Edge Hill University

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

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2. Introduction

- This guidance is to be used by researchers when they intend to apply to EHU to act as a sponsor for a research study designed by them. It also contains some guidance to consider when a researcher is applying for Health Research Authority (HRA) Approval.
- 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 the organisation who is providing the funding.
- 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) will complete the authorisation procedure for sponsorship. Please send your requests for

authorisation through IRAS to Katelyn Williams (Research Governance and Contracts Manager) in the first instance – Williaka@edgehill.ac.uk

3. Does the study require sponsorship? When and how do I 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; for example, an NHS Trust can sponsor a study).
- The researcher should apply for sponsorship at EHU after they have received their internal ethical approval from their relevant FREC (faculty research ethics committee). The RO will require sight of the letter of approval which provides evidence that there has been a rigorous review of the research project and a risk assessment.
- Once the researcher has made their application through IRAS for EHU to act as a sponsor to their study, the researcher will receive authorisation from the RO to book their study for NHS Ethical approval/HRA Approval via the IRAS system. This authorisation is the "in principle" agreement for EHU to sponsor the study. This means it is subject to the research receiving all relevant regulatory permissions including NHS Trust Ethical and HRA Approval.
- The researcher should then move on to complete the IRAS application to obtain the HRA approval before starting the research.

4. How is my application for sponsorship reviewed by the RO?

- The RO will consider the following:
  - Has internal ethical approval been obtained?
  - Have all questions on the sponsorship request form been completed satisfactorily?
  - Whether the study fits the research strategy
  - Financial arrangements for the project
  - What is 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?
  - Has there been an independent peer review i.e. has it been through the relevant internal FREC?
  - Patient and public involvement (PPI) – this should be the aim of the study and the university output should be a bonus
  - What is the timeline and what are the expectations of the study according to the milestones?
  - Is Human Tissue involved? Is a Material Transfer Agreement (MTA) required?
  - Are there suitable plans for dissemination of findings?

5. What else should I do before I submit the study through IRAS?

- Consider whether co-sponsorship is suitable:

- Where two or more organisations share a significant interest in a study e.g. one as employer of the CI 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 posted by the study. (This is often used in Clinical Trials of an Investigational Medicinal Product – CTIMP).

- 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 Part C of the IRAS Form.

5.1 What is HRA Approval?

- This is the process for the NHS in England that 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.

5.2 How do I obtain HRA Approval?

- The researcher should make the application through IRAS. Detailed guidance on how to complete the form can be found on the official HRA website. The IRAS website also contains a useful e-learning module about how to complete an application.
- 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 organisations as part of the UK Local Information Pack. Furthermore, for non-commercial studies 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 confirmed by the participating NHS/HSC organisation.
  - Once your application has been submitted you 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 your study to ensure that your 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 complete 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 relevant parties including the RO.

5.3 What should I do while the HRA Approval process is happening?

- At the same time as submission to the HRA, the researcher should submit the local application 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 (IRAS Help)
  - IRAS Form
  - Protocol
  - Patient information sheet and consent form
  - OID
  - Delegation log
  - Schedule of Events
  - Model non-Commercial Agreement (McCA) (if being used as the agreement – only for non-commercial clinical trials)
  - Relevant supporting documents. These will include some of the documents that have been submitted/approved with the IRAS Form submission and other documents to support study set up at the participating NHS/HSC organisations.
  - HRA and HCRW initial Assessment Letter/Approval Letter
- 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 mNCA is required. Where the OID is used, this is finalised and dated when the host NHS site confirms capacity and capability.
  - If there is a transfer of funds and if the researcher has an external funder for the research project or there is a need to put in place sub contracts or an agreement with other parties for some of the research activities, the researcher should notify the RO of this so that the relevant contracts can be put in place.

5.4 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 participating NHS organisations in England.

- As stated above, the researcher should provide the RO with the HRA Approval letter. The RO can then issue "Sponsor Green Light" confirmation allowing the study to commence at the site. Please do not start the study before this letter has been issued.

5.5 What is the sponsor green light process?

- This is the process in which the RO will review the study to decide whether it is ready to commence. We 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 all applicable regulations and the University's Code of Practice for Research.

5.6 Do I need to register my project?

- 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.

5.7 Monitoring of the study

- Sponsors should ensure that arrangements are in place to review significant developments as the research proceeds, particularly those that put the safety of individuals at risk, and to approve modifications to the study design.
- Monitoring of the study where the lead researcher is a member of staff takes place via annual review by the relevant FREC. For students, there are a series of progress forms to be filled out during meetings with their supervisory team. The University are in the process of introducing a new ethics system which will make the process more transparent and means the RO will have access to this information. In the meantime, the RO would be grateful if the researcher could keep us updated with how the study is progressing as and when they feel it is necessary to do so.
- 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, deviations etc.
- 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 by the RO of the study may well be required.

5.8 What do I do if I need to amend the study after I have received HRA Approval?

- There are two types of amendments – substantial and non-substantial. Please first check the HRA website for definitions of these terms in order to decide what the amendment would be classed as. If the researcher is still unsure, please consult with the RO.
- The researcher should also send the RO details of any amendments that are being made before submitting the same through IRAS for approval, to ensure that sponsorship can continue in light of the amendment. Please direct the RO to where in the document changes have been made so they can be reviewed easily. The researcher is expected to notify the RO of both substantial and non-substantial amendments.
- Substantial amendments:
  - Generally, these relate to the actual conduct of the research and are likely to have a significant impact on: the safety or physical or mental integrity of the subjects, the scientific value of the study, the quality or safety of the study and the conduct or management of the study.
  - These will require favourable opinion from the REC and HRA Approval.
  - Notice of substantial amendment forms are created in IRAS and should be completed and authorised using electronic authorisation in IRAS. The researcher should submit a single copy of the form to the REC, together with all relevant enclosures.
- Non-substantial amendments:
  - These tend not to have significant implications on the study like as described above.
  - They should be notified by using the template form on the HRA website which should also be submitted to the RO.
- What happens internally at EHU:
  - Non-substantial amendments are reviewed by the chair of the relevant FREC. Substantial amendments return to the FREC for review.
  - RO acting as sponsor will complete the amendment sponsor green light process once all queries and revisions have been satisfied. The sponsor will notify the researcher that authorisation is given and to proceed with the study/application to the relevant regulatory authorities.
  - Once the researcher has received confirmation from the HRA assessment team they should send the amendment and categorisation information to participating NHS organisations.
  - The researcher must then implement the amendment to all participating NHS organisations within 35 calendar days from the day on which the researcher provides the organisation with the categorisation email and amended documents.

5.9 End of study

- The end of the research should be defined in relation to the collection of all data required to answer the research questions. Final analysis of the data and report writing is normally considered to occur after formal declaration of the end of the research.
- Where a project has HRA Approval and has been reviewed by REC the researcher only needs to inform the REC when the study has ended. Where a project has HRA Approval and was not

reviewed by an NHS REC, the researcher will need to tell HRA when the project has ended. The researcher should send this notification by 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.

5.10 Checklist

1. Internal ethical approval
2. Application for EHU to act as sponsor through IRAS (subject to HRA Approval being obtained)
3. Application for HRA Approval via IRAS
4. HRA Approval
5. Sponsor "green light" confirmation
6. Keep sponsor updated with the study in accordance with the monitoring plan
7. Comply with the end of study obligations

5.11 FAQs

1. When can I start the study?

- The researcher should not start the recruitment of research participants until all approvals are in place and the RO has issued the "green light" confirmation.

2. Does the study have insurance cover?
    - Please see guidance on the Insurance wiki written by Susan O' Neill (EHU Insurance Officer) on this topic. There are also some suggested answers to the IRAS Questions which deal with this particular topic.
3. When will the study require NHS ethical approval and HRA approval?
    - If it involves NHS patients, clients/carers or staff.
4. Should the study be adopted onto the NIHR CRN Portfolio?
    - Please 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. The researcher should do this by answering yes to question 5b on the IRAS Project filter and complete a submit a portfolio application form in IRAS to the NIHR CRN. A decision will be made by the NIHR CRN.
    - The CRN can do the following:
    - Help 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 can contact the local study support team at cmnwcoast@nhs.ac.uk

5. 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 if required.
- If the research is being conducted as part of an academic qualification below doctoral level the responsible supervisor should request sponsorship on behalf of the individual undertaking the qualification.