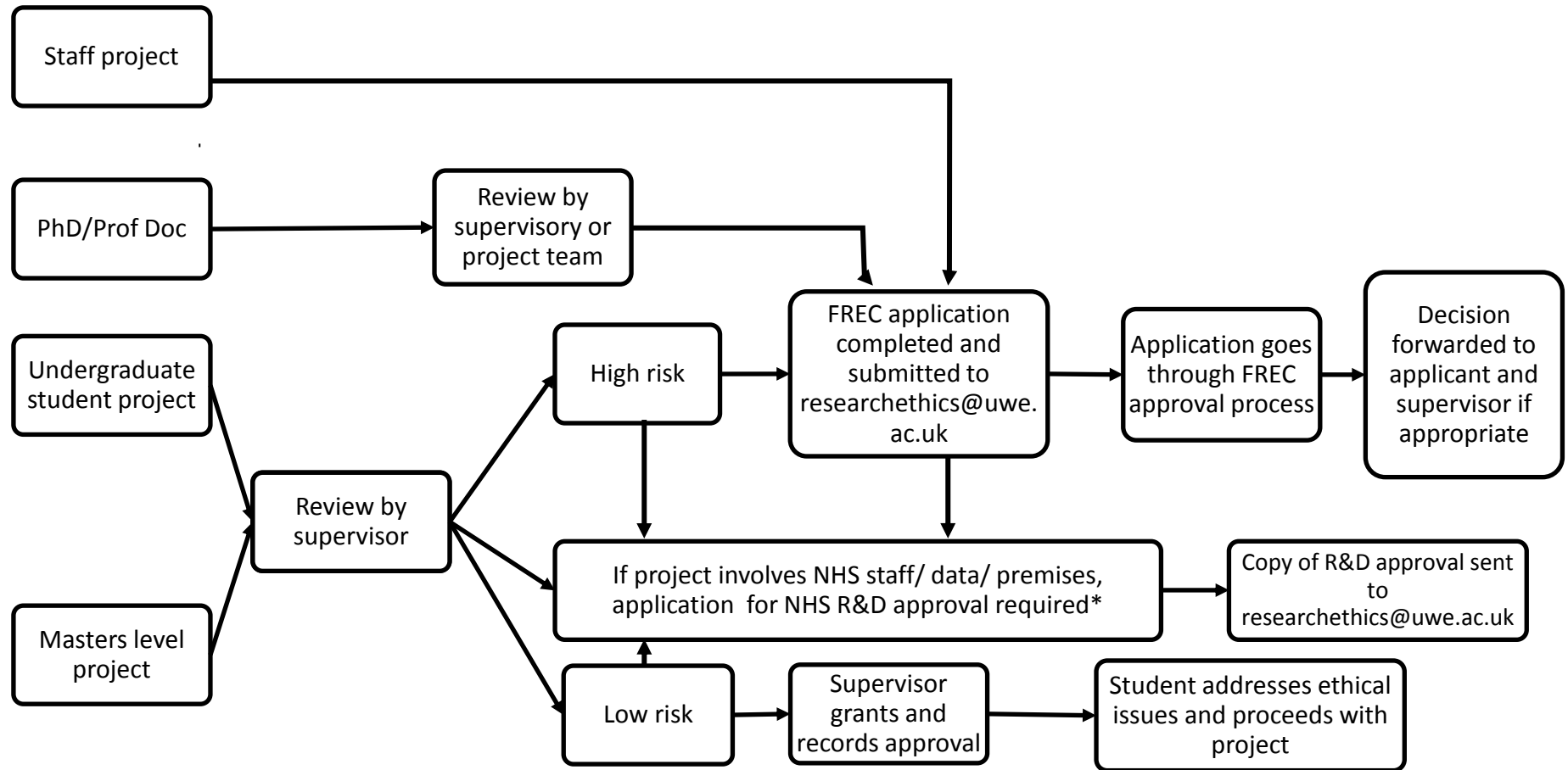
Category C project

EXTERNALLY/INTERNALLY funded project using HUMAN TISSUE as defined by the Human Tissue Act



Category D Project

INTERNALLY funded projects involving HUMAN PARTICIPANTS (not NHS patients)



*It may be possible to apply for NHS Trust R&D approval in tandem with UWE research ethics approval, however some Trusts will require confirmation of UWE ethics approval before R&D approval is given. If in doubt, please contact the relevant Trust R&D office.