

Research sponsorship at UWE Bristol Bristol: Guidance for staff and students

What is a research sponsor?

The Research Sponsor takes ultimate responsibility for the conduct and integrity of the research, ensuring that research projects have adequate indemnity/insurance arrangements, are registered, are approved by the appropriate bodies and are subsequently monitored.

Who acts as a research sponsor?

UWE Bristol will normally act as research sponsor for research conducted by its staff and students. However there are circumstances when this may not automatically apply:

- When a staff member has an NHS contract, and is employed within the NHS where the research is being carried out, it would normally be expected that the employing Trust would act as sponsor for the research.
- When a student is an NHS employee where the research is being conducted, it is normally expected that the employing Trust would act as sponsor for the research.
- Exceptionally it may be appropriate for joint sponsorship of a study.
- When research is being funded by a commercial organisation, they may act as the sponsor.
- UWE Bristol rarely acts as sponsor for drug clinical trials but may act as sponsor for other clinical trials. Where the member of staff or student has a clinical contract, the sponsor will normally be their employing Trust. A Trust may also take the sponsor role if they hold the funding award.

Do I need a sponsor for my research?

All research conducted in the NHS needs a sponsor to comply with the Department of Health Research Governance framework and Clinical Trials Regulations. UWE Bristol acts as sponsor for all staff and student research that does not already have an external sponsor such as an NHS Trust (that may be hosting the research), a pharmaceutical company, charity or other university.

What do I need to do to ensure I have appropriate approval for my research?

In addition to requiring a sponsor research involving human participants, their data or tissue requires ethics approval. There are different categories of projects which have different pathways to approval and different levels of risk associated with them.

- Category A externally funded project involving human participants (not NHS patients)
- Category B externally/internally funded project involving human participants (NHS patients)
- Category C externally/internally funded projects using human tissues
- Category D internally funded projects involving human participants (not NHS patients)

First, decide which category your project falls within.

A. *What do I need to do if my project is Category A externally funded project involving human participants (not NHS patients)?*

1. You will need your project approved through PASS if you apply for external funding. Approval is given by your Associate Dean Research or designated senior manager.

2. You will need to apply for ethics approval for your study via your Faculty Research Ethics Committee (FREC) or the University Research Ethics Committee (UREC) if the project is funded by the ESRC.
3. There will be no separate process to verify sponsorship arrangements.

B. What do I need to do if my project is Category B externally/internally funded project involving human participants (NHS patients)?

1. You will need your project approved through PASS when you apply for funding. Approval is given by your Associate Dean Research or designated senior manager.
2. If your project involves NHS patients, you will need to apply for NHS REC ethics approval through the Integrated Research Application System (IRAS). To do so, you will need sponsorship arrangements confirmed. If the study involves NHS staff or premises but not patients, you may still need approval from the Research & Development office (or equivalent) and apply via IRAS for this. Ethics approval must be sought from UREC/FREC (see Category A projects).
3. If you are a member of staff, you will need to contact the FREC Officer to notify them of your intention to submit an IRAS application. Once your application is completed, you will need to transfer it to the Chair of FREC for them to view and comment on your application. This is to ensure that there are no potential risks or issues which need to be raised before sponsorship is agreed. A copy of your final IRAS application and NHS REC approval will need to be submitted to the FREC Officer (see 8).
4. If you are employed on an NHS contract where the research will be hosted, you should approach your NHS employer (R&D office or equivalent) to see if they are willing to act as sponsor for your study.
5. If you require UWE Bristol to act as sponsor, then you will need authorisation from the Associate Dean Research for this on your IRAS form. The FREC Officer will guide you through this and arrange for a sponsor letter to be prepared. After this you can submit your IRAS form to the NHS REC for approval
6. If you are a student, you will first need your supervisor to approve your IRAS application **before** approaching the FREC Officer or seeking authorisation from the Faculty.
7. If you are a student employed on an NHS contract where the research will be hosted, you or your supervisor should approach your NHS employer (R&D office or equivalent) to see if they are willing to act as sponsor for your study.
8. Once you have received your NHS REC approval, please send a copy of the approval letter together with any associated documentation (ie consent forms, information sheets etc) to the FREC Officer.

C. What do I do if my study is a Category C externally/internally funded project using human tissues (as defined by the HT Act 2004)?

1. Familiarise yourself with [the standard operating procedures for human tissue research at UWE Bristol](#).
2. If you are a member of staff, you will need to contact the FREC Officer to notify them of your intention to submit an IRAS application for NHS REC approval. Once your application is

completed, you will need to transfer it to the Chair of FREC for them to view and comment on your application. This is to ensure that there are no potential risks or issues which need to be raised before sponsorship is agreed. A copy of your final IRAS application and NHS REC approval will need to be submitted to the FREC Officer (see 8).

3. If you are employed on an NHS contract where the research will be hosted, you should approach your NHS employer (R&D office or equivalent) to see if they are willing to act as sponsor for your study.
4. If you require UWE Bristol to act as sponsor, then you will need authorisation from the Associate Dean Research for this on your IRAS form. The FREC Officer will guide you through this and arrange for a sponsor letter to be prepared.
5. If you are a student, you will first need your supervisor to approve your IRAS application **before** approaching the FREC Officer or seeking authorisation from the Faculty.
6. If you are a student employed on an NHS contract where the research will be hosted, you or your supervisor should approach your NHS employer (R&D office or equivalent) to see if they are willing to act as sponsor for your study.
7. You will need to register your research on the UWE Bristol Human Tissue Research Register and submit copies of your NRES application and approval to Research Administration Leigh.Taylor@uwe.ac.uk.
8. Once you have received your NHS REC approval, please send a copy of the approval letter together with any associated documentation (ie consent forms, information sheets etc) to the FREC Officer.

D. What do I do if my project is a Category D internally funded project involving human participants? (not NHS patients)

1. If you are a member of staff or PhD student, then you will need to submit an ethics application to FREC for approval of your study.
2. No separate process is required for sponsorship arrangements (unless it involves a clinical intervention?)
3. If you are an undergraduate or Masters level student, then you will need to submit an ethics application to FREC for approval only if your project is identified as 'high risk' by your supervisor. See [SOPs ethics review of student projects](#).

Roles and responsibilities

Principal investigator/student supervisor responsible for seeking project and ethics approval and sponsorship for the study.

FREC Officer (Research Administration RBI) – receives requests for guidance on authorisation of IRAS applications and sponsorship by UWE Bristol.

Guides you through authorisation by the sponsor representative– usually the Faculty

Associate Dean Research

Receives completed IRAS applications and NHS REC approvals.

Receives FREC/UREC applications.

Maintains a list of approved projects for which UWE Bristol is sponsor.

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FREC Chairs – act on behalf of UWE Bristol to oversee IRAS application process and ratify NRES approvals. Carry out risk assessment and advise on potential risks to UWE Bristol of research proposed.

UREC Chair – receives reports on approved projects and monitors research through annual audit. Receives reports of adverse events relating to clinical trials/ clinical investigation studies.

Faculty Associate Dean Research – acts as sponsor representative on behalf of UWE Bristol authorising projects on PASS and on IRAS. Receives notification of adverse events or misconduct.

Contracts and Legal team – can provide advice on matters arising in relation liability issues.

Insurance/Data Protection Compliance Officer, based in Finance - can provide insurance advice.

Julie Kent
Chair of UREC
November 2013

Amendments to your protocol and study design

If your study has received NHS REC approval, you should familiarise yourself with your obligations regarding the notification of amendments to the protocol and study design. These may be found at:

<http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>

It is the responsibility of the sponsor to decide whether an amendment is substantial and should be notified to the REC or minor and need only be notified to the REC at the sponsor's discretion. If in doubt it is advised to report the amendment to the NHS REC.

If you wish to amend your protocol or study design, and need advice on this, please contact your Chair of FREC for advice.

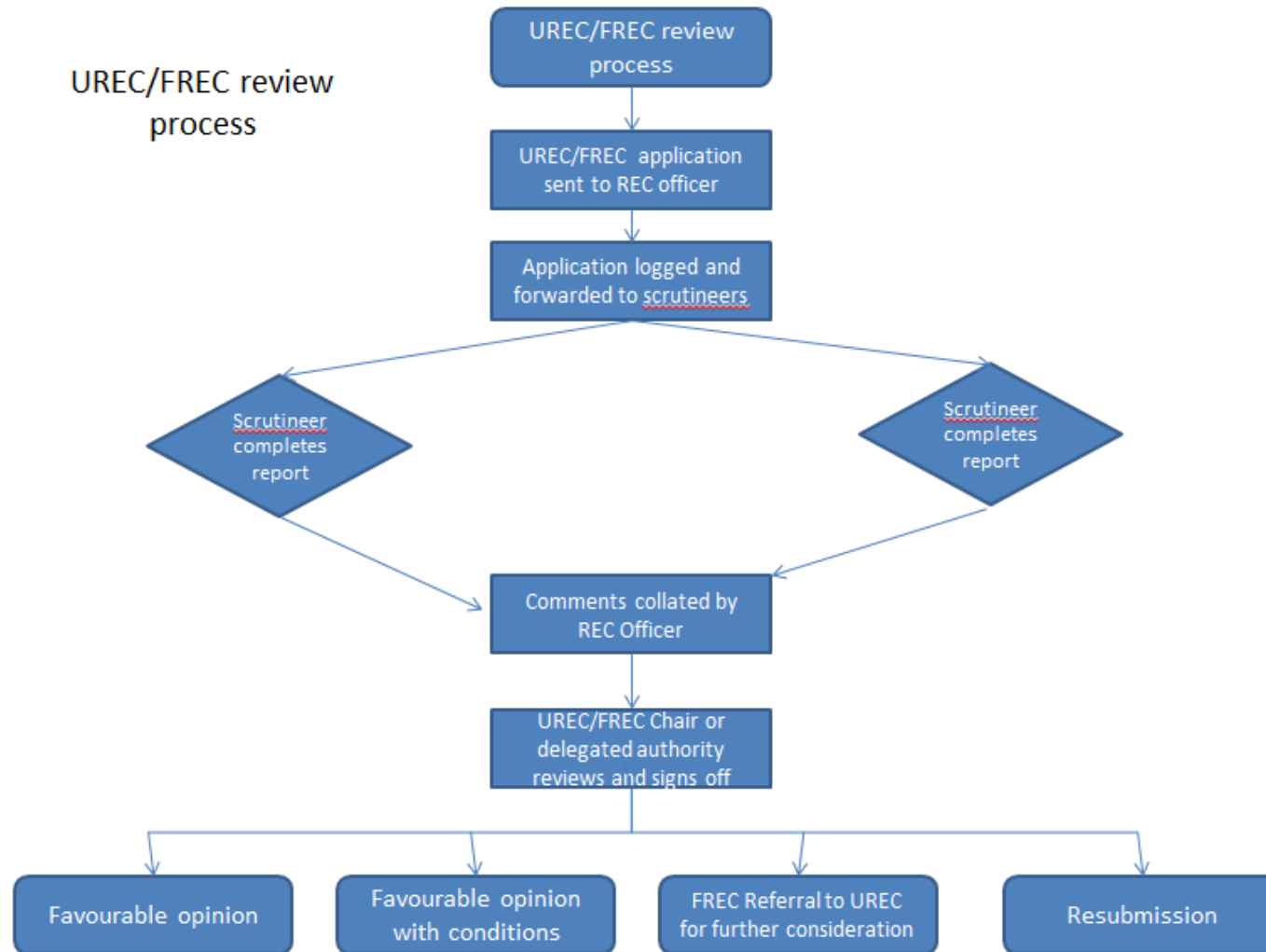
You may also seek advice from NRES helpline on whether an amendment should be considered substantial but it is the sponsor who decides.

(See REC SOPs Version 5.1 March 2012.)

If your study has received FREC approval you should familiarise yourself with your obligations regarding the notification of amendments to the protocol and study design (these will be set out in your letter of approval). If you need to make amendments to your study, please complete the 'Amendment to existing ethical approval form' which can be found at:

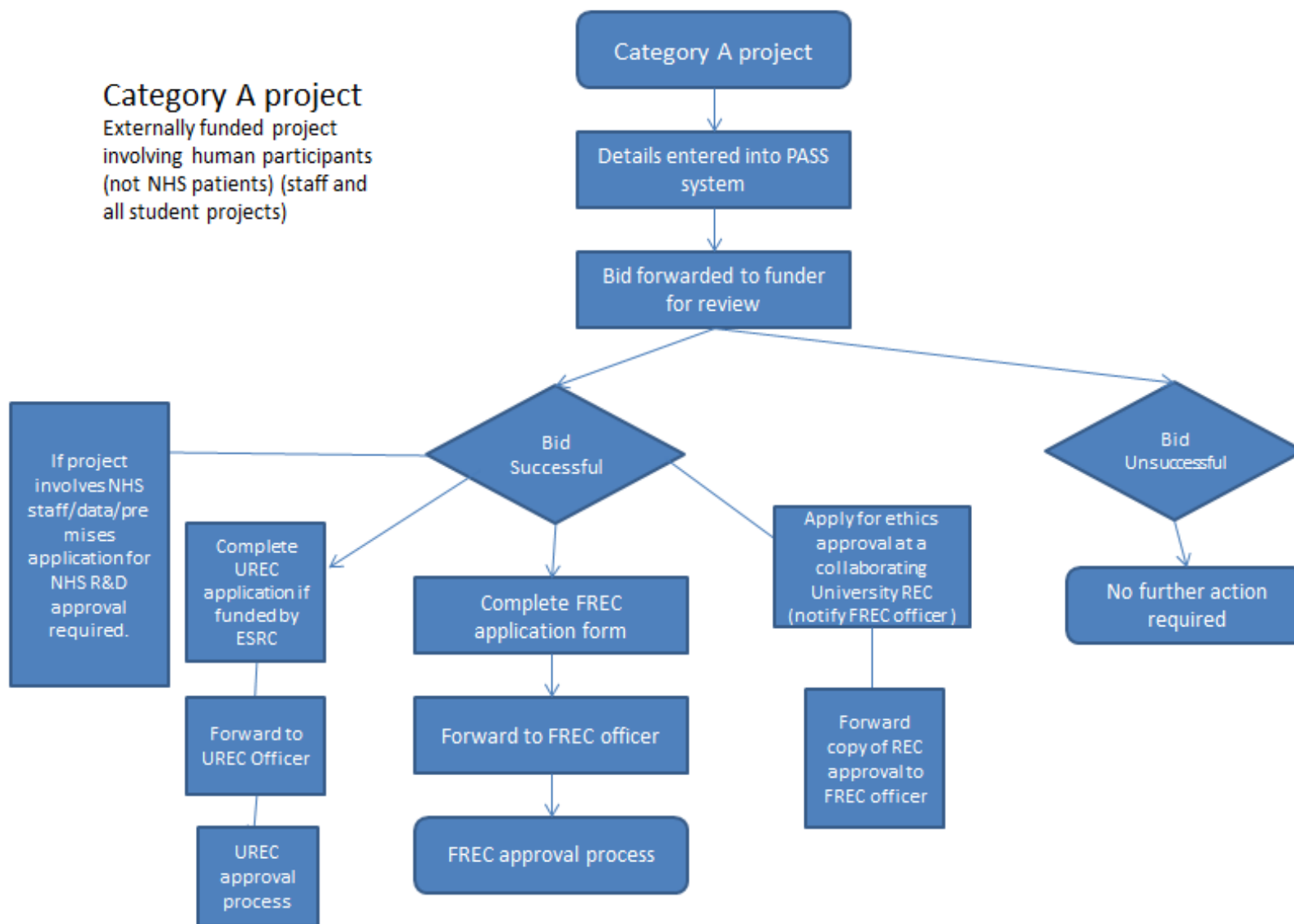
<http://www1.uwe.ac.uk/hls/research/researchethicsandgovernance.aspx>

Ethics review processes



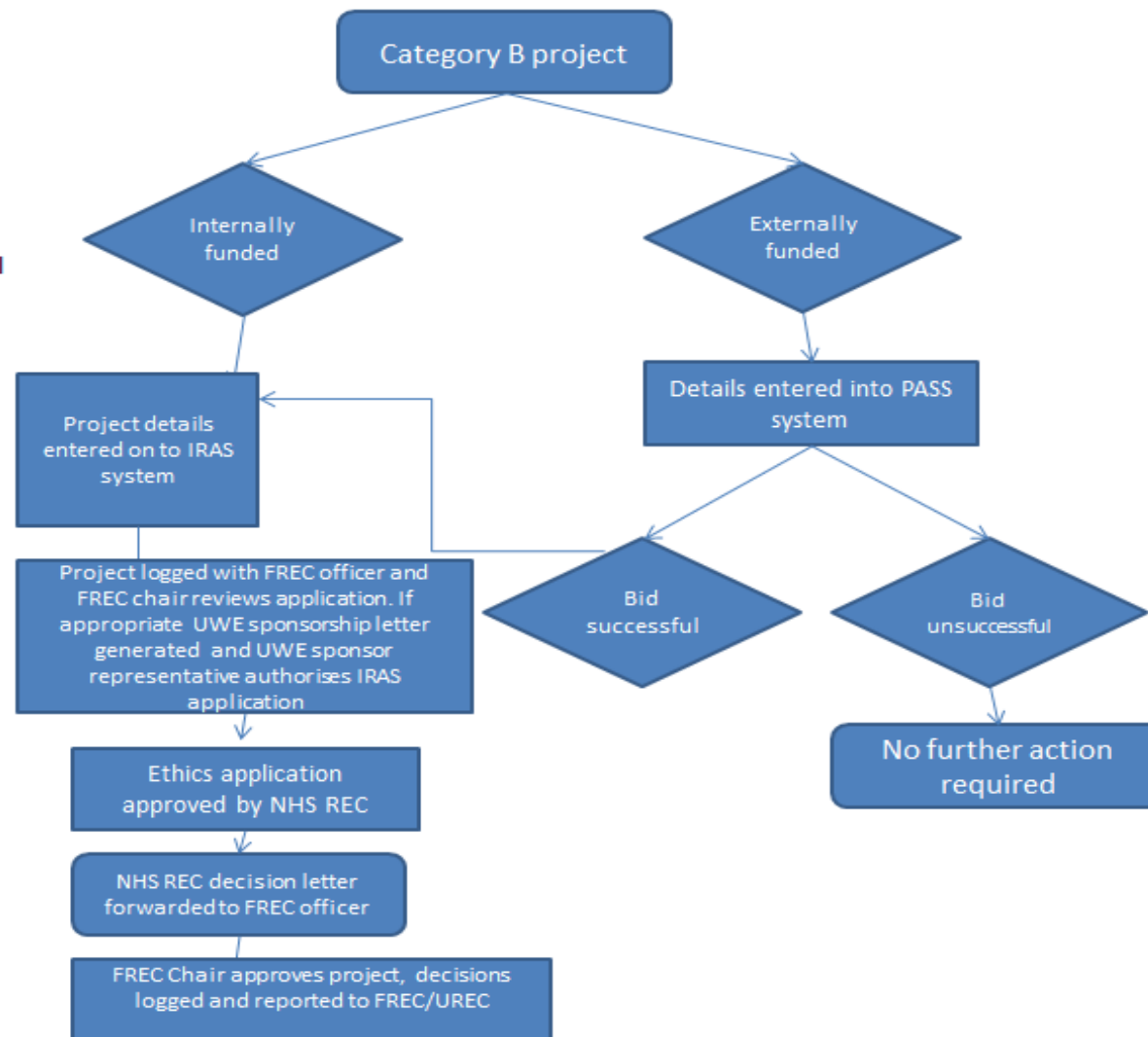
Category A project

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 2004

