Guidance when Applying for Sponsorship at Edge Hill University

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Edge Hill University

Guidance when Applying for Sponsorship at Edge Hill University (EHU)

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Introduction

This guidance document is to be used by researchers at EHU when they intend to apply to EHU to act as Sponsor for a research study designed by them. The UK Policy Framework for Health and Social Care Research defines a Sponsor as "the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project." Therefore, the Sponsor of the research is not necessarily an organisation who is providing any funding for the study. EHU is registered as a research Sponsor with the Department of Health and routinely takes responsibility as Sponsor for research activities within the NHS. The Research Office (RO); namely Katelyn Williams (Research Contracts & Governance Manager) or Nikki Craske (Director of RO) will complete the authorisation procedure for sponsorship.

Guidance

1. Does the study require sponsorship? When and how should you apply?

If the research is carried out within the NHS or within a social care setting it will require a research Sponsor (which may not always necessarily be EHU; an NHS Trust can Sponsor a study). The researcher should apply for sponsorship after they have received their internal ethical approval from the relevant SREC. The RO will require sight of the letter of approval which provides evidence that there has been a rigorous review of the research study and a risk assessment. Sponsorship is also usually applied for once funding (if applicable) has been confirmed for the study.

Sponsorship is applied for through the Integrated Research Application System (IRAS) as part of the application for the study to receive HRA and Research Ethics Committee (REC) Approval). This brings together the assessment of governance and legal compliance with the independent ethical opinion by a REC, so only one application should be submitted.

Please send your requests for EHU to act as Sponsor firstly in draft form via email to Katelyn Williams at Williaka@edgehill.ac.uk. Once reviewed and approved the application should then be submitted through IRAS for formal approval.

2. How is an application for sponsorship reviewed?

The RO will consider the following;

- Has internal ethical approval been obtained from the relevant SREC?
- Financial arrangements for the study
- The researcher's experience
- Has there been early communication with the trust?
- Is there relevant insurance in place?
- Is there a clear delegation of responsibilities?
- Are processes in place for the sponsor to be alerted to significant developments/milestones?

- Patient and public involvement (PPI) – where members of the public are actively involved in the study. PPI is expected for many funding streams and can have clear benefits for the study such as additional expertise and improving patient experience.
- What is the timeline and what are the expectations of the study according to the milestones?
- Is Human Tissue involved?
- Are there suitable plans for dissemination of findings?

3. What else should be done before applying for sponsorship?

3.1 Consider whether co-sponsorship is suitable:

- Where two or more organisations share a significant interest in a study e.g. one as an employer of the Co-Investigator and another as the principal host institution, they may elect to act as co-sponsors.
- Co-sponsors agree an allocation of defined sponsor responsibilities. They divide amongst themselves both the responsibilities and the liabilities associated with sponsorship. The allocation of sponsor responsibilities will be determined by the expertise and capacity of the individual or institution to discharge them in relation to the risk posed by the study.

3.2 Initiate discussions with the participating NHS sites:

- Before finalising the IRAS form, the researcher should initiate preliminary discussions with potential NHS organisations in order to understand if those organisations have the potential to participate. To start this discussion, the researcher should send the protocol to the potential participating NHS organisation.
- If they confirm that they may be able to participate in the study, this should be identified on the IRAS Form.

4. What is HRA Approval?

This is the process which brings together the assessment of governance and legal compliance, undertaken by HRA staff, with the independent REC opinion provided through the UK research ethics service.

Please note that HRA Approval only applies to the NHS in England. If the study has sites in Northern Ireland, Scotland or Wales then the researcher will not apply to the HRA and should instead apply through the appropriate NHS/HSC permission process for that lead nation.

5. How should HRA Approval be obtained?

The researcher should make the application through IRAS. Detailed guidance on how to complete the form can be found on the IRAS website.

The researcher should complete the following for each site type (not each site):

- Schedule of events (this should be saved as an excel file and the filename should include the IRAS ID): This is the timeline for the study which outlines both the activities which relate to the study in general at that site type and that relate to each research participant at that site.
- Organisation Information Document (OID): This document provides key information to facilitate the regulatory review of the submission. Following its submission, it is localised and shared with the participating NHS/HSC organisation as part of the UK Local Information Pack. Furthermore, for non-commercial studies (EHU is a non-commercial Sponsor) that are not clinical trials or clinical investigations, the agreed final OID (taken together with the documents in the local information pack) forms the agreement between the participating NHS/HSC organisation and the Sponsor.
- Once the application has been submitted the researcher will receive a validation/initial assessment letter containing details of the NHS REC meeting at which the study will be reviewed; it is recommended that the researcher attends this meeting. The RO should be kept updated with all communications which take place between the researcher and the NHS REC.
- At the same time the HRA will undertake an initial assessment of the study to ensure the application is valid. The outcome of this initial assessment will be communicated to the researcher and the NHS REC.
- Once both the HRA Assessment and the NHS REC review are completed, the researcher will receive notification of the outcome from the HRA in the form of a letter and guidance on what should happen next.
- The researcher should keep both the Sponsor and the NHS organisation updated with the progress of the HRA process and once the HRA Approval letter has been provided it should be forwarded to all the relevant parties including the RO.

6. What can be done whilst the HRA approval process is happening?

At the same time as submission to the HRA, the researcher should submit the local information package to the NHS organisation. The RO should be copied into the correspondence when this is done. For Non-Commercial Studies, this package should include the following:

- Covering email using standard template format (see IRAS Help)
- IRAS Form
- Protocol
- Patient info sheets and consent forms
- OID
- Delegation log
- Schedule of events
- HRA initial assessment letter/HRA Approval letter (once received)
- Any other documents the researcher wishes to provide to the site to support the set up and delivery of the study

6.1 Contracts

Where there is no transfer of funds between EHU and the NHS site, the researcher should check with the RO whether the OID can be used as the contract between EHU and the NHS Trust or whether an alternative document is required. Where the OID is used, this is finalised and dated when the host NHS Trust confirms capacity and capability.

If there is a transfer of funds, usually when there is an external funder for the research study, or there is a general need to put in place some sort of contract which has not been put in place already, the researcher should contact the RO of this in advance of the HRA Approval process taking place.

7. What happens after HRA Approval has been obtained?

The HRA Approval letter should guide the researcher as to the next steps to take. It will ask the researcher to re-confirm capacity and capability from the participating NHS organisations in England.

7.1 Sponsor Green Light

This is the process in which the RO will review the study to decide whether it is ready to commence. The RO will check that the following conditions have been fulfilled:

- HRA Approval has been obtained;
- Re-confirmation of capacity and capability has been received from the relevant trust;
- The researcher has complied with the applicable regulations and the University's Code of Practice for Research.

The RO can then issue "Sponsor Green Light" confirmation via email allowing the study to commence. The study should not be started before this confirmation has been issued.

8. Registration of the Study

It is good practice for all studies to be registered in a publicly accessible database, and in certain cases, particularly involving clinical trials, it is a condition of the REC's favourable ethical opinion to do so. The HRA publishes research summaries for all studies that receive a final opinion from the REC.

Reference to the IRAS ID number should be made in any publications and reports to allow tracking of transparency commitments made to the funder and REC/HRA.

9. Monitoring of the Study

Monitoring of the study takes place via annual review by the relevant SREC. For students, there are a series of progress forms to be filled out during meetings with their supervisory team. The University's online ethics monitoring system, Haplo, makes the process more transparent and the RO has access to this information. It is vital, therefore, that project details and amendments are properly recorded in Haplo.

Monitoring by the RO will usually be done remotely i.e. regular communication from the researcher is expected regarding how the study is progressing in terms of recruitment, any operational issues such as staff changes, key document amendments, funds running out and deviations.

The RO will also need to be aware of any issues that could lead to possible amendments being made to the study (please see below).

An annual progress report should be submitted to the NHS REC and HRA, 12 months after the date on which the NHS REC favourable opinion and or HRA Approval was given.

Please note that an internal audit of the study by the RO may well take place.

10. Amendments

All amendments should be made through the IRAS system by completing the "Amendment Tool". Please see IRAS for help on how to complete this.

Researchers should send a copy of the Amendment Tool to the RO to approve before sending it through the IRAS system. Researchers should then ensure the Amendment Tool is uploaded onto the amendment workflow in the Haplo system so that there is a full record in Haplo of any Amendments that have been made to the study.

11. End of Study

The end of the study should be defined in relation to the collection of all data required to answer the research questions. Final analysis of data and report writing is normally considered to occur after formal declaration of the end of the research.

Where a study has HRA Approval and has been reviewed by the REC the researcher only needs to inform the REC when the study has ended. Where a study has HRA Approval and was not reviewed by an NHS REC, the researcher will need to tell the HRA when the study has ended. The researcher should send this notification via email to hra.approval@nhs.net including the IRAS ID and the researcher's contact information.

The researcher should notify the NHS REC in writing of the conclusion (or early termination) of the study using the appropriate form. The form should be sent within 90 days of the end of the study. The researcher is also required to send a summary of the final research report to the NHS REC within 12 months of the end of the study. This information should also be sent to the RO.

It is expected that all commitments made to the participants as described in the IRAS application, the protocol and the patient information leaflet will be fulfilled. This may include providing information about the outcome of a study.

11.1 When the lead researcher leaves EHU

If the lead researcher (i.e. the Principal Investigator) is leaving EHU whilst the study is ongoing, they should notify the RO that they are leaving and confirm whether they will continue to act as PI on the Study whilst working at another institution. If so, the Sponsor will need to be amended.

12. Checklist

- Internal ethical approval from SREC
- Application for sponsorship and HRA Approval via IRAS
- HRA Approval
- Sponsor green light confirmation
- Keep Sponsor updated with the study in accordance with the monitoring plan
- Comply with the end of study obligations

13. FAQ's

13.1 Does the study have insurance cover?

EHU should be able to provide the study with the relevant insurance cover. However, please discuss the specific study with Susan O'Neill (EHU Insurance Officer). Susan will be able to provide the relevant insurance and indemnity confirmation letter for the application.

13.2 When will the study require NHS ethical approval and HRA Approval?

If it involves NHS patients, clients/carers or staff.

13.3 Should the study be adopted onto the NIHR CRN Portfolio?

The researcher should firstly check whether the study is eligible to be adopted onto the Portfolio by consulting the NIHR website. If it is, the researcher should seek to engage with the local CRN office and apply for the study to be adopted onto the portfolio as soon as possible. If doing so, the researcher should answer yes to question 5b on the IRAS form and submit an application to the NIHR CRN through IRAS.

The CRN can do the following:

- Help to identify recruitment of NHS patients into studies
- Ensure the researcher has access to experienced frontline staff
- Provide support by linking the researcher to regional and national leads within the speciality areas
- Secure placements to help where there are capacity issues

If the researcher has any queries, they should contact the local study support team at cmnwcoast@nhs.ac.uk

13.4 Who should request sponsorship?

It is the responsibility of the lead researcher of the study to request sponsorship. However, it is recognised that this responsibility may be delegated to another member of the research team with sufficient knowledge of the research activity.

Endmatter

Title	Guidance on applying for sponsorship at EHU
Policy Owner	Research Office
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