

UNIVERSITY OF WOLVERHAMPTON INSTITUTIONAL SPONSORSHIP PROCESS - HEALTH AND SOCIAL CARE RESEARCH

To be read in conjunction with Institutional Sponsorship Policy - Health and Social Care Research

Background

HRA approval applies to all project-based research taking place in the NHS in England and Wales.

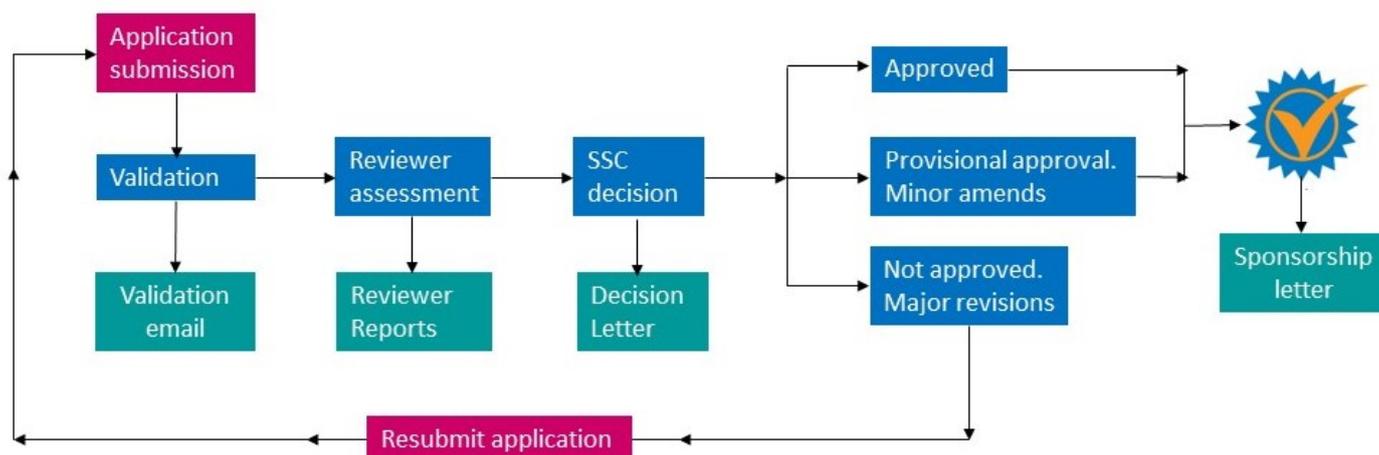
HRA approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC) so that you only need to submit one application. The application is submitted via the Integrated Research Application System (IRAS).

For more information regarding the HRA approval process visit: <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/>

Before applying for HRA approval, the research must receive from the University:

- Ethical approval, and
- Sponsorship approval

Applying for Institutional Sponsorship



Validation & Review

Once an application for sponsorship has been submitted to researchsponsorship@wlv.ac.uk, the Research Policy Unit will acknowledge receipt by email and validate the application within 5 working days. This involves ensuring that the document set contains the correct forms prior to issuing it to Sponsorship Sub-committee (SSC) members for review.

Once allocated to the reviewers, in 95% of cases initial feedback will be communicated to the applicant within 15 working days. If review times are expected to be longer, the applicant will be informed.

Following review a decision letter will be sent to the applicant. The reviewers may require that an applicant make amendments to the IRAS form if these are needed, and/or suggest changes for advisory purposes prior to further review, before approval is granted.

The full SSC will meet on an ad hoc basis at least once per annum to review ongoing sponsored projects and receive reports on progress.

Approved Sponsorship

Once an application for institutional sponsorship has been approved by the SSC, the committee will appoint a named sponsor from an approved list. A sponsorship letter will be issued to the applicant which will form part of the study document pack. The letter will include an application number (internal ID) and a sponsor's protocol number, and the relevant insurance certificate will be appended.

The sponsor allocated to the project will usually be from the subject area that the research is based in, but may be from another subject area involved in health & social care research.

The sponsor will be the signatory to the IRAS form and will discharge all the sponsor responsibilities on behalf of SSC.

All sponsors will be required to:

- undertake training on:
 - their responsibilities as a sponsor
 - Approving IRAS forms
- Sit on at least one NHS REC as a volunteer to gain understanding of the decision making processes

Good Conduct during the study

In addition to meeting the University of Wolverhampton conditions of sponsorship, researchers must meet the requirements of their ethical approval, and comply with the University Ethics Policy and Code of Good Research Practice.

Once REC/HRA approval has been granted, researchers must send the final submitted documentation set, favourable ethical opinion letter from the Research Ethics Committee (REC) and the HRA approval letter to the named sponsor, and the SSC at researchsponsorship@wlv.ac.uk.

Submitting Amendments to the study

Amendments are defined as any changes to the protocol, supporting documents or any other information that has received approval. Amendments can be substantial or non-substantial depending on the proposed changes.

Amendments must not be submitted without prior authorisation from the sponsor.

HRA approval for amendments is automatically sent to the named sponsor, and the researcher should forward a copy to researchsponsorship@wlv.ac.uk

The [HRA Amending an approval guidance](#) provides more information.

Providing regular updates on the study

Depending on what approval has been received, researchers will be asked to complete a progress report to keep the HRA up to date with how the research is progressing.

The researcher will ensure that, where required, progress reports are submitted and that a copy is sent to the named sponsor.

The [HRA guidance on progress reports](#) provides more information.

Ending the project

Where a project has HRA Approval and has been reviewed by an NHS REC, you need only inform the REC when your study has ended.

Where a project has HRA Approval and was not reviewed by an NHS REC, you will need to tell HRA when the project has ended. You should send this notification by email to approvals@hra.nhs.uk if it is England-led or HCRW.approvals@wales.nhs.uk if Wales-led. The email should include your IRAS ID and contact information (i.e. your phone number and email address).

The named sponsor should be informed and the SSC should also receive notification by email to researchsponsorship@wlv.ac.uk

The [HRA End of Study guidance](#) provides more information.

After the project

Study documents and data should be archived. This should include the data collected and any tools or documents needed to reproduce the study results from those data. It should be possible for someone looking at the archived material to reconstruct the study in detail and validate the results.

Researchers should ensure that these are secured for 10 years (or 25 years for regulated trials such as CTIMPs or studies using Human Tissue for Human Application).

Staff Leavers

Staff members with University of Wolverhampton sponsorship for a study that is current, who are planning on leaving the University, must notify the name sponsor, and the SSC by emailing researchsponsorship@wlv.ac.uk at least 3 months before leaving so that appropriate arrangements are made regarding your study and associated sponsorship.