Procedures (v2.7)

University Research Ethics Procedures

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	University Research Ethics Committee
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Responsible Office:	Research Engagement

PROCEDURES

HERIOT-WATT UNIVERSITY
RESEARCH ETHICS PROCEDURES

CONTENT

1. **INTRODUCTION**

These Procedures should be used in conjunction with the **Research Ethics Policy**, which sets out a general framework for ethical conduct in relation to research activity at Heriot-Watt University (henceforth, the University).

These Research Ethics Procedures (henceforth, the Procedures) provide a framework for School research ethics practice at the University, including the Animal Welfare and Ethical Review Body (AWERB)

The Procedures will be adopted by School research ethics committees.

2. **RESEARCH ETHICS PROCEDURES**

The research ethics process makes it possible for staff and students to conduct research safely and legally and this document is intended to help guide applicants through the process.

2.1 **SCOPE**

The Research Ethics Procedures:

a. provide a framework for the conduct of ethical procedures for School committees;
b. sit within the broader framework of research integrity and values of the University;
c. conform with all related legislation, e.g. Human Rights Act 1998, UK Data Protection Act 2018, Human Tissues Act 2004, Equality Act 2010, Animals (Scientific Procedures) Act 1986, Genetically Modified Organisms (Contained Use) Regulations 2014.
d. are consistent with research ethics procedures and systems of key external institutions, e.g. professional associations, research councils, the National Health service (NHS) and local authorities;
e. conform with the fundamentals of academic freedom; and,
f. cover all forms of academic research, as well as situations involving the development and interpretation of existing knowledge within a professional setting, consultancy work and professional practice.

2.2 **PURPOSE**

The purposes of these Procedures are to:

a. provide a range of recommended guidelines to help inform committees of good research ethics practice;
b. harmonise research ethics procedures across the University;
c. complement the research ethics procedures of key external/international institutions, e.g. professional associations, research councils, the NHS and local authorities; and
d. reinforce how research ethics link with the University's Strategic Plan, in that shared good practice in this aspect of research contributes to the aim of the University of becoming a world leader in a wide-range of academic disciplines.

2.3 WHAT IS ETHICAL REVIEW/APPROVAL?

Heriot-Watt University **Research Ethics Policy**, Section 7, states that "All research requires ethical review and, if deemed necessary, formal ethical approval should be sought".

In terms of process, the university differentiates between a) *Ethical Review* and b) *Ethical Approval* :

a) *Ethical Review* – assesses whether or not ethical implications are present (i.e. the study involves human participants, animals, personal data from external sources, or raises other ethical issues).

Schools may adopt different approaches to the **ethical review** process for different groups conducting research (e.g. staff, postgraduate students, undergraduate students).

Examples of challenge questions that may be used for the *ethical review* process include: *'Does your project include human participants, personal data from external processes, living animals, medicines/drugs/medical appliances, or present other ethical considerations?'*

b) *Ethical Approval* –involves a more rigorous assessment of ethical implications and researchers' plans regarding how they will adhere to ethical principles and relevant legislation. Further to this, there are different types of ethical approval:

1) **"In Principle Approval"** – **must be obtained before applying for funding through the RMAS/Worktribe online system**. Approval is granted after a relatively light touch review to ensure that initial research plans are defensible on ethical grounds; and

2) **"Full Approval"** – **must be obtained before data collection commences**. Approval granted after a more rigorous assessment of applicants' plans regarding ethical risks, mitigations, and conduct.

Where required, all applications requiring **ethical approval** (either "in principle" or "full") must be processed via the University's centralised Ethics Management System (see below).

The ethics tab in RMAS/Worktribe should not be used to obtain ethical approval and any ethics applications submitted through the ethics tab on RMAS/Worktribe will not be considered.

A project that has been approved in principle must still obtain full approval for its work packages before data collection begins. Failure to obtain full ethical approval, where it is required, may be considered academic misconduct (see Section 9 in the University **Research Ethics Policy**).

Ethical approval for research at the University is a devolved matter and is the responsibility of each School's Research Ethics Committee.

2.4   WHEN SHOULD ETHICAL APPROVAL BE SOUGHT?

Where the ethical review process indicates that **full approval** is required, it would normally be applied for when the overall concept, goals and methodology of the study have been agreed.   When required, **full approval must be obtained before primary data collection (or collection of secondary personal data) commences.** This applies whether the research is conducted by staff or students.

It is a University requirement that when applying for external funding for projects with ethical implications through the RMAS/Worktribe on-line system, and before submission, that either "in-principle" or "full approval" must be obtained in advance of project approval by the Research Grants Finance Team. **The Research Office will not sign off a project until at least "in-principle" approval has been obtained.**

In-principle ethical approval can be granted for studies where an outline of the work with ethical implications has been described (e.g. use of animals or human data) but full details of the studies have not yet been defined or ethical permission from external partners is pending (e.g. NHS approval or licences for work with animals). If the external funding application is successful, then **full ethical approval** should then be sought prior to data collection.

Full ethical approval for student research projects, internally funded or **unfunded** staff-led research projects must also be obtained if the ethical review process indicates that this is required, even if such projects are not recorded in RMAS/Worktribe. This should be done before data collection commences.

Researchers should re-apply for ethical approval if their study changes in such a way that new ethical implications are raised. If there is any doubt regarding whether this is necessary advice should be sought from the relevant School Ethics Committee.

Applications for detailed 'full approval' must be made for every specific data collection activity in a project rather than for the whole project unless the project contains only one such data collection activity. Again, if there is any doubt regarding whether this is necessary advice should be sought from the relevant School Ethics Committee.

Ethical approval also needs to be sought for the reuse of data previously obtained during another research project.

Research projects that have no ethical implications do not need full ethical approval.

2.5   WHO SHOULD APPLY FOR ETHICAL APPROVAL?

For **staff-led** research, responsibility for gaining full approval lies with the project's Principal Investigator, as indicated in the University Research Ethics Policy.

In the case of **student-led** research, the University Research Ethics Policy specifies that "It is the responsibility of programme and/or course leaders, research project supervisors, to make students aware of the Policy" and "It is the responsibility of student researchers to follow their School's guidelines and declare where necessary conformance to codes of ethical conduct".

2.6 HOW TO APPLY FOR ETHICAL APPROVAL?

2.6.1 Research conducted by staff.

If the ethical review process, described above, indicates that a staff member's research project requires ethical approval, then this should in all instances be obtained through the university's on-line **Ethics Management System** (EMS), as described in the flow diagram in Appendix 1. Supporting documents and training videos for using the EMS can be found on the University **EMS SharePoint Site**.

EMS applications are assessed, and ethical approval granted (or denied) by the relevant School Research Ethics Committee. Changes to an application may be required before approval is granted.

Where appropriate, EMS applications involving animals will be directed to and reviewed by the Animal Welfare Ethical Review Body(AWERB).

The EMS integrates an assessment of potential data protection issues to ensure that the research complies with **data protection legislation**. If a project is deemed to pose particular data protection risks, the applicant will be asked to complete a Data Protection Impact Assessment (DPIA), and this will be reviewed by the University's Data Protection Officer (DPO).

Applicants should allow at least 10 working days, depending on School requirements, for the review of an application for "in principle" or "full ethical approval". The process may take longer if changes are requested by reviewers or a DPIA is required. This should be considered when fieldwork is scheduled as no primary data collection should begin until "full ethical approval" has been granted (see above).

Once an approval letter in PDF format has been emailed to the applicant from the School Ethics Committee via the EMS, this should be uploaded to the document tab on the RMAS/Worktribe system and tagged as 'ethics', along with any relevant supporting documents (such as evidence of external ethical approval).

For your **awarded grant** to be set up by the Research Grants Finance, you must provide to the Research Grants Finance Team a PDF copy of the 'in principle' document that you received from the EMS system before your grant application.

'Full approval' might need to be obtained for a project after being awarded funding and the award has been setup, see above. The 'full approval' can only be given for **specific data collection activities** and at the point where they can be described in the necessary detail including the **informed consent and information for participants documents**, the data to be collected, and the uses to which the data will be put. At that point you must include any additional information, such as ethical permission from any external partners, if applicable (see Appendix 2).

Help with technical issues (e.g. system navigation, uploading files, or signing applications) can be obtained from the Information Services team via ishelp@hw.ac.uk. If specialist advice regarding the substantive content of an ethics application is required, applicants and/or supervisors should contact their School's Research Ethics Committee.

2.6.2 Research conducted by students.

Where the School Level ethical review process indicates that a student-led research project requires full approval, this should be also be obtained via the EMS (see above and Appendix 1).

In the case of student-led research, applications for full approval can be shared between student and supervisor and edited collaboratively prior to submission.

Supervisors will be asked to sign a student's application digitally before a student can submit it.

A letter confirming ethical approval (or rejection) will be generated automatically by the EMS and emailed to students at the end of the review process.

2.7 DATA PROTECTION CONSIDERATIONS

Under General Data Protection Regulation (GDPR) and other data protection legislation, the University must embed data protection by design and default into all research activities involving personal data. Proposed projects that present a potentially high risk to privacy require a data protection impact assessment (DPIA) to be completed, and measures to mitigate their risks to be in place before the activity can begin. The Ethics Management System therefore requires applicants using personal data to complete a DPIA if the screening process integrated within the system indicates that this is necessary, in accordance with university **Data Protection Policy**.

2.8 ADDITIONAL RESEARCH APPROVAL

It is incumbent on the staff and students undertaking the research to check whether approval from other relevant research authorities may be necessary and, where relevant, obtain such an approval.

This includes approval from an NHS Research Ethics Committee if the study involves:

- NHS patients (including deceased patients) and their relatives.
- NHS staff.
- NHS premises.

3. DIFFERENT LEVELS OF RESEARCH ETHICS COMMITTEES

3.1 Delegated authority of the University Committee for Research and Innovation

Ethical standards in the conduct of research in the University are the responsibility of the University Research Ethics Committee, and of School and Institute sub-committees, whose work it oversees.
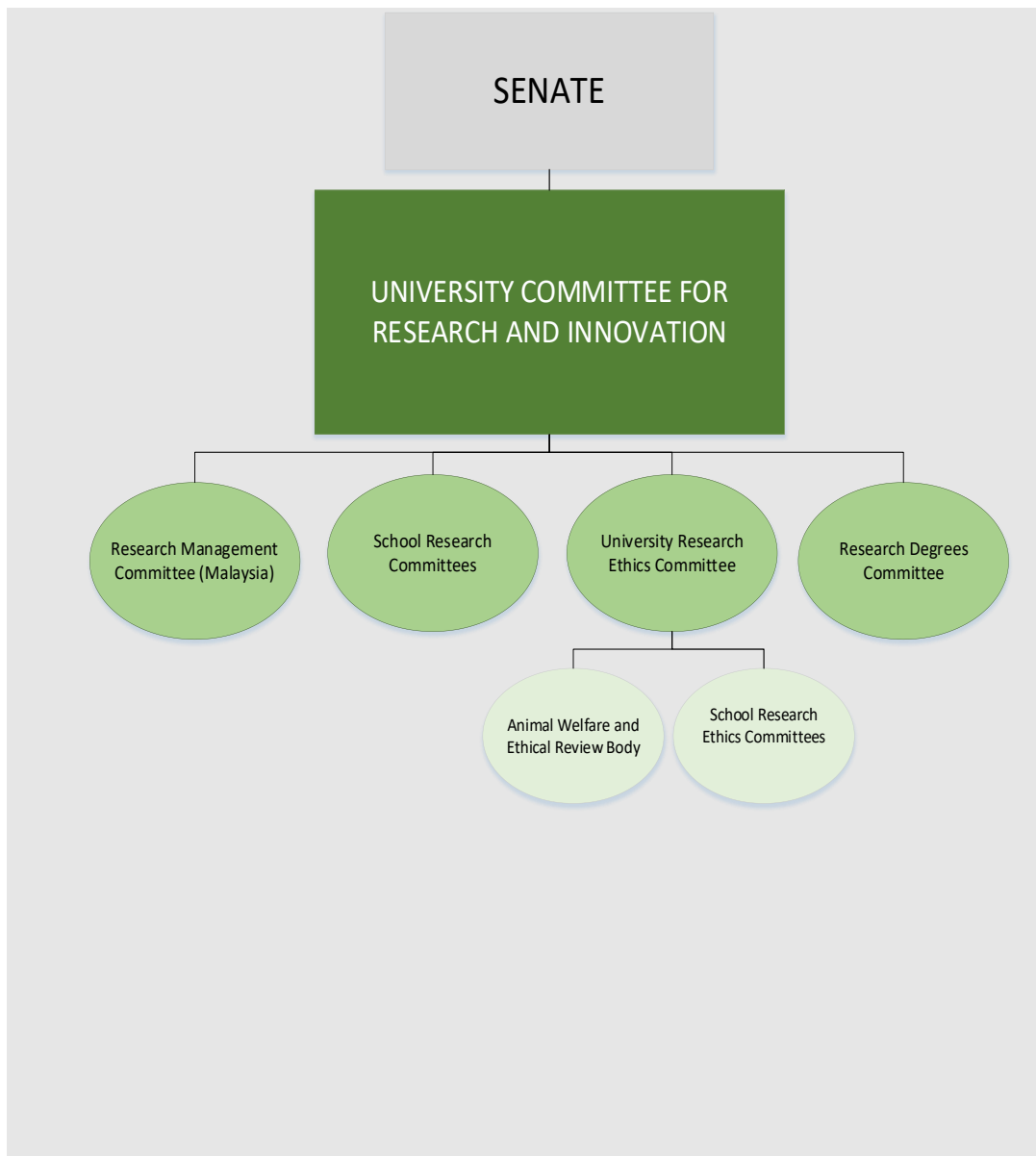
3.2 UNIVERSITY RESEARCH ETHICS COMMITTEE (UREC)

The purpose of UREC is to maintain oversight of ethical matters in relation to the University's research and innovation activities.

UREC does not, except in very unusual circumstances, carry out research ethics checks on projects.

School research ethics committees sit under and feed into UREC via a nominated representative of each, typically the Chair of the committee. UREC is available to be consulted on matters unresolvable or beyond the expertise of the School committees.

3.3   SCHOOL RESEARCH ETHICS COMMITTEES

All Schools are expected to have a research ethics committee. The principal purposes of School Research Ethics Committees are to:

a. oversee the governance of research ethics according to local and specific areas of research; and,
b. establish and operate ethical review procedures for local and specialised areas of research.

See Appendix 3 for the terms of reference for School committees.

3.4   ANIMAL WELFARE AND ETHICAL REVIEW BODY (AWERB)

The principal purposes of the [Animal Welfare and Ethical Review Board](#) (AWERB) are to:

a. oversee the use of animals in research and teaching.
b. approve and monitor the use, supply and housing of animals for these purposes; and
c. ensure all activities they review comply with relevant animal research legislation.

The AWERB (as depicted in Section 3.1) feeds into UREC in a similar manner to School research ethics committees.

No animal research or teaching may be carried out without the approval of the Animal Welfare and Ethical Review Body.

It is important that proper account is taken of all possibilities for reduction, refinement and replacement of animals in scientific research (the 3Rs principles). For animal work the following tool can be used to design experiments (many funders now request that this is used):

https://www.nc3rs.org.uk/our-portfolio/experimental-design-assistant-eda

If animal work is being performed at another institution in the UK or another country then evidence should be presented through ERS that appropriate licenses will b /are in place before the research commences

4.   ESCALATION OF PROJECT PROPOSAL FROM SCHOOL RESEARCH ETHICS COMMITTEE TO UNIVERSITY RESEARCH ETHICS COMMITTEE

Research ethics approval is a matter devolved to School-level committees and individuals. However, research ethics approval can be sought from UREC when a decision cannot be made at School-level or sufficient expertise can only be found by accessing UREC.

5.   TRAINING

UREC will identify and agree the research ethics training needs for the University. Research Engagement is responsible for all research-related training and development opportunities and will take a lead in responding to research ethics

training needs identified by UREC, drawing on appropriate ethics expertise across the University to develop and deliver any activities and programmes (e.g. Research Engagement, Registry, Academic departments, Data Protection Officer, etc.). UREC may request reports on activities taking place from the Learning and Teaching Academy.

For Student research, research ethics training, including privacy and data security should be taught as part of the student programmes. Further, it is the responsibility of the supervisor to make the student aware of the need to design research that complies with the University Research Ethics Policy and wider professional standards and values if applicable.

6. RELATED POLICIES AND PROCEDURES AND FURTHER REFERENCE

Data Protection by Design and Data Protection Impact Assessment Toolkit for Researchers

Data Protection Policy

Disciplinary Code

Disciplinary Policy

GDPR and Research Guide

Student Discipline Policy and Procedure

University Research Ethics Policy

Research Data Management Policy

7. FURTHER HELP AND ADVICE

Questions related to these Procedures should be directed to the Chair of the University Research Ethics Committee or visit:

https://intranet.hw.ac.uk/ps/res/Pages/Ethics-Committee.aspx

The Chair and Clerk of UREC can be contacted via UREC@hw.ac.uk

A current copy of these Procedures can be found at: http:// *(to be inserted)*

The Data Protection Officer can be contacted via: dataprotection@hw.ac.uk

8. DEFINITIONS

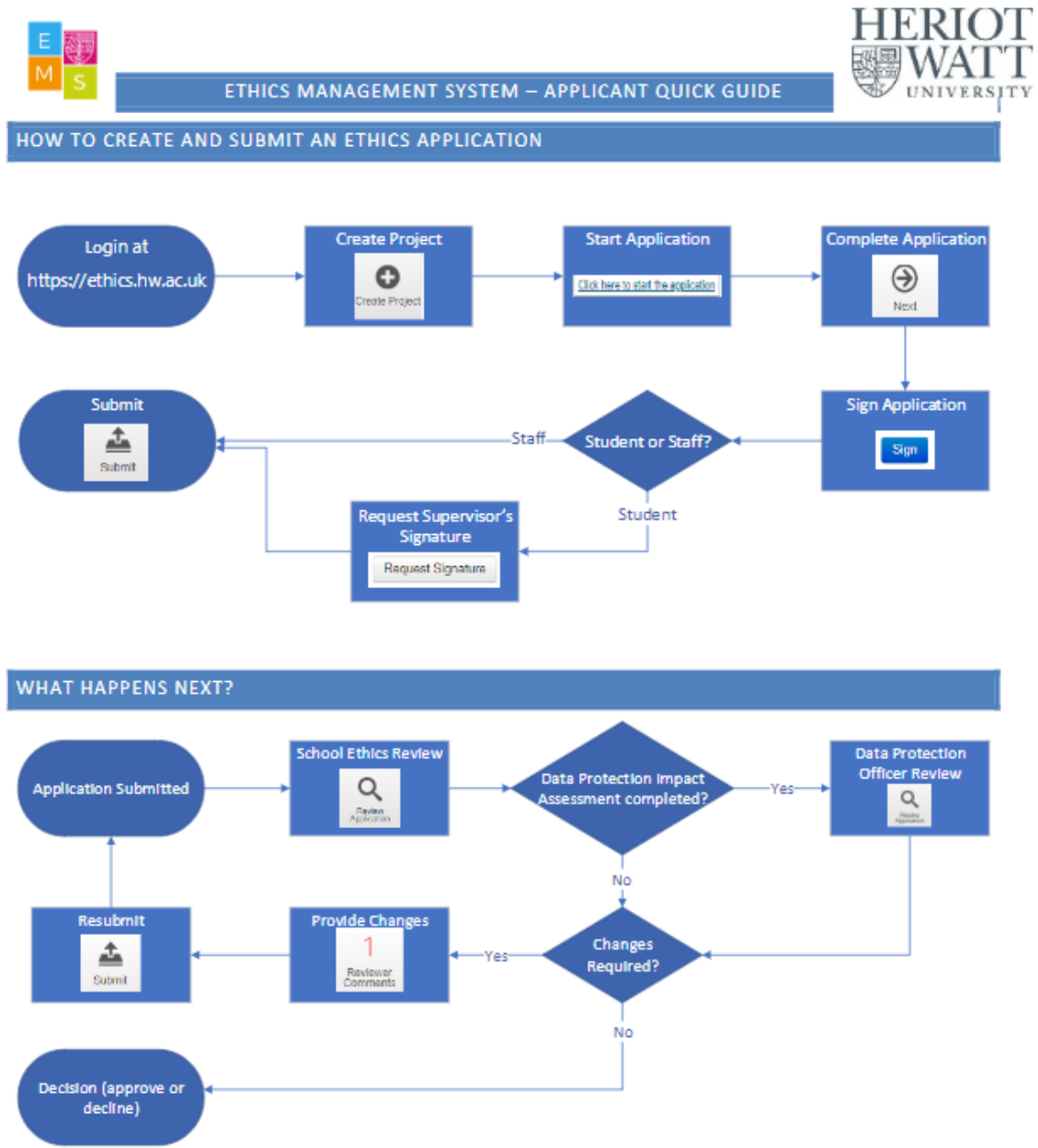|	
Animal	A vertebrate or invertebrate animal but does not include a human being.
Anonymised data	Irreversible removal of personal identifiers from information so that the data subject is no longer

identifiable. Anonymised information therefore no longer falls within the definition of personal data.

Data Controller

An organisation which determines the purposes for which personal data is processed and is legally accountable for the personal data that it collects and uses or contracts with others to process on its behalf. In this context the Data Controller will usually by the University.

Participant

A person who serves as a data source for research as a 'participant'.

Personal data

Any information that could be used directly or indirectly to identify a living person

Pseudonymised data

The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable person. Pseudonymised data is therefore re-identifiable and falls within the definition of personal data. Pseudonymised data is sometimes also referred to as "linked-anonymised" data because the key can be linked to the dataset to re-identify people who might otherwise (but not always) be anonymous without the key.

School

A primary academic unit of the University devoted to one or more academic discipline.

9. PROCEDURES VERSION AND HISTORY

Version No	Date of Approval	Approving Authority	Brief Description of Amendment
V. 2.7	22.03.2023	University Committee for Research and Innovation	Complete review undertaken by UREC and UREC sub-group

APPENDIX 1: An overview of the Ethics Management System Approval Process

APPENDIX 2: Obtaining "In-Principle" and "Full" Ethical Approval[1]

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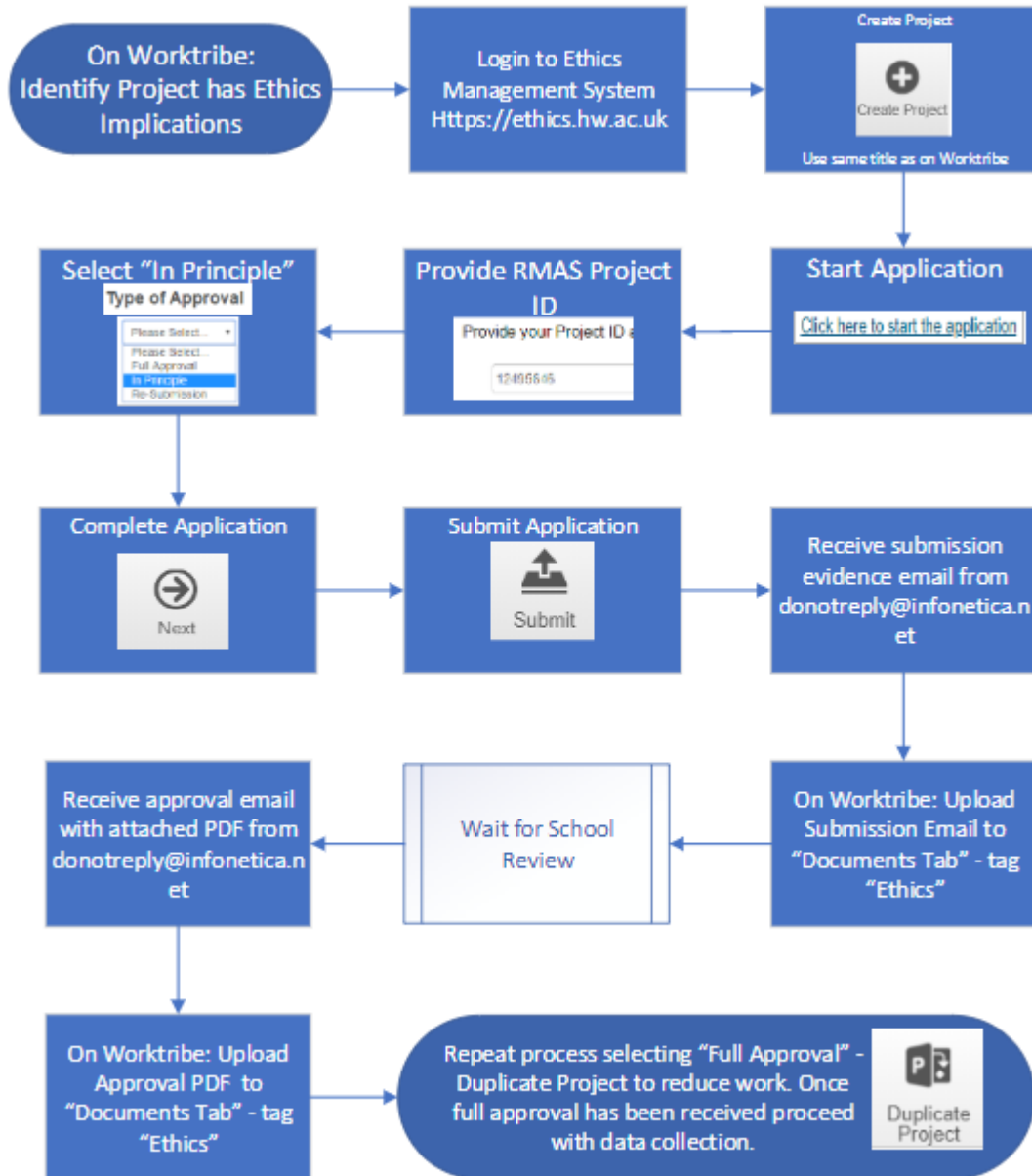
[1] If you are looking to acquire ethical approval from an external body (e.g. NHS) seek advice from RES. For research involving animals, contact the Animal Welfare and Ethical Review Committee (AWERC).

APPENDIX 3: Terms of Reference for School Research Ethics Committees

1. **REMIT**

   The principle purposes of School Research Ethics Committees are to:

   a. oversee the governance of research ethics according to local and specific areas of research;
   b. establish and operate ethical review procedures for local and specialised areas of research; and
   c. provide guidance and recommendations on research ethics training for Staff and Students.

2. **MEMBERSHIP**

   The broad membership of committees should reflect the University's commitment to equality and diversity via the Athena SWAN initiative. Such committees should aim to base membership on the following positions and forms of representation:

   - Chair
   - Deputy Chair
   - Doctoral Student representative
   - Appropriate representation from departments/institutes/research centres within the School

   Notes:
   Committees should also draw on the necessary locally available expertise required of a research ethics committee.

   In certain circumstances, it may be necessary for committees to draw on external expertise, leading to one-off or re-occurring invitations to attend.

3. **MEETINGS**

   Committee meetings should be decided on the basis of the needs of the School. However, meetings should be planned and advertised a year in advance.

   Meetings should be arranged to allow reporting to each UREC meeting and, therefore, take place a minimum of two weeks before UREC meetings. School committees should provide a short-written report to each UREC meeting.

   UREC meeting dates can be found at:

   https://intranet.hw.ac.uk/ps/res/Pages/Ethics-Committee.aspx

   All such meetings should be clerked and formal meeting minutes made available on the relevant Intranet system.

4. **QUORACY**

   The quoracy for each meeting should be 50 per cent of all members.