Research Sponsorship Policy

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State whether this document is applicable to the University's collaborative partners

Related documents:	Click to list any documents which have been referenced within this document, or should be considered in conjunction with this document.
University document:	Yes

A University document applies across the institution, is approved by a committee of Council or Senate and is held in the University Policy Directory on SharePoint.

Published location:	This is an internal policy and should be available on the staff intranet only

· The University has adopted the principles of Designing for Diverse Learners, and all policy documents should be written with reference to these principles. Further information is available at the Designing for diverse learners website.

· An Equality Impact Assessment (EIA) must be considered for all new and amended policies. Further information is available from the EIA section of SharePoint.

· This document is available in alternative formats from **policy@hull.ac.uk**.

· All printed or downloaded versions of this document are classified as uncontrolled

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Contents

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1. Introduction

1.1 All research requires a sponsor to take on legal responsibility for the study. The sponsor may be an individual, organisation or partnership and must be in a position to ensure that the design and implementation of the study meet required standards and provide assurance, as appropriate.

1.2 The University of Hull automatically acts as sponsor for most research undertaken by its staff and students when they are working under the auspices of the University. Sponsorship is a requirement for all clinical (health) and social care research under the UK Policy Framework for Health and Social Care Research (2017); and, for research involving NHS/HSC facilities, staff or service users, formal arrangements are in place for the University to consider sponsorship and provide written approval of sponsorship arrangements.

A   Scope

1.3 This policy applies to University of Hull staff and students requesting confirmation of formal sponsor approval either via IRAS (Integrated Research Application System), or as a decision in principle in support of a funding application.

1.4 IRAS supports applications to the HRA (Health Research Authority) and NHS/HSC REC (Research Ethics Committee) for the sponsorship of health and social care research involving NHS patients or facilities or local authority social care staff, carers or service users. IRAS also covers research involving Her Majesty's Prison and Probation Service (HMPPS) and the Confidentiality Advisory Group (CAG).

1.5 The University does not sponsor CTIMPS or investigations of a medical device.

2. Definitions

2.1 *Clinical trial* – a study in which participants are assigned to receive one or more interventions (or no interventions) so that researchers can evaluate the effects of the intervention on biomedical or health related outcomes. Randomised controlled trials or studies that are non-CTIMPs may also be interventional studies.

2.2 *Non-interventional study* - a study that does not involve a clinical intervention – i.e. not a clinical trial.

2.3 *Medicinal product* - any substance or combination of substances presented as having properties for treating or preventing disease in human beings.

2.4 *Medical device* - any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, which is intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process, or control of conception.

3. Study types

3.1 The [project filter](#) within the online IRAS guidance provides detailed definitions and examples of study types. Researchers should familiarise themselves with all guidance on IRAS before completing their submission.

3.2   *Clinical trial of an investigational medicinal product (CTIMP)* - a clinical trial that tests, or uses as a reference, a pharmaceutical form of an active ingredient or placebo. This can include a product with a marketing authorisation when used or assembled in a way different from the approved form, or for an unapproved indication, or to gain further information about an approved use. **The University does not sponsor CTIMPS.**

3.3   *Clinical investigation or other study of a medical device* - any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device. **The University does not currently sponsor studies involving a medical device**.

3.4   *Combined trial of an investigational medicinal product and an investigational medical device* – a combination of the above two definitions. **The University does not sponsor combined trials of an investigational medicinal product and an investigational medical device**.

3.5   *Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice* – A clinical trial, as defined above, which does not incorporate medicinal products or devices. Or where a medical device will be used in accordance with the manufacturer's intended use. This option should be selected for clinical research not involving investigational medicinal products or medical devices.

3.6   *Basic science study involving procedures with human participants* – studies which may involve patients or healthy volunteers as participants, but the study does not affect any clinical care that the participant may be receiving. It is appropriate for scientific investigations involving procedures with participants that are additional to any clinical care but not studying a novel clinical intervention or involving randomisation between treatment groups or any other change in existing clinical care.

3.7   *Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology* – studies which do not involve clinical interventions or procedures but do involve administering a questionnaire, or conducting interviews or focus groups with participants; and will use quantitative analysis, or a mix of quantitative and qualitative analysis methods.

3.8   *Study involving qualitative methods only* - studies which do not involve clinical interventions, procedures, or the use of human tissue samples or other human biological materials; which will use only quantitative analysis methods.

3.9   *Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)* – studies which are based entirely on the analysis data and/or use of human tissue samples or other human biological material. It must involve no change to the normal clinical care or treatment of participants. There will be no participant contact or observation other than to collect samples and seek informed consent where appropriate.

3.10   *Study limited to working with data (specific project only)* – studies based entirely on the use of data from patients, service users or other data subjects. It must involve no change to the normal clinical care or treatment of participants. There will be no participant contact or observation other than to seek informed consent, where appropriate. This category applies to research involving data relating to the deceased, as well as to living data subjects.

3.11   *Research tissue bank* - Organisations responsible for the management of research tissue banks (RTB) anywhere in the UK may apply for ethical review of their arrangements for collection, storage, use and distribution of tissue. A research tissue bank is a "collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending" (Research Ethics Service Standard Operating Procedures). **If your research is a specific**

research project involving human tissue you should select another option on the Project Filter.

3.12 *Research database* - Organisations responsible for the management of research databases anywhere in the UK may apply for ethical review of their arrangements for collection, storage and use of data, including arrangements of release of data to researchers. A research database is defined as a "collection of data, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending" (IRAS).

4. Principles of University sponsorship

4.1 The [UK Policy Framework for Health and Social Care Research](#) (2017) states that "The sponsor is 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".

4.2 The University of Hull will consider acting as the sponsor for projects that have no obvious sponsor elsewhere, provided they are undertaken by University of Hull employed staff or registered PGR students.

4.3 In most circumstances, the CI must be an employee of the University; the UK Policy Framework for Health and Social Care Research sets out a limited exception in which a student undertaking a post-doctoral programme may fulfil this role.

4.4 The University will not sponsor any Clinical Trials involving an Investigational Medicinal Product (CTIMP)

4.5 The University does not currently sponsor studies involving medical devices

5. Determining who should act as sponsor

5.1 The University usually assumes sponsorship when a University employee / post graduate student has designed the study and/or is acting as the chief investigator.

5.2 The sponsor is not necessarily the funder and many funding bodies are unable to provide sponsorship.

5.3 If the University is not the substantive employer of the CI then the University will not sponsor the study, unless the criteria in para. 5.4 is met.

5.4 As a general rule, the University will not formally sponsor an application for research where the student is the CI. However, the University may consider acting as sponsor for a study where the CI is a University PhD student provided the exceptions detailed within the [UK Policy Framework for Health and Social Care Research](#) have been met. This decision will be taken by Research Governance, following recommendation from the student's supervisor.

6. Co-sponsorship

6.1 At present, the University does not co-sponsor studies. In the event that a researcher, the University, or an external body feels co-sponsorship is the most appropriate route then the researcher should discuss this with the Head of Research Excellence, Governance and Impact at their earliest convenience.

6.2 Final decisions on whether to enter into a co-sponsorship arrangement will be taken by the Pro Vice-Chancellor (Research and Enterprise).

7. Collaboration with other organisations

7.1 In most cases, sponsored research will require collaboration will external research sites, either within or outside the NHS. The CI will be ultimately responsible for providing assurance regarding the conduct of the study, as detailed within the UK Policy Framework for Health and Social Care Research. However, in many cases (as detailed by the HRA) the CI should also ensure that a Local Collaborator or a Principle Investigator (PI) is appointed at each site (which may also be the CI, if appropriate). The PI should manage the day to day operational aspects of the study within that site and must report into the CI on any matters affecting the study as detailed within the framework.

7.2 Researchers must not commence their study or recruit patients from a site until the site has confirmed capacity and capability to support the study (for NHS sites) or site management approval has been issued (other sites) in accordance with section 10.F, below.

8. Trials units

8.1 Researchers may approach a trials unit (either within the University or externally) to request support for their proposed study. Trials units offer support for study set up and management in exchange for a fee (which is usually factored into the grant application). Various trials units have their own specialisms and UoH researchers are welcome to approach a trials unit with their proposed study design to investigate what support may be available.

A Hull Health Trials Unit (HHTU)

8.2 The University of Hull Health Trials Unit (HHTU) is hosted by the Institute for Clinical and Applied Health Research (ICAHR), which is an interdisciplinary, cross-faculty University of Hull Institute.

8.3 HTTU is a resource for University staff wishing to undertake clinical research. The trials unit will assess each request for collaboration based on strategic fit and current capacity within HHTU. If the unit decides to support a study, staff in HTTU will work with the CI to provide a range of practical and specialist support throughout the clinical research process, including:

- Study design and funding applications
- Study management including regulatory approvals
- Data management with secure online eCRF and randomisation
- Data Safe Haven for storage and processing of sensitive health data
- Statistical analysis and reporting

8.4 There are costs associated with HTTU collaboration which would be factored into the study costs. These include staff costs such as trial and data managers, data management systems, randomisation, monitoring, trial oversight, and quality assurance. The trials unit supports researchers in determining the overall costs of the study.

9. Roles and responsibilities

9.1 The UK Policy Framework for Health and Social Care Research details all responsibilities relating to research sponsorship and should be reviewed by researchers (particularly CIs) prior to submitting an application. In summary, however, there are a number of key responsibilities:

A Sponsor

9.2 The sponsor takes on the legal responsibility for the research, including the initiation and management of the study.

9.3 The sponsor should also provide insurance and indemnity arrangements for the study.

9.4   The official contact on behalf of the sponsor is the Pro Vice-Chancellor (Research and Enterprise). The PVC (R&E) delegates responsibility to the Head of Research Excellence, Governance and Impact to ensure research sponsorship applications are appropriately reviewed and recommendations are made regarding the suitability of sponsorship applications / amendments. The PVC (R&E) remains the ultimate signatory on IRAS. The Head of Research Excellence, Governance and Impact is supported by a Research Governance Officer who administers a number of research sponsorship administrative, review and oversight functions. The Research Governance Officer has delegated responsibility to fulfil the role of the Head of Research Excellence, Governance and Impact in relation to research sponsorship approval and management, as required.

9.5   In the event of long term absence of the PVC (Research and Enterprise), any functions fulfilled by the PVC (Research and Enterprise) may be delegated to a person who will be suitably qualified by status within the University (another PVC or the Director of Research and Innovation) and will not have any conflict on interest in relation to the decision or function they are required to complete.

B   Chief Investigator (CI)

9.6   The CI should be an employee of the University. Where the CI leaves the University before completion of the study, this role must be transferred to another appropriate member of staff at the University in accordance with section 20, below.

9.7   The CI is responsible for the overall conduct of a research project.

9.8   For most research conducted as part of a programme of study, the student should not act as CI. The CI may be the student's supervisor or another appropriate University employee.

9.9   In some exceptional circumstances such as those detailed within the UK Policy Framework for Health and Social Care Research, the University may consider acting as sponsor for PhD students on a particular programme of study. In such cases, the student in question should outline which exception detailed within the UK Policy Framework applied to their study within the sponsorship application form.

C   Research Teams

9.10   The research team is the group of people involved in the conduct of a research project. Not all members of the team need to be employed by the University. The team may include care professionals, academics, patients and service users, members of the public, research professionals, students and/or scientists.

9.11   Research team members' accountability and responsibilities should be clearly defined and documented, particularly where research spans multiple sites or involves collaboration with other bodies.

9.12   Ultimately, research teams are responsible for conducting research in accordance with the agreed protocol and the requirements set out by the CI and the sponsor.

10.   Decisions in principle

10.1   Where the researcher is required to provide confirmation of sponsorship to an external body, usually due to external funder requirements, Research Governance will provide this in the form of a decision in principle.

10.2   The approval issued will be on the basis that the study will be subject to further internal and external scrutiny and final subsequent approval, once funding has been awarded.

10.3   In order to obtain a decision in principle, the researcher should contact research governance and include all relevant information relating to the request as detailed on Research

Sponsorship – Decisions in Principal SharePoint.

10.4   Most bodies will accept confirmation of a decision in principle to sponsor a study via email. The researcher should indicate if a formal letter is required, or if the decision will need to be made via an external platform / account.

10.5   The decision in principle to sponsor a study may be approved by Research Governance on the condition that a formal sponsor application will be submitted for review in due course, as appropriate.

A   SoECATs (Schedule of Events Cost Attribution Templates)

10.6   Researchers may also request confirmation of sponsor approval of a SoECAT to fulfil funder requirements at an application phase; or request approval of an amended SoECAT for an ongoing study in advance of submission of a formal request to the HRA (or other appropriate external body) to amend the study. In such cases, researchers should email research governance, providing the information detailed on SharePoint.

10.7   The SoECAT may be approved by Research Governance on the condition that a formal amendment request will be submitted for review in due, course.

11.   Applications for sponsorship

11.1   The University must actively consent in writing if it is to act as sponsor. As such researchers must follow the process and submission guidance detailed within the Research Sponsorship SharePoint prior to submitting an application through IRAS.

11.2   In order to apply for sponsorship from the University, researchers must submit all relevant documentation and the University of Hull Research Sponsorship Application Form to researchgovernance@hull.ac.uk

A   Health Research Authority (HRA)

11.3   Researchers should apply for HRA approval if:

- the lead NHS R&D Office is in England or Wales;
- it is a project-based study type (all studies listed within IRAS question 2 categories except "research tissue banks" and "research databases"); AND
- NHS premises and/or NHS patients and/or NHS staff in England and/or Wales are participating in the project.

11.4   Applications to the HRA should be submitted via IRAS in accordance with the information specified on https://www.myresearchproject.org.uk/help/hlphraapproval.aspx.

B   Research Ethics Committee (REC)

11.5   Research Ethics Committees (RECs) review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical.

11.6   Requirement for ethical review of research may be under:

- legislation applying to the UK as a whole or particular countries of the UK; or
- policy of the UK Health Departments, where research relates to the services for which they are responsible.

11.7   Some types of research require NHS REC review by law whether or not they take place within the NHS or involve NHS patients or other service users. The HRA's decision tool should be used to assist researchers in deciding whether their project needs NHS REC review.

11.8   Applications to the REC should be submitted via IRAS in accordance with the information

specified on https://www.myresearchproject.org.uk/help/hlpethicalreview.aspx.

C   Confidentiality Advisory Group (CAG)

11.9   The Health Research Authority's Confidentiality Advisory Group (CAG) provides independent expert advice to the HRA and the Secretary of State for Health on whether applications to access confidential patient or service user information without consent should or should not be approved.

11.10   Researchers should apply to the CAG if they plan to access:

- identifiable patient or service user information relating to people living in, or receiving care in, England and Wales without consent, prior to the disclosure of confidential information; or
- Human Fertilisation and Embryology Authority (HFEA) Research Register Data.

11.11   Applications to the CAG should be submitted via IRAS in accordance with the information specified on https://www.myresearchproject.org.uk/help/hlpconfidentiality.aspx.

D   Her Majesty's Prison and Probation Service (HMPPS)

11.12   Her Majesty's Prison and Probation Service (HMPPS) is responsible for running prisons and probation services across England and Wales.

11.13   Researchers should apply to HMPPS for research projects which require access across HMPPS (including headquarters) and all community-based/custodial providers in England and Wales; this includes research involving Community Rehabilitation Companies (CRCs) and their subcontractors, Contracted Prisons and Young Offenders' Institutions (YOIs) and Secure Training Centres (STCs)

11.14   Applications to HMPPS should be submitted via IRAS in accordance with the information specified on https://www.myresearchproject.org.uk/help/hlphmpps.aspx

E   Application process

11.15   Applications should be submitted to the relevant review body as detailed above within paragraphs 10.A - 10D.

11.16   Prior to external submission, internal sponsor approval is required within the University. Researchers should follow the guidance and use the forms detailed on the Research Sponsorship – Submitting a New Application SharePoint to obtain sponsor approval.

F   Capacity and capability / Site management approval

11.17   Once approval has been issued by the HRA, any research that includes NHS sites may not commence until capacity and capability has been confirmed by those sites. Capacity and capability is confirmed by submitting a Local Information Pack (LIP) in accordance with the site specific information on IRAS and the internal guidance provided on the Research Sponsorship – Post Approval Local Arrangements https://hullacuk.sharepoint.com/Services/RI/SitePages/REGI/Research%20Sponsorship/Local%20Arrangements.aspx in consultation with the CI / delegated researcher.

11.18   Where NHS organisations are acting as Participant Identification Centres (PICs) only, the CI for the project will be responsible for completing the model Non-Commercial PIC Agreement (mNC-PICA) and submitting this to research governance. The research governance team will liaise with the Lead NHS R&D contact at that site to secure arrangements prior to the researcher commencing the study there.

11.19   For Non-NHS sites which are included within a research project that requires sponsor approval via IRAS, the University has a number of template contracts which can be used to

formalise agreements with such non-NHS sites. These are available in the sponsorship SharePoint site. The researcher must liaise with the Research Governance team (researchgovernance@hull.ac.uk) to complete the contract, before providing this to the research site for signature.

11.20 Similarly to other sponsorship documents, site agreements require formal signatory on behalf of the sponsor. In this case, the delegations detailed within paragraph 9.4 apply.

11.21 Researchers must not commence their study at a site until the sponsor (via the research governance team) confirms they are satisfied that all arrangements are in place.

12. Submission of sponsor requests

12.1 Researchers must submit their application as early as possible in advance of the research start date. The application process contains a number of stages, both internally and externally, in order to ensure appropriate assurance. The process cannot generally be expedited and researchers should be mindful of timescales during the planning phase.

12.2 Applications should be submitted to the research governance following the guidance and using the templates detailed on the Research Sponsorship – Submitting a new Application SharePoint.

12.3 The CI is usually expected to submit the application for sponsorship as they are ultimately responsible for the study.

12.4 The University may accept applications submitted on behalf of the CI, provided the CI has reviewed and completed all necessary documentation and is copied into the submission.

13. Document management

A Version control

13.2 Good document management and version control are essential so that the same single version of the research documents, such as the proposal or protocol, is being followed in the same way by everyone involved.

13.3 Any amendments to research documents or process must be submitted for review via the process detailed in section 14, below and each amendment submission should be recorded as a new version of the document concerned.

B Data and information security requirements

13.4 Researchers must conduct their research in accordance with relevant legislation, notably UK GDPR and Data Protection Act 2018. In addition, all research must be conducted in accordance with all requirements set out within the University's own policies and procedures, including, the Research Data Management and Sharing Policy, Data Protection Policy; Data Retention Policy; Data Breach Policy; and File Storage Policy. These documents are available in a secure format on the University of Hull website.

13.5 Researchers must also complete a Data Management Plan in accordance with the guidance on the University's libguides page, and using the templates provided.

13.6 Further guidance and information on research specific data security requirements for University of hull sponsored research is available on Research Sponsorship – Data Management SharePoint. This page includes a link to The Medical Research Council's Good Research Practice: Section 2 - Guidelines and Standards.

14.   Insurance and indemnity

14.1   Where the University agrees to act as sponsor, it is required to ensure appropriate insurance and indemnity arrangements are in place.

14.2   In most cases, researchers may download a copy of the University's limited liability insurance certificate and submit this along with the application for sponsorship.

14.3   For certain types of research, however, including clinical trials, a more specific policy will be required. Researchers are responsible for reviewing the requirements of their study and following the guidance set out by the University's Insurance Office available on [the Insurance Services SharePoint](#).

15.   Registration of clinical research

15.1   The HRA expects all research to be registered in a publicly accessible database. For clinical trials, it is a condition of a favourable ethical opinion to do so. For all other studies, it is a good practice expectation.

15.2   Researchers conducting clinical trials under the auspices of the University must ensure their study is registered. Researchers should refer to the guidance on the [Research Sponsorship – Clinical Trial Research Registration SharePoint](#) for further information and support.

15.3   Registration may be via HRA automated registration, or submission to the PRS ClinicalTrials.gov registry, depending on the HRA guidance issued with study approval.

16.   Training requirements

16.1   The HRA details the sponsor's requirement to ensure adequate training is in place for its researchers. The University of Hull fulfils this responsibility via its mandatory training provision and requirements detailed on the [Research Sponsorship – Training and Guidance SharePoint](#). In addition, the SharePoint area also provides a plethora of optional training and guidance for staff and students to access.

A   Student researchers

16.2   Most post-graduate research students are required to complete the compulsory 'Modern Researcher' module of the postgraduate training scheme (PGTS) programme, overseen by the Doctoral College. A small number of students may be exempt due to the professional nature of their course. Any student wishing to submit an application for sponsorship via IRAS must have completed and passed this module prior to submitting their application or must report where the professional exemption applies in the UoH sponsor application form.

B   Staff researchers

16.3   Research members of staff at the University must complete mandatory e-learning modules on research integrity, safeguarding, and data protection, and any other compulsory modules as specified within the University of Hull Training Needs Map.

17.   Amendments to sponsored research

17.1   All amendments must be submitted to research governance@hull.ac.uk. It is important that all amendments both substantial and non-substantial are recorded on the central record and version control of study documentation is maintained and recorded.

17.2   It is the CI's responsibility to ensure submission of amendments in a timely fashion to the Sponsor, via research governance using the tool provided within IRAS.

17.3   CIs must review the HRA guidance on examples of substantial and non-substantial

amendments before classifying their amendment as such, although Research Governance may reclassify the amendment type, as appropriate.

17.4 Researchers must follow the process detailed on the [Research Sponsorship – Amendments to Sponsored Research SharePoint](#) to obtain approval for both substantial and non-substantial amendments.

A   Post HRA approval

17.5 The HRA / REC detail within the amendment tool, the process for obtaining approval, notifying sites and for implementing the amendment and this will vary depending on the nature and classification of the amendment.

17.6 Researchers must not implement amendments until they have been approved, and the University has taken action to notify sites as appropriate.

18. Oversight of University sponsored studies

18.1 The Pro Vice-Chancellor (Research and Enterprise) maintains oversight of research sponsorship as the Chair of the University Research Committee. Reports containing research sponsorship key performance indicators are submitted annually for the preceding academic year to the committee for review.

18.2 In addition to the annual reports, the Head of Research Excellence, Governance and Impact, as a member of the committee, is responsible for bringing to the attention of the committee any reports of adverse events or breaches at its subsequent meeting throughout the year.

18.3 CIs are responsible for ensuring they submit the following reports, as relevant, to the HRA / other approval body (such as REC / CAG etc.), the University, or both, as appropriate.

- Annual progress report
- Notification of end of study
- Final study report
- Breach of protocol / Good Clinical Practice
- Adverse event
- HRA non-CTIMP safety report to REC
- Data breach
- Health and safety incident

18.4 Further detail and templates are available on the [Research Sponsorship – Reporting SharePoint](#). Submission of all the above reports must be copied to Research Governance.

19. Research misconduct

19.1 Failure to adhere to the requirements detailed within this or any University policy, or breach of HRA regulations or procedural guidance issued on SharePoint will constitute misconduct under the University's https://www.hull.ac.uk/work-with-us/research/site-elements/docs/code-of-practice-for-research-misconduct.pdf and may be investigated in accordance with that policy.

20. Withdrawal of sponsorship

20.1 The University has the discretion to withdraw sponsorship of a study where information or application of the study protocol changes without prior approval by the sponsor representative or person acting on behalf of the sponsor. This includes but is not limited to changes to:

- Partners and collaborators, including co-sponsor

- The Chief Investigator

- Funding arrangements

- Participant recruitment and data protection arrangements

20.2   In addition, sponsorship may also be withdrawn if there is a failure to comply with any internal or external requirements in relation to research sponsorship, including the UK Policy Framework for Health and Social Care Research; relevant legislation, research site requirements, and University policies and procedures.

21.   Arrangements for CI leaving the University

21.1   Where the CI leaves the University of Hull before the closure of the study, the CI role should be transferred to another UoH researcher via the amendment procedure detailed under section 14, above, preferably within 2 weeks of notice of termination of employment, but at a minimum of 1 month prior to CIs contract end date.

21.2   Where the study has closed, every effort should be made to ensure all reporting requirements are completed prior to the CI leaving the University. Where this is not possible, as in the case of final closure reports which may be submitted within a year of the study closure date, arrangements should be made to ensure another member of the research team can submit the report on the CIs behalf. Research Governance should be notified where such arrangements are necessary.

Version Control

Version	Author	Date approved	Relevant sections / amendments
1.0	Research Governance and Policy Manager	31/1/22	New document
1.1	Research Governance and Quality Officer	22/6/23	Typographical corrections and update to links/names/policy
2.0	Research Governance and Quality Officer	10/07/25	Addition of 11.19 regarding the introduction of UoH approved site agreements for use with non-NHS sites, and the addition of 11.20 clarifying delegated responsibility for signing site agreements. Typographical corrections also made.