Operating Procedures for Ethics Review of Student research projects

Following a review of diverse current practices across UWE by the University Research Ethics Committee (UREC) this paper sets out the operating procedures relating to the ethical review process for student research projects.

1. What kind of student projects need ethical review?

All U/G, M level, PGT and PGR research projects – carried out as part of a 'research' module or for a research qualification (PhD, Prof Doctorate) fall under the UWE Research Governance Framework found at http://www1.uwe.ac.uk/research/researchgovernance.

Within the terms of the framework **all** research involving human subjects, or using human tissue, requires ethical review. Evaluation studies with human subjects or research using identifiable personal data also require ethical review (even if they are exempt from review by an NHS Research Ethics Committee).

It is not normally expected that U/G students will be collecting human tissue for research. U/G projects will usually be attached to an existing staff project which has been approved by the Health Research Authority (HRA).

M level and PGR students using human tissue will need to familiarise themselves with the Guidance on Research Using Human Tissue found at:

http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx

2. What is the role of the supervisor?

All student research must be supervised and the supervisor is responsible for the conduct of the research. A formal project proposal is needed which clearly discusses and addresses any ethical issues in order for it to be reviewed and approved. The supervisor and student should retain a copy of the project proposal and the ethics approval. The University approach to student research is proportionate to the level of study and the potential risks of doing the research.

For U/G research projects supervisors will review the ethical issues of a project with a student and may formally approve the project if it is deemed 'low risk'. For any project which is not low risk, (see Appendix 1) a full ethics application will need to be completed and submitted to a Faculty Research Ethics Committee (FREC). It will need scrutinising by a second scrutineer (another member of staff) and authorisation by FREC.

For M level research projects supervisors will review the ethical issues of a project with the student and may formally approve the project if it is deemed 'low risk' and does not require

approval by an NHS REC or other external body. For any project which is not low risk, a full ethics application will need to be completed and submitted to FREC. It will need scrutinising by a second scrutineer (another member of staff) and authorisation by FREC. See below for details about applications to the Health Research Authority (HRA) to an NHS REC or other external body via the Integrated Research Application System (IRAS).

For PhD and Prof Doc research projects supervisors should review the ethical issues of a project with the student. Because PhD and Prof Doc research is expected to be in more depth, takes place over a longer period of time and is expected to achieve best practice in relation to research, these projects should be submitted for full ethics review and independent scrutiny. So, regardless of the level of risk of these projects, a full ethics application form should be submitted to FREC unless an application is being made to an NHS REC or other external body via IRAS. The application should first be approved by the supervisory team before submission.

Additionally a supervisor may request independent ethical scrutiny by FREC of any student project if they have ethical concerns.

3. Where can supervisors go for advice?

Normally each Department has two members of FREC - a person who acts as Ethics Lead and a second person who may be Associate Head of Department Research and Knowledge Exchange (RKE) lead. They can advise supervisors on the risk assessment of any student project and whether it should be referred for ethical review by FREC.

4. How does a student submit an application to FREC for ethics review?

The application form for research using human subjects may be downloaded from the Research Ethics webpage
http://www1.uwe.ac.uk/research/researchethics/applyingforapproval.aspx

The form should be completed and sent, together with supporting documentation, (see checklist on the form) to the supervisor(s) for approval and endorsement before being submitted to the Secretary of the FREC. The application will then be sent to another scrutineer for review. The second scrutineer may, or may not, be in the same department.

5. How is an application reviewed by FREC?

Scrutineers from the scrutineer pool are allocated by the Secretary of FREC. The scrutineer submits a report on the application to FREC. Their report will be circulated to the Chair of FREC (or the Department RKE lead in the relevant department) for authorisation. A letter will be prepared by the Secretary of FREC with the decision and any comments which need to be fed back to the student. In some faculties, Department RKE leads have delegated authority for signing off applications on behalf of the Chair.

6. How does a student apply to an NHS REC?

Supervisors and students applying to an NHS REC should familiarise themselves with the Health Research Authority (HRA) guidance found at:

http://www.hra.nhs.uk/research-community/before-you-apply/

Applications to an NHS REC should be completed using the IRAS system. Once the application has been prepared and approved by the supervisor(s) notification of an intention to submit the application should be sent to the Secretary of FREC. The application will need to be checked by the Chair of FREC before a sponsor letter and signature is prepared if UWE is the sponsor. The HRA usually expects supervisors to attend the NHS REC meeting where a student application is being discussed.

Once the application has been reviewed and approved by an NHS REC a copy of the final application and approval letter should be sent to the Secretary of FREC. The Chair of FREC will need to give UWE ethics approval before the study can begin. This will normally be a ratification of the NHS REC approval.

It is important for students and supervisors to be familiar with the requirements for Research & Development (R&D) approval for research projects in the NHS including those research projects (involving NHS Staff or data) where NHS REC approval may not be needed. You should approach the R&D department at an early stage in the planning of the research project for advice about their approval process. Normally an application for R&D approval using the IRAS online system may be required.

7. Why is audit important?

The University needs to be confident that its ethical review policies and procedures are robust and appropriately implemented. Being able to demonstrate this is part of quality management in relation to educational provision but also an important aspect of good research governance and ensuring that human participants in research have ethical protection. Departments therefore have an important responsibility to ensure that there is an auditable process relating to the review of student research projects. Each Department will be expected to hold a register of U/G and M level student projects with human participants.

Professor Julie Kent, Chair UREC. June 2013

Updated August 2016

APPENDIX 1

DEFINING HIGH/LOW RISK RESEARCH (revised October 2012)

Defining what is meant by low or high risk research is not primarily about rule-making. Rather it is a professional judgement made by the researcher, or research supervisor for student projects, about the potential risks of the research to harm participants. This guidance is to assist in making that risk assessment. If in doubt please seek advice from your Departmental Ethics Lead or a member of your Faculty Research Ethics Committee or the University Research Ethics Committee.

All staff and PhD projects involving human participants (high or low risk) should be scrutinised and approved by FREC or UREC.

Student research at U/G and M level is usually subject to 'light touch' scrutiny as part of a proportionate approach to research ethics review. In order for an application to qualify for 'lighttouch' scrutiny the research must not normally fall into any of the following categories (which isadapted from the ESRC Research Governance Framework) *but it is not assumed that allresearch falling into these categories will always be high risk*. High risk U/G and M level studentresearch should be referred to the relevant FREC or UREC it may include research of the following types:

- Research involving potentially vulnerable groups – for example, children andyoung people, those with a learning disability or cognitive impairment or individuals in a dependent or unequal relationship. (Vulnerability should be considered on a case-by-case basis: groups or individuals not conventionally considered to be vulnerable may become exposed to issues as a result of participating that make them vulnerable.)

- Research involving those who lack capacity – all research involving those wholack capacity, or who come during the research project to lack capacity, must be approved by an "appropriate body" operating under the Mental Capacity Act, 2005.

- Research involving highly sensitive topics – for example, *participants'* sexual behaviour, their illegal or political behaviour, their experience of violence, theirabuse or exploitation, their mental health.

- Research involving individuals or groups where the permission of a gatekeeper is required for initial or continued access to participants, and research where participants are in a dependent relationship with the gatekeeper.

- Research involving deceased persons, body parts or other human tissues and cells.

- Research using administrative data not in the public domain or secure data.

Researchers/research centres using these data sets will need to be approved by the body supplying the data and keep data in secure areas.

- Research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out.

- Research involving access to records of personal or sensitive confidential information, including genetic or other biological information concerning identifiable individuals.

- Research which would or might induce psychological stress, anxiety or humiliation or cause more than minimal pain.

- Research involving intrusive interventions or data collection methods – for example, the administration of substances, vigorous physical exercise or techniques such as hypnotism. In particular where participants are persuaded to reveal information which they would not otherwise disclose in the course of their everyday life.

- Research where the safety of the researcher may be in question.

- Research undertaken outside the UK where there may be issues of local practice and political sensitivities

- Research involving respondents through social media and where sensitive issues are discussed.

- Research involving visual/vocal methods where participants or other individuals may be identifiable in the visual images used or generated.

- Research which may involve data sharing of confidential information beyond the initial consent given – eg where the research topic or data gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

APPENDIX 2

Underlying principles and values informing the consultation paper

1. Dissertation and project supervisors are expected to have competence to conduct a risk assessment of the student's research and ensure that ethical issues are identified and adequately addressed. They are best placed to judge whether or not the project is low risk.
2. Ethical review processes should be proportionate to risk and consistent with UWE's definition of what constitutes low risk research. 'Light touch' review is for low risk projects only.
3. If research is **not** low risk research it should be subject to independent scrutiny and at least one scrutineer, other than the supervisor, should review the proposal. Authorisation of the project can only be given by FREC.
4. Authorisation of projects by FREC may be by delegated authority of the Departmental RKE lead.
5. The administrative burden and staff costs of ethical review need to be proportionate to the risks associated with the research. While no category of research (U/G, M level, PGR) can be assumed to be low risk it is expected that PGR /doctoral students engage fully with the ethical review process and therefore are subject to the same level of ethical scrutiny as staff research.
6. There should be a consistent approach to ethical review of student projects across Departments.
7. Ensuring there is an audit trail detailing the ethical review and approval process is the joint responsibility of the supervisor, the module leader and FREC.

APPENDIX 3
Frequently Asked Questions

Frequently Asked Questions relating to ethics review of student research.

1. *Do I need research ethics approval to conduct interviews, observations or focus groups as part of my module?*

   All research projects involving human participants that have specified research questions, use a recognised research methods and methodology and form part of an assessment require research ethics review (see 4-6 below). Please see the Guidelines on Ethical Review of Evaluation Studies and Evaluation Research for the requirements for ethical review of evaluation projects.

2. *Does a research project using questionnaires in an online survey require research ethics review?*

   Yes, **research projects involving human participants** includes the use of data collection methods which are not face to face such as online surveys, postal surveys (see 4-6 below).

3. *If I am using secondary data, anonymised data that has previously been collected, do I need research ethics approval?*

   No, only where secondary datasets contain personal, identifiable data would you need to obtain research ethics approval for its use in a research project.

4. *I am an Undergraduate doing a dissertation – do I need to complete the Faculty Research Ethics application form?*

   You will need to provide your supervisor with information about your research project in accordance with module requirements. Your supervisor will then assess whether your project is 'low risk' or not. If the project raises no significant ethical issues and is considered 'low risk' your supervisor can approve it and you will not need to submit an application to the Faculty Research Ethics Committee (FREC). If your supervisor decides that the project should be reviewed by FREC then you will need to complete a full ethics application form and submit it to FREC. If your research involves staff, patients or NHS premises see below.

5. *I am a Masters level student doing a dissertation – do I need to complete the Faculty Research Ethics Application form?*

   You will need to provide your supervisor with information about your research project in accordance with module requirements. Your supervisor will then assess whether your project is 'low risk' or not. If the project raises no significant ethical issues and is considered

'low risk' your supervisor can approve it and you will not need to submit an application to the Faculty Research Ethics Committee (FREC). If your supervisor decides that the project should be reviewed by FREC then you will need to complete a full ethics application form and submit it to FREC. If your research involves staff, patients or NHS premises see below.

6. *I am a PhD/ Professional Doctoral student – do I need to complete the Faculty Research Ethics Committee Application form?*

   Yes, if your research involves human participants you will need to complete a full application to the Faculty Research Ethics Committee (FREC) so that your research project can be independently reviewed and approved. If your research involves staff, patients or NHS premises see below.

7. *My research project involves patients in the NHS how do I get ethics approval?*

   You will need to apply to an NHS Research Ethics Committee for approval via the online Integrated Research Application System (IRAS). You will also need NHS R&D approval for your project from the hospital trusts where your project will take place. You must advise the FREC secretary, Leigh Taylor, that you will be applying for NHS REC approval using the HRA and IRAS. Your IRAS application will need authorisation from the Chair of Faculty Research Ethics Committee and Associate Dean for research before you submit it.

8. *My research project involves staff in the NHS (or NHS data/premises) how do I get ethics approval?*

   Since your research involves human participants you will need research ethics approval. Your supervisor will assess whether your project is 'low risk' or not. If the project raises no significant ethical issues and is considered 'low risk' your supervisor can approve it and you will not need to submit an application to the Faculty Research Ethics Committee (FREC). If your supervisor decides that the project should be reviewed by FREC then you will need to complete a full ethics application form and submit it to FREC. Because your project involves NHS staff you will need NHS R&D approval and will need to contact the relevant R&D office and apply for R&D approval via the IRAS system. Your IRAS application will need authorisation from the Chair of Faculty Research Ethics Committee and Associate Dean for research before you submit it.

9. *Where can I get advice on ethical review of my research?*

   Your supervisor can advise you on ethical issues relating to your research. They can help you complete an application to the FREC or to an NHS REC using IRAS. The FREC application form can be found on the University Research Ethics Committee webpage. Details of how to apply for NHS REC approval or NHS R&D approval can be found on the IRAS webpages. There is also an IRAS helpline.

10. *Why does my research need ethical review and approval?*

    The primary purpose of research ethics review is to protect human participants who take part in research.

11. *My research project involves using human tissue so how do I get approval for this?*

    Research using human tissue is strictly regulated and there are separate University guidelines on this type of research which you need to understand and familiarise yourself with. These guidelines may be found on the Research Governance webpages. Your supervisor can advise on this type of research and what kind of ethics approval is needed.

APPENDIX 4 Research Ethics process flowcharts

UREC/FREC review process

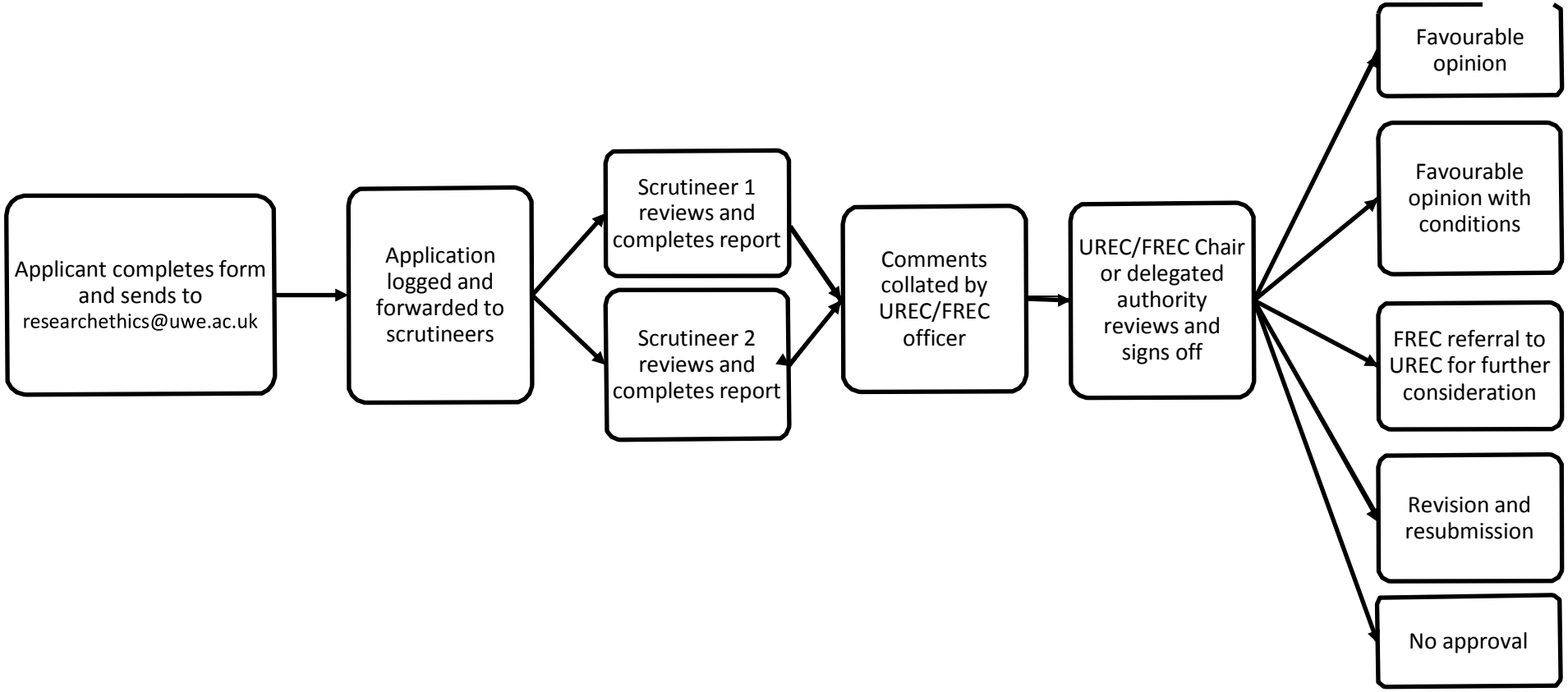
EXTERNALLY funded project involving HUMAN PARTICIPANTS (**NOT NHS PATIENTS**)

EXTERNALLY/INTERNALLY funded project involving HUMAN PARTICIPANTS (**NHS PATIENTS**)

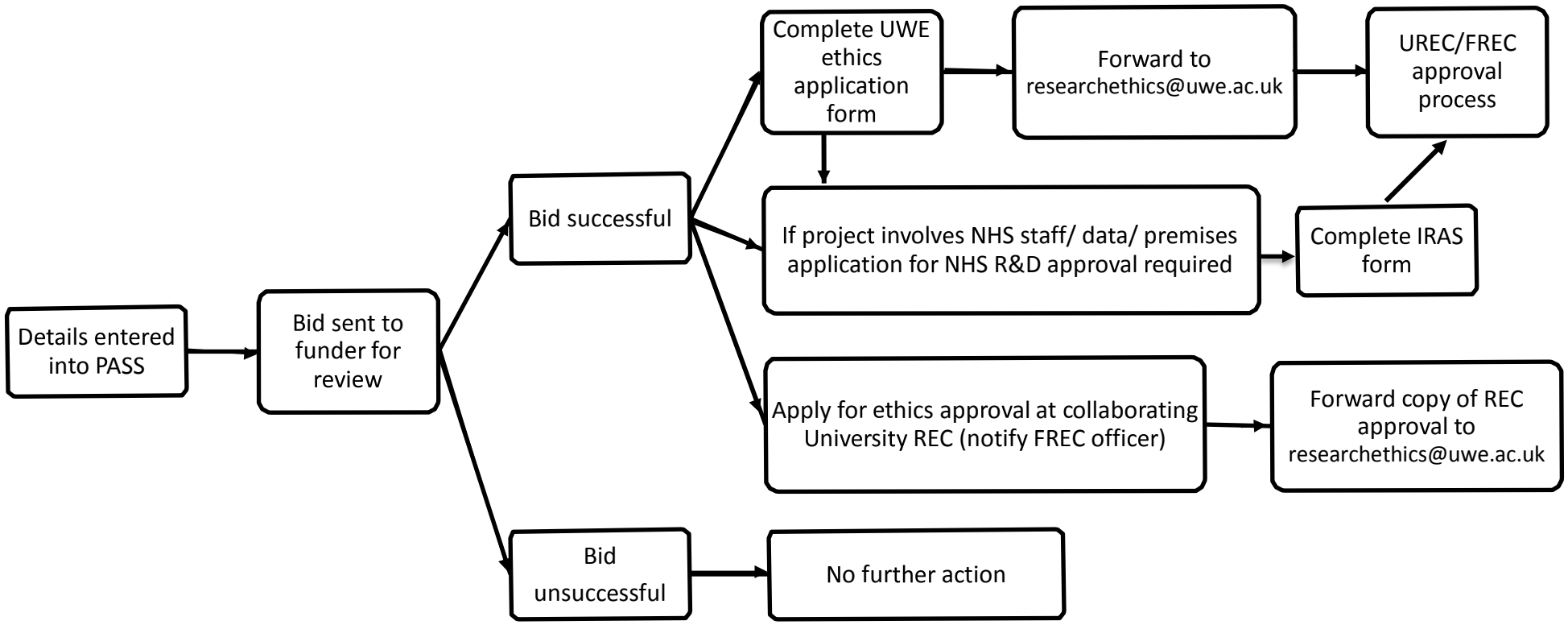
EXTERNALLY/INTERNALLY funded project using **HUMAN TISSUE** as defined by the Human Tissue Act

INTERNALLY funded projects involving HUMAN PARTICIPANTS (**NOT NHS PATIENTS**)

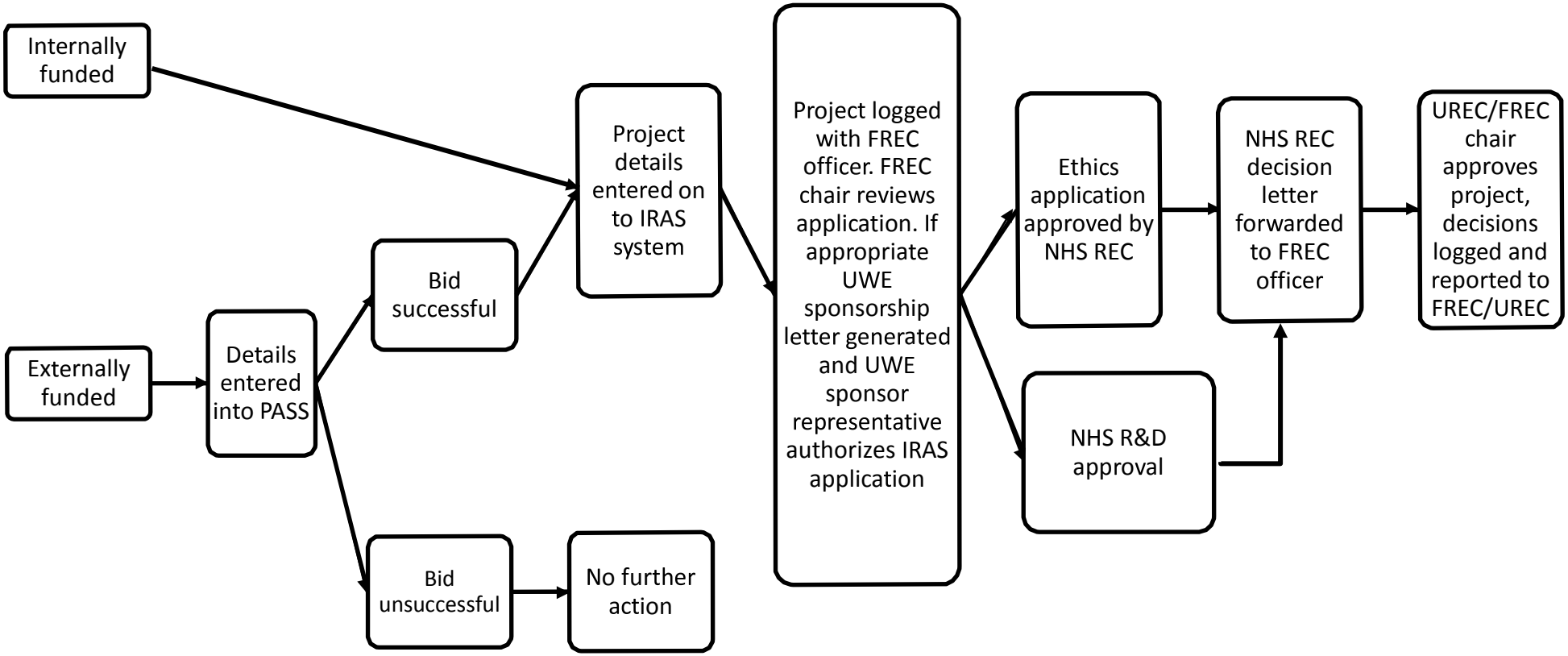
UREC/FREC review process



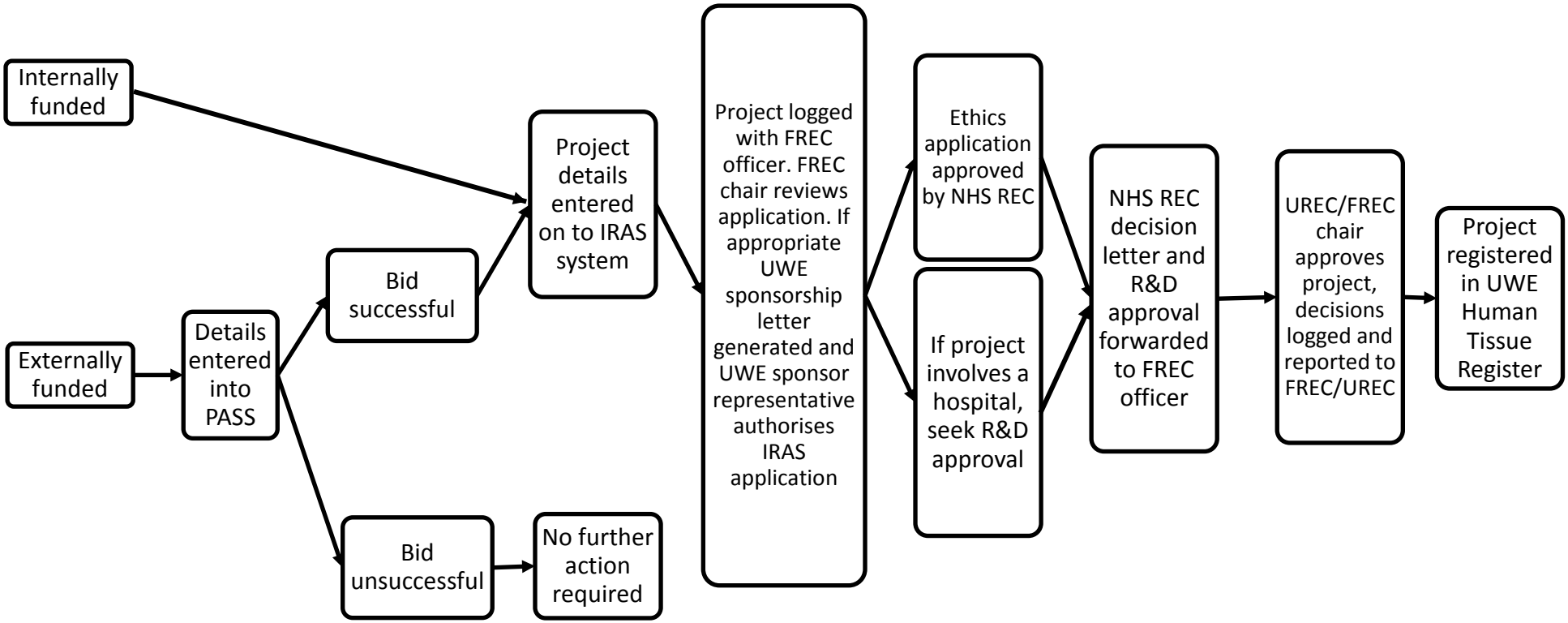
EXTERNALLY funded project involving **HUMAN PARTICIPANTS (NOT NHS PATIENTS)**



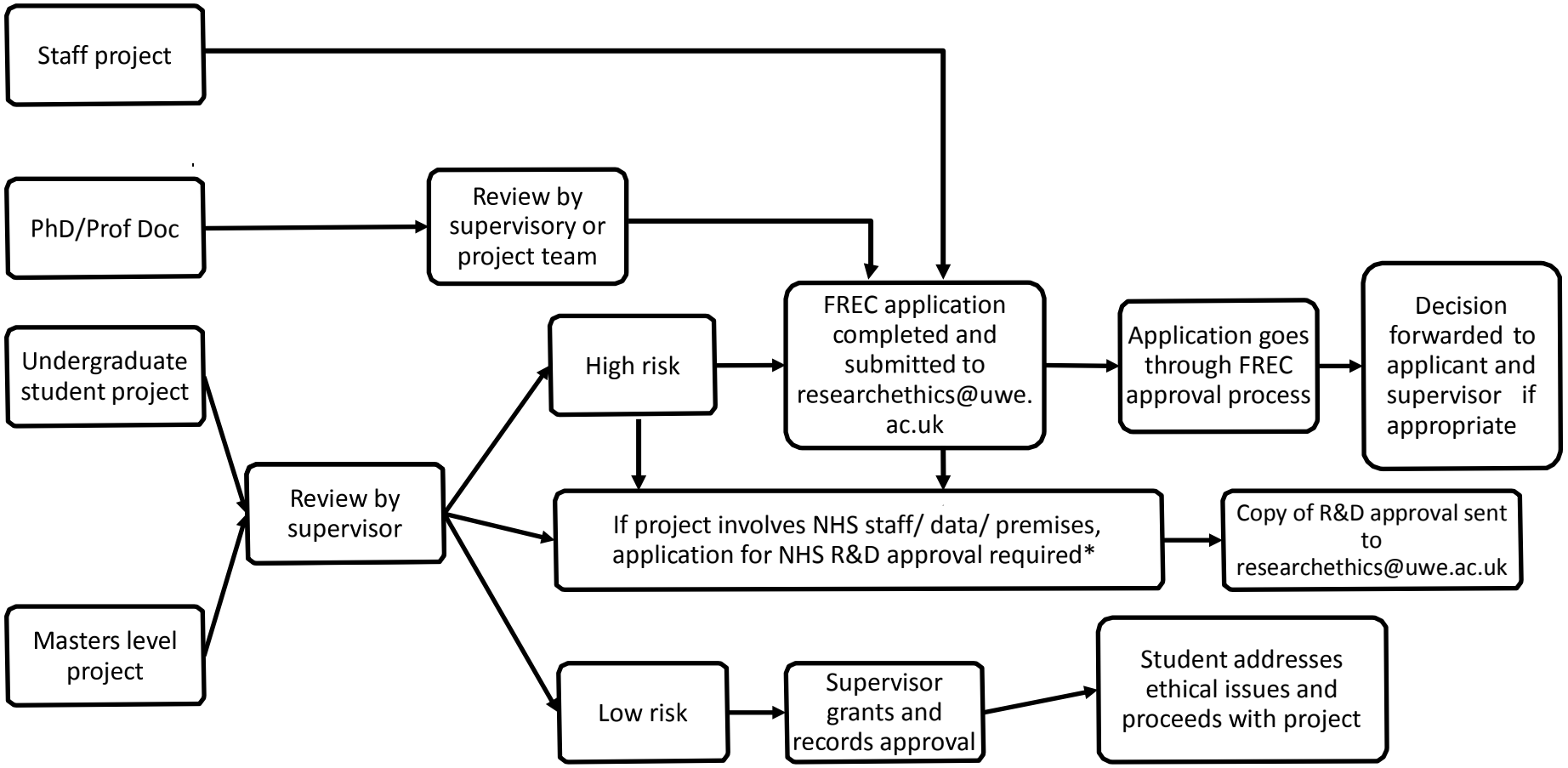
EXTERNALLY/INTERNALLY funded project involving **HUMAN PARTICIPANTS (NHS PATIENTS)**



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



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.