Version: 3.0
Effective from: 1 January 2025
Policy owner: Head of Research

Research Ethics Policy and Procedures

1. Scope and purpose

1.1. The Health Sciences University Research Ethics Policy and Procedures applies to all staff and those contracted by Health Sciences University (those undertaking research and those involved in the supervision of student research), all undergraduate (first qualification students), all postgraduate taught and research students and all visiting staff undertaking research under the auspices and sponsorship of Health Sciences University.

1.2. Health Sciences University recognises the importance of reviewing the ethical aspects of all research conducted at the University. The purpose of ethics review is fourfold:

- Reflects Health Sciences University's commitment to good ethical practice.
- Assists researchers and supervisors undertaking research to identify appropriate ethical issues and address these in the development and implementation of research proposals.
- Acts as a safeguard to researchers and supervisors who can be confident of the ethical propriety of their project once it has been approved.
- Satisfies current GDPR legislative expectation in regard data collection, storage and dissemination.

1.3. This Policy is designed to provide guidance about conducting ethical research and to provide details of Health Sciences University processes and procedures for ensuring appropriate consideration and ethical scrutiny of research sponsored by HSU.

1.4. For the purposes of this Policy, research is defined as[1]:

'The attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. It includes activities that are carried out in preparation for or as a consequence of the interventional part of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non-interventional research, projects that aim to generate hypotheses, methodological research and descriptive research. It excludes audits of practice and service evaluations.'

1.5. For research projects that require access to NHS facilities, time or resources or for projects in which participants are identified due to their being NHS patients or service users, approval by the Health Research Authority (HRA) is required and most projects will also need approval from the NHS Research Ethics Committee (REC). Please see the *HSU External Approvals and Ethics Review Policy and Procedures*, for more information.

1.6. In broad terms, research requires an ethics review whereas clinical audit and service evaluation does not. The exception to this rule is the special case of health services evaluation research, which does not normally require ethics review. The reasoning behind this is that normally both clinical audit and health services evaluation are observational, and do not involve either any intervention to, or any departure from routine clinical management and care of patients. In all cases, irrespective of the type of inquiry, and whether or not a study requires ethics review, it is required that all data collection adheres to the General Data Protection Regulations and associated research provisions are adhered to.

1.7. Applicants carrying out audit or service evaluation studies and literature based studies will be required to sign and submit a Statement of Ethical Compliance, in which they commit to abiding by Department of Health (2021) Research governance framework for health and social care. This

[1] UK Policy Framework for Health and Social Care Research

must be co-signed by the applicant's supervisor. The form will be sent out to all who do not submit an ethics application.

1.8. Ethics review covers the ethics of conducting a research study and how research data and observations are handled in ethical terms. Ethics review does NOT consider the merits (or otherwise) of a research study in terms of feasibility, design, and methods of collection of data or observations and methods of analyses except where this directly impacts ethical considerations.

1.9. All researchers and research supervisors must read this Policy prior to commencement of any research. Additional documents relating to this policy includes *Data Protection Policy*, *Research Misconduct Policy and Procedure*, *Research Data Management Policy and Procedures*, and *Privacy Notice (Research Participants)*. If further clarification or guidance is needed, the Chair of the School Research Ethics Panel (SREP) or the Institutional Research Ethics Committee (IREC) should be consulted. Further details on the SREP/IREC are given in Health Sciences University Academic Committees Membership and Terms of Reference.

1.10. Failure to conduct research in accordance with this Policy and related policies may result in personal disciplinary or legal action taken against the researcher, supervisors or Health Sciences University as documented in Section 10 and the *Research Misconduct Policy and Procedure*.

2. Key Responsibilities

2.1. This document is part of Health Sciences University's Academic Regulations, Policies and Procedures which govern the University's academic provision.

2.2. Responsibility for drafting and reviewing research ethics policies and procedures as set out in this document lies with the **Research and Innovation Committee** with delegated authority to the SREP/IREC who are also responsible for implementation of these policies.

2.3. The **School Research Ethics Panel (SREP)** is responsible for encouraging a culture within the School which recognises the importance of ethical considerations in the design and performance of research. The SREP receives, considers and provides favourable opinion (or not) on applications for the ethics review of school staff, undergraduate and postgraduate student research. For cases outside the remit of the School or where there is a need to escalate a case, the SREP will refer to the **Institutional Research Ethics Committee (IREC).**

2.4. The **Institutional Research Ethics Committee (IREC)** is responsible for overseeing the research and research culture at Health Sciences University to meet the standards required by the Concordat to Support Research Integrity. This includes ensuring HSU policies and procedures protect and safeguard the welfare of research participants and researchers, understand the broader research environment, developing and amending strategy and policy to maintain ethical standard of practice in research. The IREC will also receive, consider and review applications for the ethics review of staff and postgraduate student research in the circumstances where no independent reviewers are available at the SREP level or this panel has determined to escalate the application or; provide an ethical opinion in cases where ethics review is considered not appropriate or necessary or; consider appeals arising from School Research Ethics Panel (SREP) decisions.

2.5. For the purposes of ethics review, Health Sciences University is designated as the **SPONSORING** organisation. The UK Policy Framework for Health and Social Care Research states that a sponsor is an *"individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report on a research project"*

2.6. The **SPONSOR** has overall responsibility for the research, including:

a) Identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols and applications and ensuring that research proposals and protocols

i. consider systematic reviews of relevant existing research evidence and other relevant research in progress,

ii. make appropriate use of patient, service user and public involvement and

iii. are scientifically sound (e.g., through independent expert review), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing

b) Satisfying itself that the investigators, research team and research sites are suitable
c) Ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented
d) Ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project
e) Ensuring appropriate arrangements are made for making information about the research publicly available before it starts; agreeing appropriate arrangements for making data accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants
f) Ensuring that, where expected or required, the research has favourable ethics review from a research ethics committee and any other relevant approval bodies before it begins
g) Verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner
h) Putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management
i) Ensuring that effective procedures and arrangements are kept in place and adhered to for reporting and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

Health Sciences University can, when requested (e.g. for IRAS or HRA applications) provide a **SPONSORSHIP** letter and any other documents such as confirmation of appropriate indemnity insurance where necessary and requested. Please see the *Research sponsorship policy and procedures* for further information on how to apply for sponsorship.

2.7. Where favourable ethics review has been granted through another body/organisation who provide a sponsorship role external to Health Sciences University, but the data is to be collected at Health Sciences University, HSU will issue a **GATEKEEPER** letter to the organisation providing ethics review by Health Sciences University to allow data collection. For the purposes of this policy and in relation to gatekeeper roles a research site will be defined as on the Parkwood Road, Garnett or London campuses. A copy of the ethics approval from the external body will be required as a minimum.

3. Research Ethics Principles

3.1. Research should be designed, reviewed and undertaken to ensure integrity, value and quality.

3.2. Research should be undertaken in accordance with commonly agreed standards of good practice which include the concept of 'beneficence' (do positive good), 'non-maleficence' (do no harm), autonomy and justice.

3.3. Participants should be fully informed about the purpose, methods and intended possible use of the research. Section 7 provides detailed guidance on informed consent.

3.4. Researchers should respect the human participants involved in their research as persons of worth whose participation is a matter of their autonomous choice (Section 7.2 provides further guidance on research on participants who lack the capacity to consent. See also the *HSU Safeguarding Policy*). The process of securing informed consent upholds the principle of

respecting autonomy, and the Dignity, Diversity and Equality (DDE) principles and practice as detailed in the University's *Equality, Diversity, Inclusion and Belonging Policy.*

3.5. Research participants must normally participate voluntarily, free from coercion. Notwithstanding, incentive payments are permissible as long as they are proportionate to the burden of the research participation, not so excessive as to lead to poor judgement about potential risks and there is a clear rationale for such payment including how and when the payments will be made, as per the University's *Recognition & remuneration policy for research contributors & participants*.

3.6. Researchers must consider the physiological, psychological, social, political and economic impact of their research on participants. Efforts must be made to protect participants against physical, mental, emotional, economic or social injury to ensure, as far as possible, that no harm comes to them as a result of being involved in the study.

3.7. The confidentiality of information supplied by participants must be respected. Any limits to confidentiality must be explained to participants (see 3.9).

3.8. Issues of anonymity and anonymisation of results should be fully considered, and where personal disclosure or identification is likely, this must be discussed with the participants and their specific consent to this obtained. Pseudonyms do not always protect anonymity and researchers need to ensure other personal information is not given that could make the participant identifiable.

3.9. All research data collection and processing must comply with the General Data Protection Regulation (see guide here https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/). For the purposes of collecting and processing research data, Health Sciences University would normally operate under the lawful basis of necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the University.

3.10. The health and safety of those involved in the research should be considered in the design and execution of research projects. This should include the health and safety of the researchers, participants, members of collaborating or partner organisations, the households or family members of those participating in the research, and members of the communities/organisations in which the research will be carried out (where the research might impact on them).

3.11. Research outcomes should be disseminated in a manner which makes them accessible to participants.

3.12. The independence of the research outcomes must be ensured. External sources of funding and any potential conflict of interest must be declared during the ethics review process, and in the information to participants.

3.13. Failure to comply with the terms of favourable ethics review for a research project, or failure to seek further review if required, may lead to action under Health Sciences University's *Research Misconduct Policy and Procedure.*

4. Research Ethics Definitions

4.1. Research ethics are the moral principles guiding the planning and conduct of research. These include the following principles: *minimising the risk of harm, obtaining informed consent, protecting anonymity and confidentiality, avoiding deceptive practices, providing the right to withdraw without detriment.*

4.2. Research with human participants should be taken in its broadest possible sense and includes questionnaires, observations and the use of materials derived from human participants as well as invasive or intrusive procedures. Thus, ALL research involving human participants requires ethics review.

4.3. Types of research or activities requiring ethics review include, but are not limited to, those listed below:

- Staff Research: an agreed programme of research undertaken by a member of Health Sciences University staff to include staff, students, visiting or emeritus staff, associates, honorary or clinical contract holders, contractors and consultants.
- Postgraduate Research Degrees: a research degree involving a programme of research undertaken by a postgraduate student registered at Health Sciences University or registered at another institution
- Undergraduate and Postgraduate Taught Dissertations or Projects: a research programme for a project or dissertation undertaken by an undergraduate (including first qualification programmes) or postgraduate student at Health Sciences University.

4.4. If, after reading the **Guidance on Ethics Review**, you are unsure if your study is considered as research, you should consult with a member of SREP or your supervisor for guidance and clarification. For the purposes of best practice, or where there is any doubt as to whether ethics review should be sought, it is recommended that Health Sciences University's standard ethical procedures are followed (see Section 8). If ethics review is either not appropriate or necessary, this will be communicated through the either the SREP or IREC Panel (see section 8).

5. Researcher Responsibilities

5.1. Responsibility for obtaining ethics review and ethical conduct of the study primarily rests with the researcher. The researcher (staff or student) is responsible for the following:

Prior to commencing the research study, the researcher must:

- In the case of students, ensure you discuss the project with your supervisor prior to seeking ethics review.
- Read all appropriate Policies.
- Ensure compliance with any other additional requirements (such as those defined by GDPR, the NHS, external ethical processes (e.g., other universities or collaborative partners) and the law of the country within which the research is taking place). Where ethics review is sought either through the NHS, or from external recognised ethics review (e.g., other universities or bodies in the country in which the research is being conducted), the first stage of Health Sciences University's ethics process **must still be completed**.
- Complete the relevant checklist according to the School Research Ethics Panel process and follow University procedures (see section 8).
- For research which proposes to use HSU clinical facilities, you must ensure you have discussed this with the Director of Clinical and Rehabilitation Services.
- Obtain favourable ethics review **BEFORE** any recruitment of participants or data collection commences for the project as ethics review cannot be sought retrospectively (i.e., after data collection has commenced).

Throughout the research study, the researcher must:

- Operate in an ethical manner with due regard to the ethical considerations and other related Health Sciences University policies or statuary expectations or challenges relevant to the study;
- Operate within the provisions of the favourable ethics review granted;
- Detail any adverse events arising during the research to the IREC, and provide a summary on completion of the research;
- Comply with the monitoring requirements detailed on favourable ethics review from the SREP/IREC;
- Ensure that where the scope or details of the research project changes, that such changes are approved as a modification to your original application. If you are uncertain as to whether changes require approval discuss the proposed changes with a member of SREP, IREC or your supervisor to ensure the favourable ethics review you have been granted remains

appropriate (**you must re-submit any modifications for ethics review if changes to the research project mean that your previous favourable ethics review is no longer valid**).

Following completion of the research project, the researcher must:

- Ensure dissemination of the findings is appropriate in terms of anonymity and confidentiality as laid out in your original ethics review.

5.2. It is the researcher's responsibility to abide by the terms of the favourable ethics review given.

5.3. All researchers must take full responsibility for ensuring appropriate storage and security for all study information, including research data and consent forms. All stored data must comply with Health Sciences University's *Data Protection Policy.*

5.4. All research undertaken by staff or students must comply with the legal requirements of the UK, and/or the country of location of the research study.

6. Ethics panels and supervisor responsibilities

6.1. It is the responsibility of the SREP/IREC to determine whether a research project is ethically sound and to grant favourable ethics review based on the following:

- That every effort has been made to protect participants against harm and injury as a result of being involved in the study
- That participants are appropriately, clearly and fully informed of what is involved should they agree to participate, and their rights in agreeing or refusing to participate
- That informed consent to participate is appropriately obtained, and that no coercion is brought to bear
- That participants are appropriately protected with reference to anonymity and disclosure (confidentiality) of their data, both in terms of its storage and its use. See Health Sciences University's *Data Protection Policy* and *Privacy Notice (Research Participants).*
- That information is provided on how any data obtained as part of the study are eventually destroyed (see Health Sciences University's *Data Protection Policy a*nd *Privacy Notice (Research Participants))*

6.2. Supervisors overseeing research studies have a responsibility to discuss research ethics with their student(s) at the design stage and ensure the student submits an ethics application in all cases.

7. Informed consent

7.1. Informed consent entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision on their possible involvement (see also 3.5).

7.2. The quality of the consent obtained is critical to its validity. The onus is on the researcher to ensure that the consent is freely given and fully informed. The quality of the consent is affected by a number of factors, these being: the format of the record of consent, the competence and capacity of the participant to give consent, and the clarity of the information provided to the participant.

- Wherever possible a signed consent form should be obtained. If written consent is not possible, oral consent can be given after the researcher has read out the details of the consent form and information sheet. This should be witnessed by a second person
- There are a number of circumstances where the competence and/or capacity of participants is absent or compromised. Normally such instances of research will be addressed in the initial ethics screening process. Such circumstances typically fall within the following categories; however, this list is not exhaustive, and researchers should independently consider the issues of competence and capacity for all participant groups before submission for ethics review.

- Children (under 16) and young people (under 18): If children are involved in a research study, they should be included in key aspects of the process of consent (e.g., have information on the study explained in terms they are able to understand). The child's parent/legal guardian must be informed and give their consent to participate in the study. Further more detailed guidance can be found here: *Research with Children and Young People*; *HSU Safeguarding Policy*.
- Adults lacking capacity to consent to research: In the case of research with adults who lack capacity under the terms of the *Mental Capacity Act 2005*, these projects must be reviewed by *National Research Ethics Service (NRES)*. Guidance on the Act states that researchers should assume that a person has capacity, unless there is proof that they do not have capacity to make a specific decision, and those potential participants must receive support to try to help them make their own decision. The potential participant has the right to disagree with the decisions that others (such as relatives or carers) might make. See the *HSU Safeguarding Policy* for further information.
- Other vulnerable groups: There are many factors that may affect the ability of participants to freely give informed consent, for example institutional groups (e.g. employees, prisoners, patients) may feel coerced into taking part in research by the consent of the institutional authority to carry out research within their domain. Researchers should therefore ensure that members of an institutionalised group understand that the institutional consent places them under no greater obligation to participate in the research. See the *HSU Safeguarding Policy* for further information.
- Other factors which may affect voluntariness: Voluntariness can be called into question when other pressures may be an influence, for example, when a researcher at an educational institution proposes to use students as participants in their research, or when researchers propose to pay participants more than their expenses and lost earnings (see section 3.5. for guidance on the use of incentives). It is important that payment does not override the principles of freely given and fully informed consent. It is imperative that participants know, before they start the research, that they can withdraw from the study at any time without losing any payment. See the *Recognition and Remuneration Policy for Research Contributors and Participants* for further guidance.
- In cases where significant cultural differences may affect understandings about the nature of informed consent the researcher should employ culturally appropriate methods to allow participants to make decisions whether to participate or to withdraw from the research process.

7.3. Where the nature of the research is such that informing participants of some details before the work is carried out might render the results invalid, for example in some randomised controlled trials, there must be appropriate explanations following the study. These explanations should also include the opportunity to confirm or withdraw consent. In these circumstances, justification for this course of action is required to be submitted as part of the ethics process for review to the SREP or the IREC. Researchers must provide convincing reasons why such research should proceed without the necessary fully informed consent.

7.4. Participants should be provided with an information sheet which outlines in layperson's terms the purpose of the research, potential hazards, any discomfort participation may entail, emphasise the right to withdraw from the study, state their rights under the Data Protection Act 2018 (DPA 2018), provide researcher contact details and indicate the period of data retention (see *Privacy Notice (Research Participants)*. This should also include who to contact if they have any questions or concerns, and where appropriate, signposts to support in the event they are impacted by the research.

7.5. Participants should also sign a consent form. This does not apply to survey research, where potential participants should be provided with an information sheet and return of the completed survey is accepted as an expression of consent to participate. This should be communicated transparently to participants. Covert studies are exempt from providing information sheets and consent forms for participants. Where possible after the research study, researchers should debrief participants about the true nature and purpose of the research. A document on how to

prepare a participant information sheet and a sample consent form are available under separate cover to this policy (*How to Prepare Your Participant Information Sheet and Sample Informed Consent Form*).

7.6. Participants should be given sufficient time to understand the information, to ask questions and to express any concerns that they may have. They should also be provided with contact details for the research team, should they have any further questions after participating.

7.7. In all cases of research, researchers should inform participants of their right to decline to participate or to freely withdraw from the investigation whenever they wish without penalty or giving a reason.

7.8. Where a participant is interviewed as part of any research, they should be informed of the nature and purpose of the project and given a clear explanation as to why they have been asked to contribute and be informed as to the areas of questioning. The participant should be made aware of any significant changes to the research as it develops which might reasonably affect their original consent to participate.

7.9. It is acknowledged there may be circumstances in which participants give their consent by their on-going involvement in the research. For example, informed consent is normally implicit in survey research through the completion and return of questionnaires.

8. Research ethics review process

8.1. All applications for ethics review are made via the standardised process for ethics review relevant to the School of the researcher.

8.2. In instances where a researcher sits outside of a School (for example in a Centre), they are welcome to use the ethics process for the School in which their research most closely aligns. Where the researcher is not sure, they are invited to contact the School Research Ethics Leads who will advise further.

8.3. Guidance on how to apply via the *Health Sciences University Research Ethics Application Portal (REAP)* can be found in the *Health Sciences University Guidance on Ethics Applications*. This is currently only available for researchers in the School of Health and Rehabilitation Sciences.

8.4. Appendices 1-3 provide an overview of the submission process. All individuals wishing to carry out research must complete the initial ethics screening checklist. This filters the initial application into either a **Fast Track** or **Full Ethics Application** (Appendix 2).

9. Fast Track

9.1. Fast Track applies:

a. If MINIMAL RISK is identified via the screening questions your ethics application can be fast tracked and passed onto the relevant *School Research Ethics Panel (SREP).*

b. If the application is Fast Tracked, one member of the SREP will review the application and provide feedback.

9.2. For student projects, Fast Track identification requires the student's project supervisor to approve the application before submission to the relevant SREP (Appendix 1 and 2B).

9.3. Where patient records have been requested, Fast Track is available once the section on Patient Records has been completed as above.

9.4. All Fast Track submissions referred to the School Research Ethics Panel (SREP) post screening questions will be circulated to **ONE** member of the SREP who will independently review the application and provide a decision on favourable ethics review to the School Research Ethics Lead.

10. Full Ethics Application

10.1. Where any questions on the initial checklist do not result in Fast Tracking, applicants will be required to fill in the Full Ethics application (See Appendix 2).

10.2. All Full Ethics applications referred to the School Research Ethics Panel (SREP) post screening questions will be circulated to **TWO** members of the SREP who will independently review the application and provide a decision on favourable ethics review to the School Research Ethics Lead.

10.3. For those Full Ethics applications where a consensus cannot be reached, the School Research Ethics Panel will escalate to the Institutional Research Ethics Sub-Committee.

11. Further information

11.1. Patients attending a private clinic setting (e.g., chiropractic, osteopathic, physiotherapy, podiatry clinics etc) are not, for the purposes of ethics review, normally classed as NHS patients. In these cases, the researcher must apply for ethics review from Health Sciences University. Private patients should be advised to check whether participation in a research study impacts the terms and provision of private health insurance they may hold.

11.2. Studies involving further analysis of existing data (secondary analysis) will require ethics review. These studies will normally be considered as minimal risk, and the use of such data allowed if:

- The data are completely anonymous when provided to the researcher and it is not possible to identify participants from any resulting write-up
- The data are stored securely and appropriately destroyed (usually when the research project is complete) (see the Health Sciences University *Data Protection Policy*).

11.3. All applications are reviewed for adherence to ethical principles only and not on issues of research methodology including research questions, research design, and data collection and analysis methods.

12. Appeals

12.1. If at any stage the application for ethics review is likely to be rejected, this will normally be referred back to the researcher with the deficiencies of the application identified, giving the researcher the opportunity of a further submission.

12.2. Where favourable ethics review is not given by the School Research Ethics Panel (SREP), the researcher has the opportunity to appeal through the Institutional Research Ethics Committee (IREC). To appeal, the researcher should contact the Chair of the Institutional Research Ethics Committee cc Research Administrator. The decision of this committee is final, and the matter is concluded at this point.

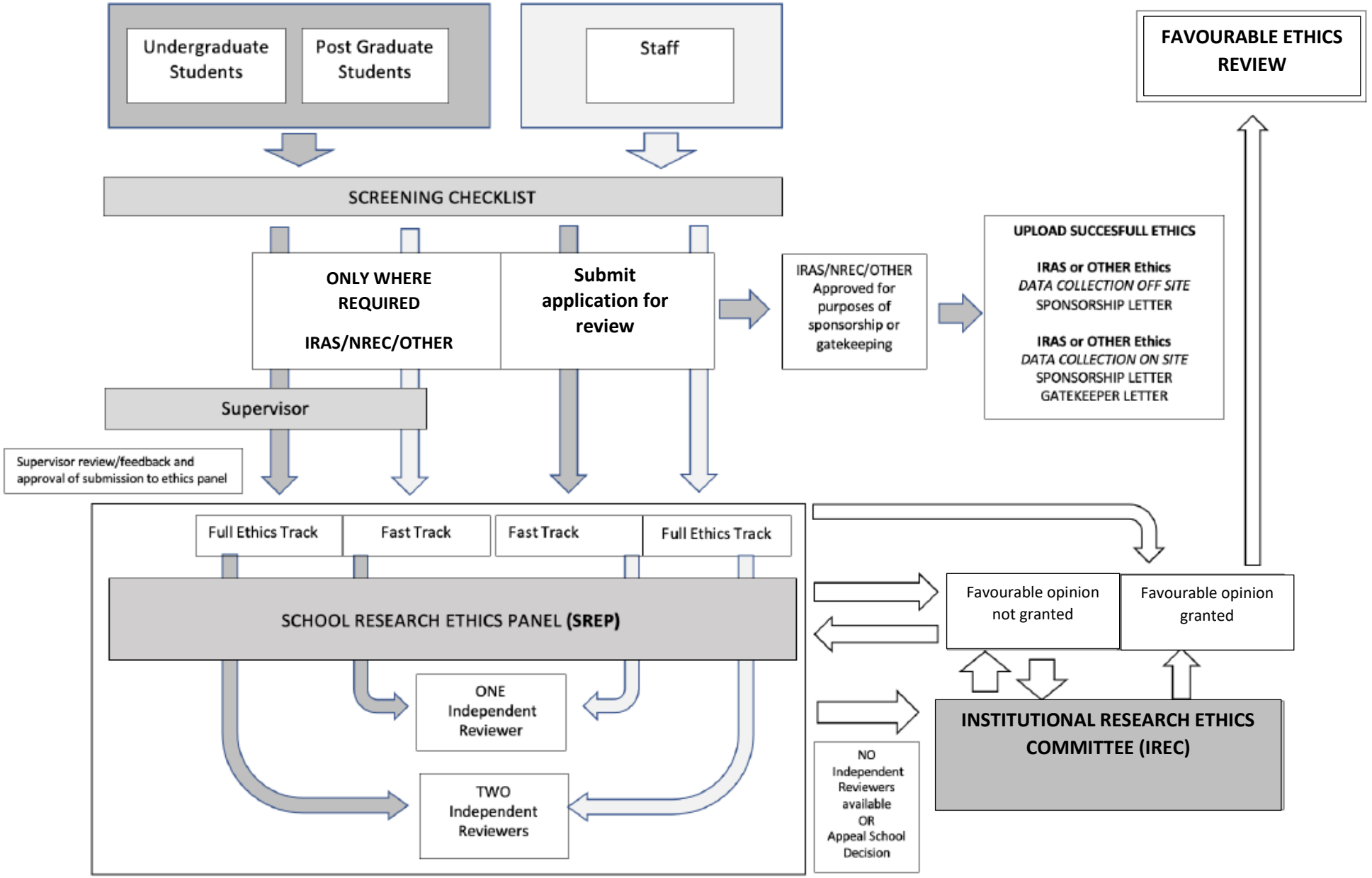
13. Other relevant documents and links

- Health Sciences University Research Ethics Application Portal (REAP)
- Academic Committees Membership and Terms of Reference
- UK GDPR Guidance and Resources
- Mental Capacity Act 2005
- Research Misconduct Policy and Procedure
- Data Protection Policy
- Privacy Notice (Research Participants)
- Guidance on Ethics Review and online submission
- Research with Children and Young People
- Safeguarding Policy

This policy supersedes any previous School specific guidance and process.

Version:	3.0
Ratified by:	Research and Innovation Committee
Originator / Author	Research
Owner:	Research and Knowledge Exchange Manager
Reference source:	Internal information, external environment, other HEIs
Date approved	December 2024
Effective from	January 2025
Review date	September 2025
Target	Staff, Students
Policy location	Staff Information Portal (SIP), RKE SharePoint site, HSU Website
Equality Analysis	This policy has been developed with due regard to the University's equality duty.

APPENDIX 1: Overview of Health Sciences University Ethics Submission Process

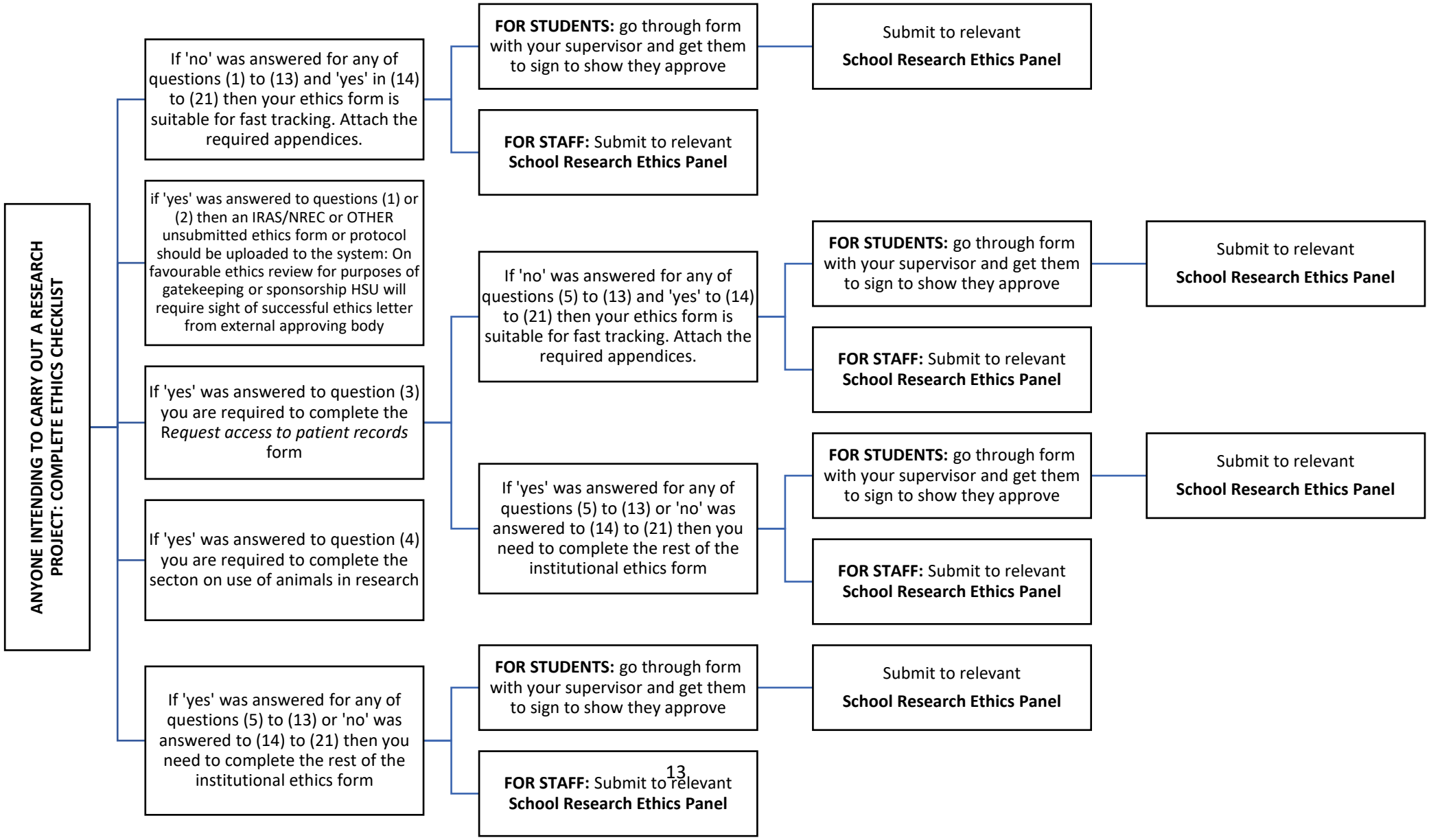


APPENDIX 2A: Initial screening checklist (All Ethics Applications)

1) Will the study involve recruitment of patients or staff through the NHS?
2) Will the study involve use of x-rays or magnetic resonance?
3) Will the study require access to patient records from the Health Sciences University clinical services?
4) Does your research involve animals?
5) Will the study involve participants who are particularly vulnerable or unable to give informed consent (e.g. children under 16, people with declared mental health issues, prisoners, people in health and social care settings, addicts, or those with learning difficulties or cognitive impairments or for faculty research, your own students?)
6) Will your research involve deliberately misleading participants in anyway?
7) Will financial inducements (other than reasonable expenses and compensations for time) be offered to participants?
8) Are there risks of participants experiencing either physical or psychological distress or discomfort?
9) Will personally identifiable data other than gender and age of participant be collected as part of the study?
10) Are drug placebos or other substances (e.g., food substances, vitamins) to be administered to participants, or will the study involve invasive, intrusive or potentially harmful procedures?
11) Will blood or tissue samples be obtained from participants?
12) Will the study involve prolonged or repetitive testing?
13) Will the study involve sensitive topics that might be considered offensive, distressing, politically or socially sensitive, deeply personal, or in breach of the law (e.g. criminal activities, sexual behaviour, personal appearance, experience of violence, addiction, religion, or financial circumstances)?

14) Will the study involve using only secondary data? This might include linking data to or collecting items like email addresses, or postcodes that could be used to link your data to an individual.
15) Will you describe the main experimental procedures to participants in advance so that they are informed about what to expect?
16) Will you tell participants that their participation is voluntary?
17) If the research is observational, will you ask participants for their consent to being observed?
18) Will you tell participants that they may withdraw from the research at any time and for any reason?
19) If using questionnaires/surveys, will you give participants the option of omitting questions they do not want to answer?
20) Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?
21) Will you debrief participants at the end of their participation (i.e. give them a brief explanation of the study and information on how to access research findings)?

APPENDIX 2B: Screening algorithm



APPENDIX 3: Ethics review process