HSU HEALTH SCIENCES UNIVERSITY

Version: 2.0
Effective from: September 2025
Policy Owner: Head of Research
Category: Research

External Approvals and Ethics Reviews Policy and Procedures

Purpose

In line with the HSU Research & Knowledge Exchange Strategy, this policy provides a supporting framework to deliver HSU's commitment to a high-quality, transparent, and ethically sound research culture. It sets out HSU's approach to securing appropriate external approvals and ethics reviews, including Health Research Authority (HRA) and NHS Research Ethics Committee (REC) approvals in England. The policy is designed to help researchers navigate the complex requirements for ethical and regulatory compliance, ensuring that research involving human participants is conducted with integrity and care. By clarifying responsibilities around study approvals and ethics review processes, HSU aims to safeguard the rights, dignity, and safety of research participants and promote the delivery of impactful, trustworthy health and social care research for public benefit.

This policy applies to HSU staff, students and those associated with the university such as visiting fellows and visiting professors (henceforth referred to as 'researchers').

This policy must be read in conjunction with HSU's Research Ethics Policy and Data Protection Policy. The HSU Research Sponsorship Policy & Procedures may also be relevant.

Regulatory Context

It is a requirement of the UK Policy Framework for Health and Social Care Research (PDF, 380kB) that any research governed by it (broadly speaking any research that requires an IRAS application) must have a designated Sponsor, who takes ultimate responsibility for the oversight of the research project. If you are an employee, are studying for a PhD or are the supervisor of a Master's student at HSU, you can request Sponsorship by the university. If this is agreed, the Research Team will act as the Sponsor's Representatives. The HSU Research Sponsorship Policy & Procedures explains the steps required to apply for HSU Sponsorship. You must obtain confirmation of sponsorship before submitting your application to the HRA and NHS REC via IRAS.

The Health Research Authority (HRA) and Health and Care Research Wales (HCRW) operate a coordinated system for the governance and approval of health and social care research conducted in England and Wales. Together, they provide a streamlined process for managing research approvals via the Integrated Research Application System (IRAS).[1] Where a research project involves sites in Scotland or Northern Ireland, and the lead site is in England or Wales (as is likely for most HSU studies), HRA and HCRW also coordinate with the relevant devolved administrations to ensure UK-wide compatibility.

HRA and HCRW primarily function as coordinating and approving bodies for research governance reviews. While they are not Research Ethics Committees (RECs), they oversee the administrative process for applying to NHS RECs, which are independent committees responsible for the ethical review of research. Some HRA assessments may also include elements of review that extend beyond governance—for example, data protection or feasibility—but formal ethics review remains the domain of the NHS REC system.

Research involving NHS patients, service users, their data, or tissue, or which requires NHS resources (e.g. staff time, facilities), must receive HRA Approval (and HCRW Approval if sites are in Wales). Most such studies will also require a favourable opinion from an NHS REC. Applications for both are submitted via IRAS, but reviews are conducted separately and approvals issued independently.

[1] The Integrated Research Application System (IRAS) (https://www.myresearchproject.org.uk) is a single system through which you can apply for many of the approvals required to conduct Health and Social Care Research in the UK.

Some studies may not require NHS REC review but will still require HRA (and potentially HCRW) approval if they use NHS resources or are conducted on NHS premises. In such cases, a HSU ethics review will be required in place of NHS REC review, and the study must still be submitted via IRAS for HRA/HCRW assessment.

Not all projects are strictly *research*. If you are unsure whether you are instead proposing an *Audit* or *Service Evaluation* (which may not require REC review), you can find further guidance via the Health Research Authority's Is my study research? decision tool. The Research Team can provide advice on this.

All research studies that involve human participants, their tissue and/or data should undergo an ethics review. If you are unsure whether your project involves relevant NHS activity, please see the Health Research Authority's Do I need NHS REC review? decision tool.

The following cases require review by one or more external bodies, and you will need to apply via the IRAS:

- **Study requiring access to NHS facilities and / or use of NHS time or resources.** In this case, a Health Research Authority (HRA) review will be needed. If your study meets this, but none of the other following categories, it will also require a HSU ethics review.
- **Study in which participants are identified due to their being NHS patients or service users.** This also applies to research using NHS data or data generated in relation to NHS services or diagnoses. An NHS Research Ethics Committee (REC) review will be required.
- **Study involving the analysis or storage of 'relevant material' under the Human Tissue Act.** An NHS REC review will be required.
- **An investigation into the safety and/or efficacy of a medicinal product.** Research of this nature requires review by an NHS REC and by the Medicines and Healthcare products Regulatory Agency (MHRA).
- **Study intended to generate data to support the licencing or marketing of a medical device.** An NHS REC review *and* MHRA review will be required. This does not apply to all research involving medical devices - the distinction is not always immediately apparent. If you think that your study *may* fall into this category, contact research@aecc.ac.uk as early as possible.
- **Research involving participants in social care who lack capacity to consent.** This study category requires a review by an NHS REC specialising in social care.
- **Research involving participants in social care.** This type of study **may** require review by an NHS REC specialising in social care. If so, this would require application via IRAS.
- **Research involving participants identified due to their being currently in prison or on parole.** This type of study requires review by His Majesty's Prison and Parole Service (HMPPS).

If none of these criteria apply. Your research will require a HSU ethics review.

Definitions

Chief Investigator (CI) – This is the individual who takes primary responsibility for the design, conduct and reporting of the study. For multi-site studies, the CI is responsible across all sites. The Sponsor must be satisfied that the CI has the necessary expertise and support to lead the research.

Principal Investigator (PI) – A researcher responsible for the conduct of a study at a particular site. There may be multiple PIs across different sites.

Sponsor – An organisation or partnership that takes overall responsibility for the initiation, management, and financing (or arranging the financing) of a research project. The Sponsor ensures the study meets regulatory, legal, and ethical standards.

UK Policy Framework for Health and Social Care Research – A set of principles and standards that govern health and social care research in the UK, applicable to all research involving NHS patients, staff, or resources.

Health Research Authority (HRA) – A UK body responsible for overseeing the ethical review and approval of health and social care research in England.

HRA approval – Approval granted by the Health Research Authority after review of governance and legal compliance, required for research in NHS organisations in England.

IRAS (Integrated Research Application System) – An online system used in the UK to apply for the permissions and approvals required for health and social care research.

NHS Research Ethics Committee (REC) – An independent committee that reviews research involving NHS patients, service users, or their data/tissue, to safeguard the rights, safety, dignity, and wellbeing of participants.

Favourable Ethical Opinion – The outcome of a positive NHS REC review, required before research involving NHS patients or their data/tissue can begin.

MHRA (Medicines and Healthcare products Regulatory Agency) – The UK authority responsible for regulating clinical trials involving medicinal products and medical devices.

CTIMP (Clinical Trial of an Investigational Medicinal Product) – A study that investigates the safety or efficacy of a medicinal product in humans and is regulated by the Medicines for Human Use (Clinical Trials) Regulations 2004. Requires MHRA authorisation and NHS REC review.

CIMD (Clinical Investigation of a Medical Device) – A study involving a medical device to assess its safety or performance in humans. CIMDs may require approval from the MHRA and an NHS Research Ethics Committee before starting, particularly if the device is not CE or UKCA marked or is used outside its approved purpose.

Key Responsibilities

The Head of Research is the owner of this policy.

The Research & Innovation Committee is responsible for endorsing the policy. The Academic Board is responsible for approving the policy.

The Research Team are responsible for:

- Providing guidance on the research ethics and approval processes, including HRA, NHS REC, and MHRA requirements.
- Supporting researchers with preparing and submitting applications via IRAS and other relevant platforms.
- Coordinating submission timelines, ensuring all necessary approvals are obtained before study initiation.
- Reviewing documentation to ensure compliance with ethical, legal, and regulatory standards.
- Advising on internal ethics approval processes for studies that do not require NHS REC review.
- Assisting with amendments to applications or studies as needed, ensuring updates are submitted to the appropriate bodies.

The Head of Finance and Procurement is responsible for reviewing and confirming that appropriate insurance and indemnity arrangements are in place for each study sponsored by HSU. This includes ensuring that cover aligns with the requirements of the research type (e.g. CTIMPs, observational studies, student research) and complies with relevant regulations, funder expectations, and institutional risk appetite.

Members of the Research and Innovation Committee, Heads of School, the Director of Clinical and Rehabilitation Sciences, and School Research Leads are responsible for:

- Providing local guidance and interpretation of this policy.
- Providing feedback on the policy and procedures to shape future direction and guidance.

The roles and responsibilities of the Chief Investigator (CI) or Principal Investigator (PI) are set out in the UK Policy Framework for Health and Social Care Research. CIs/PIs are accountable for the scientific, ethical, and regulatory aspects of the research, and they must ensure that the study is conducted in full compliance with the policy and relevant regulations.

HSU is responsible for ensuring that the systems, policies and procedures are in place to support the implementation of this policy.

Policy principles

This policy is underpinned by the following core principles, which reflect HSU's commitment to promoting high-quality, ethically sound, and socially responsible health research:

Ethical integrity: All research involving human participants, their data, or tissue must be designed and conducted in a manner that respects participants' rights, dignity, and wellbeing. Ethical considerations should be at the forefront of study design, and ongoing efforts should be made to ensure the safety and welfare of participants throughout the research process.

Compliance with regulations: HSU will ensure that all research complies with relevant local, national, and international regulations, including the Health Research Authority (HRA) guidance, NHS Research Ethics Committees (REC) reviews, the Medicines and Healthcare products Regulatory Agency (MHRA) requirements, and applicable laws governing research involving human subjects.

Transparency and accountability: HSU strives to maintain a transparent and accountable research culture. Researchers and research support teams are expected to communicate openly about the research process, regulatory requirements, and any issues that may arise. All approvals must be secured before research commences, and documentation should be clear, accurate, and readily available for audit and review.

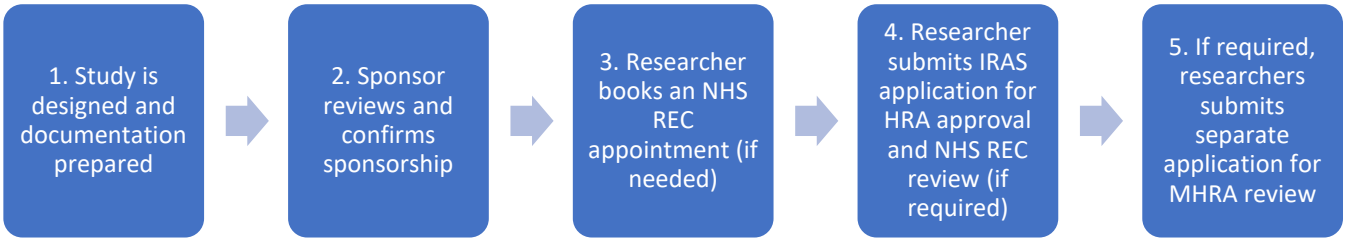
Responsibility of the research sponsor: HSU, as a research sponsor, takes responsibility for ensuring that all research studies meet the necessary regulatory, ethical, and legal requirements. This includes confirming that appropriate approvals are obtained, that research is well-governed, and that any risks to participants are identified and mitigated.

Collaboration and support: HSU encourages collaboration between researchers, research support teams, and relevant regulatory bodies. Research support teams will provide guidance and assistance throughout the approval process, helping researchers navigate regulatory frameworks and obtain the necessary approvals in a timely and efficient manner.

Participant safety and rights: HSU is committed to safeguarding the rights and safety of participants. All studies must include robust safeguards, informed consent processes, and mechanisms for reporting and addressing adverse events or breaches. The integrity of participant data must be maintained in accordance with data protection and privacy laws.

Continuous improvement: HSU will regularly review and update its processes and procedures to reflect changes in ethical, regulatory, and legal standards. Continuous improvement in the management of research approvals and ethics reviews is essential to support HSU's commitment to high-quality, impactful research.

PROCEDURES



Step 1: The study is designed and the required documentation is prepared (protocol, consent forms, etc.).

Step 2: The Sponsor (e.g. the university) reviews the study and confirms sponsorship.

Step 3: Once sponsorship is confirmed, the researcher books an NHS REC review appointment (if required, use the NHS REC Decision Tool to check) via the Online Booking Service.

Step 4: The researcher submits an IRAS application for:

- HRA Approval (required for all research in NHS settings in England)
- NHS REC review, if required

Step 5: If applicable, a separate application is made to the MHRA:

- For CTIMPs, an application for a Clinical Trial Authorisation (CTA) is required.
- For medical devices, a submission may be required depending on the type of device and study.

The HRA, NHS REC, and MHRA reviews are separate processes, though they are often run in parallel.

The flow chart in Appendix 1 summarises the HRA processes that the Chief Investigator must follow until formal notification of approval is received.

You cannot start the study until you have:

- Favourable NHS REC opinion (if required)
- HRA Approval
- MHRA authorisation (if applicable)
- Local capacity and capability (confirmation from each NHS site)

Applying for NHS REC review

You can use the Health Research Authority's Is my study research? decision tool to check whether your project is considered to be research. You can use the NHS REC Decision Tool to check whether your project requires NHS Research Ethics Committee (REC) review. From an NHS perspective, these tools help determine whether your project counts as research and, if so, whether NHS REC review is legally or ethically required.

All projects that require NHS REC approval will require a Sponsor and be submitted via the IRAS.

In most cases, a project will only need to be reviewed by a single NHS REC. If NHS REC review is required, no additional institutional ethics review is usually necessary—unless there are exceptional circumstances, such as funder requirements or additional review for non-NHS elements.

Once your IRAS application has been finalised and approved by your Sponsor, you will book a REC review appointment using the Online Booking Service. This must be done before you submit your IRAS application. Depending on the specifics of your study, you may be offered a slot with a REC that is 'flagged' for a relevant specialist area involved (e.g. clinical trials, research involving children), or a selection of times with committees that have availability. You must then submit your complete IRAS application and supporting documents by the committee's cut-off date, usually 14 calendar days before the meeting.

The Chief Investigator (CI) is normally expected to attend the REC meeting to answer any questions from the Committee. This is always done remotely—via telephone or video conference—so the committee's physical location is not relevant.

NHS RECs are required to issue an ethical opinion within 60 calendar days of receiving a valid application. If you decline the first available meeting date offered, the 60-day period begins from the cut-off date for the chosen meeting (typically 14 days before the meeting date).

If the REC requests further information during the review, they may do so once in writing, and the 60-day timeline will be paused until the requested information is received.

Applying for MHRA review

The Medicines and Healthcare Products Regulatory Agency (MHRA) are a national oversight body who oversee the safe and appropriate use of medicinal products and medical devices in the UK. This includes responsibility for overseeing research conducted in accordance with the Medicines for Human Use (Clinical Trials) Regulations and the Medical Device Regulations.

Clinical Trial of an Investigational Medicinal Product (CTIMP):

A Clinical Trial of an Investigational Medicinal Product (CTIMP) is any study that will generate new information about the safety and/or efficacy of one or more medicinal products. A medicinal product is a

substance presented in a pharmacological form with the intention of affecting a clinical or physiological outcome. A product that a CTIMP generates information about is referred to as an Investigational Medicinal Product (IMP). This includes studies of licenced medicinal products, if they will be used in any way other than as described in their licence or if new information will be generated. This includes studies where the medicinal product is not the subject of the study, but new information will or may be generated - due to its use as a control, for example. This does not include studies of foods or food supplements. For help with determining whether your study is a clinical trial of a medicinal product, see the table and flow chart here: Is it a clinical trial of a medicinal product?

The Clinical Trial Regulations refer to this type of study as a 'Clinical Trial'. It is important to note though, that there are other commonly used definitions of Clinical Trial: the World Health Organisation (WHO) use it to refer to any interventional healthcare study; some funders, such as the National Institutes of Health (NIH), use a similar definition to WHO, some insurance policies define a Clinical Trial as anything overseen by the MHRA (thereby including CTIMPs and CIMDs). In short, when discussing 'Clinical Trials' it's always best to check what definition others are using.

Applications to the MHRA are generated via IRAS (a separate submission through IRAS though coordinated in timing). For a CTIMP, selecting option 1 on filter question 2 will open follow-up filter questions and will add Section B1 to the main form. The details required by the MHRA will be recorded in this form and then downloaded. Once this has been reviewed by the Research Team at Health Sciences University, we will submit it to the MHRA - usually in parallel with the REC/HRA application.

The Clinical Trial regs require that strict Safety Reporting be observed for CTIMPs - regardless of the perceived risk of the study or the licensing status of the product.

The MHRA are required to inspect organisations conducting CTIMPs. This will either take the form of a routine inspection, usually of a Sponsor, during which they will inspect several studies from the Sponsor's portfolio; or a triggered inspection, where a concern has been raised about the conduct of an organisation, or a specific study.

Clinical Investigation of a Medical Device (CIMDs):

A Medical Device is defined, in the Medical Devices Regulations, as:

> "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which:
>
> a. is intended by the manufacturer to be used for human beings for the purpose of:
>
> i. diagnosis, prevention, monitoring, treatment or alleviation of disease,
>
> ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
>
> iii. investigation, replacement or modification of the anatomy or of a physiological process, or
>
> iv. control of conception; and:
>
> b. does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means."

A CIMD is a study intended to generate information to support the licencing (via CE mark / UKCA mark) or the marketing of a Medical Device.

Often one of the most difficult elements of setting up a study that involved a Medical Device is determining whether it is a CIMD. If there is any uncertainty at all in this area contact the Research Team as early as possible to discuss. We will generally refer the question to the MHRA devices specialists; to do this, we will need a copy of the study protocol. *This can be an early draft of the protocol, so long as the objectives and methodology are clear.*

If the Research Team and the MHRA determine that your study is a CIMD, it will need to be submitted as such via IRAS (a separate submission through IRAS though coordinated in timing). Please refer to the MHRA's detailed guidance on preparing a submission (PDF, 212kB).

As with other types of research, the appropriate level of Safety Reporting will depend on the specific study design; however, as a minimum, events that meet the Serious criteria and are possibly, probably or definitely related to a device under investigation must be reported to the Sponsor and, if unexpected, to the REC and MHRA. These events are referred to as Serious Adverse Device Effects (SADEs).

Information Management requirements

Definitive documentation relating to this policy is maintained by the Research Team.

The Chief Investigator or Principal Investigator is responsible for the management of study documentation within the Trial Master File (TMF) or equivalent study file. This includes ensuring that documentation is accurate, complete, and up to date throughout the study lifecycle.

All study documentation must be readily accessible for inspection or audit by the Sponsor, the Research Team, and authorised regulatory bodies. A clear audit trail should be maintained, and researchers must respond promptly to any requests for documentation.

At study closure, all essential documents and data must be archived in accordance with the arrangements described in the IRAS application, study protocol, and any specific funder requirements. Provided these arrangements were set out and approved during study setup, no additional approvals are required at the time of archiving.

It is not necessary to retain documentation in multiple formats. Where paper records have been digitised, the originals may be destroyed—except in the case of Clinical Trials of Investigational Medicinal Products (CTIMPs), for which the retention of validated copies is a regulatory requirement. For CTIMPs, and recommended for all studies, appropriate validation or quality assurance (QA) checks must be conducted to confirm that scanned copies are complete, accurate, and legible before the destruction of paper records.

Following the completion of the required archiving period, all records may be securely destroyed. However, this must first be formally approved by both the Sponsor and the Chief Investigator. Destruction should be done in a way that guarantees confidentiality and data security.

Data protection and confidentiality – All personal data must be managed in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. Researchers must ensure appropriate legal bases for data processing, uphold data minimisation principles, and respect participant rights including access, rectification, and erasure where applicable. Identifiable data should only be accessible to authorised personnel and must be stored using secure, University-approved platforms.

If study data will be shared or transferred (either within or outside the UK), researchers must ensure compliance with data protection laws, including data transfer agreements if applicable. This is particularly important when sharing data with third parties, external collaborators, or international partners.

Reporting and Oversight requirements

Safety reporting requirements

For studies involving human participants, Chief Investigators are responsible for ensuring that all adverse events (AEs), serious adverse events (SAEs), and—where applicable—suspected unexpected serious adverse reactions (SUSARs) are identified, documented, assessed, and reported in line with applicable regulations and procedures. The Sponsor must be notified promptly of any serious safety issues that may affect participant welfare, study integrity, or regulatory compliance. For Clinical Trials of Investigational Medicinal Products (CTIMPs), reporting must follow the requirements set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 and associated guidance. HSU expects investigators to maintain clear and timely records of all safety-related communications and assessments.

For non-CTIMP health and social care research, Chief Investigators must still ensure that any adverse events (AEs) or unanticipated problems affecting participants are recorded and assessed for potential impact on participant safety or study integrity. While formal expedited reporting may not be required, any significant concerns—particularly those that may raise ethical or legal issues—must be escalated to the Sponsor without delay. HSU encourages a precautionary approach to safety reporting and may request documentation or internal review where appropriate, even in low-risk or observational studies.

Ethical compliance

The Chief Investigator must ensure that any issues raised by the research ethics committee (NHS REC, HSU ethics process, or another committee) are promptly addressed and that any necessary amendments are submitted for approval. If there are any concerns regarding the safety, rights, or wellbeing of participants, the Chief Investigator must immediately suspend the study and inform the Sponsor and appropriate authorities.

Annual reports and end of study/trial

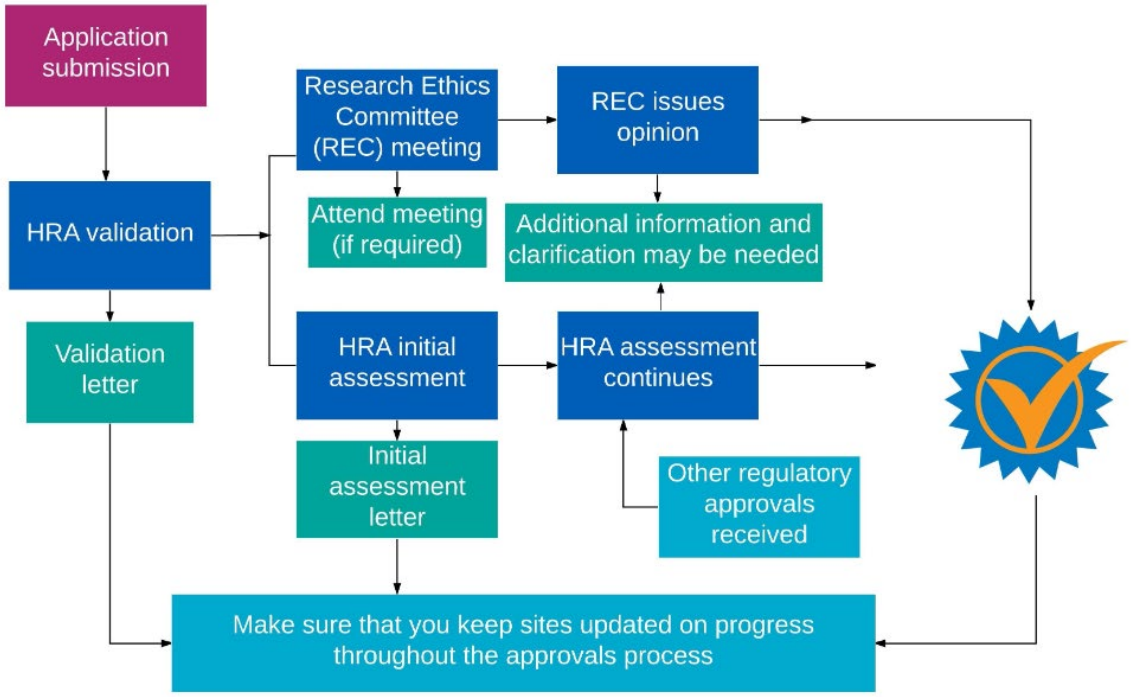
All NHS REC approved studies are required to submit an annual progress report, to the approving REC, each year after approval is granted. More details are provided by the HRA. At the end of the study, an End of Study notification must be submitted to the approving REC. More details can be found at the HRA. For Health Sciences University Sponsored studies, the Research Team will prompt you when these are due, but it is the Chief Investigator's responsibility to ensure that they are submitted.

Good practice

In drafting this policy and procedures, good practice has been adopted from the NHS, HRA and UK Government, as well as from:

- University of Bristol: https://www.bristol.ac.uk/red/research-governance/ethics/

Appendix 1: Flow chart of the HRA process steps that the Chief Investigator must follow until formal notification of approval is received.



Version	2.0
Approving body	Academic Board
Policy Owner	Head of Research
Date approved	11 June 2025
Effective from	September 2025
Review date	2025/26
Target Audience	Health Sciences University staff and students conducting research (this includes visiting fellows/professors)
Publication	HSU Staff Resource SharePoint site
Equality analysis	This Policy has been developed with due regard to the University's general equality duty and no direct impact has been identified.