1. Introduction and Purpose

Royal Holloway is committed to protecting the dignity, rights, and welfare of all those involved in research and to promoting the highest ethical standards of research. This policy details the principles and procedures that underpin the promotion and maintenance of an ethical culture throughout the university.

Royal Holloway will:

- Promote a culture that embraces the principles set down in this policy
- Provide ethical guidance and support and training to staff and students; and
- Maintain a review process that subjects research to a level of scrutiny in proportion to the risk of harm or adverse effect.

This policy should be read in conjunction with the College Code of Good Practice in Research, Ethics guidance documents and associated policies. It reflects the principles and commitments outlined in the Concordat to Support Research Integrity.

Failure to adhere to the policy can also lead to consequences that include and are not limited to, legal, financial, safeguarding, and reputational risks for researchers, collaborators, research participants and Royal Holloway as an institution.

2. Scope

This policy addresses both funded and unfunded research and knowledge exchange activity in the UK and abroad and applies to staff, students, collaborators, sub-contractors or other individuals acting with or on behalf of Royal Holloway (researchers).

3. Policy Statement

Royal Holloway is committed to the core principles of the Concordat to Support Research Integrity (2019): honesty, respect, rigour, transparency and accountability.

Royal Holloway requires that anyone undertaking research in the name of Royal Holloway should:

- Engage with the commitment to conduct research to the highest ethical standards;
- Understand the circumstances in which ethical approval is appropriate and, when appropriate, participate fully in Royal Holloway’s ethical review process; and
- Fulfil their moral and legal responsibilities in respect of the rights and welfare of research collaborators and participants.

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1 The Economic and Social Research Council provide the definition of knowledge exchange as:

The two-way exchange between researchers and research users to share: ideas; research evidence; experiences; and skills. Knowledge exchange is often associated with activities that can be planned and costed, including: seminars; workshops; placements; collaborative research. (https://www.ukri.org/councils/esrc/impact-toolkit-for-economic-and-social-sciences/defining-impact; 23 September 2021)
Respect for persons
All researchers must demonstrate a commitment to safeguarding and promoting the rights, interests and well-being of students, colleagues, and research participants\(^2\) both within and outside Royal Holloway. This may also involve raising and escalating concerns about unethical practices, research misconduct or academic misconduct in accordance with Royal Holloway processes.

Respect for non-human subjects
All researchers must demonstrate a commitment to safeguarding and preserving the rights, interests, and well-being of non-human species. They must also adhere to the three R’s of animal research: replacement, reduction and refinement. This may involve raising and escalating concerns about unethical practice, research misconduct or academic misconduct in accordance with Royal Holloway processes.

Respect for the environment, culture and heritage
All researchers should consider the risk of damage to the environment and impact of their research or knowledge exchange activity on culture and cultural heritage. This may also involve raising and escalating concerns about unethical practices, research misconduct or academic misconduct in accordance with Royal Holloway processes.

Promotion and maintenance of an ethical research culture
All researchers have an obligation to undertake research and knowledge exchange activity ethically. This involves conducting research in ways that commit to honesty, rigour, transparency, accountability and respect for individuals, the environment, culture, and cultural heritage.

Ethical engagement with external organisations and the international community
All researchers have an obligation to act ethically in their engagement and collaboration with external organisations in the UK and internationally when developing and carrying out research and knowledge exchange activities.

Where research activities are conducted in other jurisdictions, there needs to be adherence to the local policies and laws that apply, unless the local policies and laws conflict with other policies on research ethics, legal obligations to data protection, and the safeguarding of researchers, participants, collaborators and any other involved parties (for instance in jurisdictions where the imposition of laws would undermine academic freedom, or in jurisdictions where there is a history of extrajudicial repercussions for academics, research collaborators, and research participants).

4. College Commitments
Royal Holloway will provide the infrastructure, processes, and policies to facilitate high standards of ethical research and engagement both locally and internationally.

Training and Development
Royal Holloway will ensure that comprehensive guidance is available to facilitate a good understanding and knowledge of ethics and ethical processes. It will also ensure that there are ethics and integrity training and development opportunities available for all researchers and will mandate training where necessary. Royal Holloway will monitor and facilitate training and development through the College Research Ethics Committee. Schools and Departments will provide appropriate ethics and integrity training and guidance for Undergraduate and Postgraduate Taught students.

\(^2\) Research participants are defined in this policy document as people who are the subject of study and whose personal information are used in a research project.
Ethical Review Principles

In accordance with the Concordat to Support Research Integrity, Royal Holloway is committed to implementing research ethics review structures and processes for all research undertaken by Staff and Students. Royal Holloway is also committed to an ongoing assessment of the effectiveness, comprehensiveness, and proportionality of these structures and processes. Detailed research ethics review structures and processes are to be set out in Annexes to this Policy, which are to be monitored, reviewed, and updated through the College Research Ethics Committee, and approved by the appropriate Council committee. However, there are certain principles that underpin the review structures and processes that are to be implemented at Royal Holloway. These are:

- That Royal Holloway provides resources to enable research to be scrutinised and assessed.
- That Royal Holloway implements a risk-based approach to the suitability of research ethics review.
- That researchers at Royal Holloway (Staff and Student researchers) ensure that they seek ethical approval for research that Royal Holloway deems it is appropriate to review.
- That while it is acknowledged that neither research ethics review nor institutional research ethics approval are legal requirements, the absence of – and poorly formulated – research ethics review poses significant legal, financial, safeguarding and reputation ramifications, for researchers, research collaborators, subjects, Royal Holloway, partner organisations, and the contributions of research to society more broadly. More specifically:
  - That without research ethics approval, researchers and institutions can be denied funding, or be found in breach of the terms and conditions of funding contracts, and publishers may decline to publish research outputs.
  - That the research ethics review process is the process by which researchers at Royal Holloway and Royal Holloway as an institution evidence compliance with GDPR obligations.
  - That the research ethics review process is the process by which researchers at Royal Holloway and Royal Holloway as an institution evidence compliance with safeguarding obligations.
  - That the research ethics review process facilitates the reporting of research that involves animal subjects, and therefore facilitate compliance with legal compliance with the Animal (Scientific Procedures) Act 1986 Amendment Regulations 2012 (ASPA), and ultimately project licences, personal licences and the Establishment Licence issued by the Home Office.
- That, as is the sector standard, Royal Holloway does not suggest that all research involves risks that warrant research ethics review.
- That Royal Holloway commits to providing a framework for assessing whether research warrants ethics review.
- That when research warrants research ethics review, approval is only required by Royal Holloway for the specific research activities that warrant approval, and that Royal Holloway recognises that initial research, for instance involving literature reviews and research design, may not warrant ethical approval.
- That for research activities that warrant approval, researchers must receive approval prior to the start of that research activity, and that Royal Holloway does not provide retrospective research ethics approval on the basis that it undermines the commitment to implementing practices that facilitate research that is ethical, compliant with legal, financial, and safeguarding obligations, and protects Royal Holloway’s reputation.
- That if approval is sought for research that has either already commenced or taken place, Royal Holloway provides a review process, albeit without the possibility of approval, that assesses the risks involved with the research and offers suggestions if a project can be more ethical.
- That Royal Holloway recognises that certain research may need to be reviewed by external research ethics committees (for example, NHS Research Ethics Committees), and that Royal Holloway will endeavour to implement structures and processes that facilitate the recording of the research and institutional sponsorship.
5. Reporting

To meet its obligations to the Concordat to Support Research Integrity, Royal Holloway is to undertake an annual monitoring exercise to demonstrate that the institution has met the commitments of the concordat.

The Research Ethics Committee has a dual reporting role to the Research & Knowledge Exchange Committee and to Council via the appropriate committee, providing them with an annual Research Ethics Report that details annual approval statistics and an Annual Integrity Statement.

6. Roles and Responsibilities

College Research Ethics Committee (REC)
The REC is responsible for overseeing all research ethics matters concerning research conducted by Royal Holloway’s researchers and for ensuring compliance with the College Ethics policy and processes. The REC is accountable to the College Council and has a dual reporting role to the Council’s appropriate committee and to the Research and Knowledge Exchange Committee, providing them with the Annual Ethics Report and Annual Integrity Statement.

Researchers
Researchers at Royal Holloway – staff, students, collaborators and anyone carrying out research on behalf of Royal Holloway – are responsible for ensuring that they and their research team members are familiar with and adhere to institutional and governing policies and codes throughout the lifecycle of the research project.

Senior Vice-Principal (Research)
The Senior Vice-Principal for Research has overall responsibility for research ethics and integrity at Royal Holloway. The Senior Vice-Principal for Research has the responsibility of either acting as or nominating the Chair of the Research Ethics Committee (REC).

Chair for the Research Ethics Committee
The chair provides the final stage of decision making and ethical approval on behalf of the REC.

School and/or Department Research Ethics Committee Representatives
Research Ethics Representatives are appointed by Heads of School and Heads of Department and have delegated responsibility for taking part in the activities of the Research Ethics Committee, promoting awareness of policies and guidelines among their colleagues, signposting training and development opportunities, and generally promoting robust ethical standards in their respective Departments and Schools.

Reviewers
Are responsible for reviewing research ethics applications and for ensuring that they are familiar with ethical principles and institutional policies and processes.

Research and Innovation
Research and Innovation is responsible for promoting and advising on ethical research, supporting the Research Ethics Committee, overseeing the Ethical Approval system, and for nominating members of professional services to service the College Research Ethics Committee, to administrate and advise on the Ethics review processes across Royal Holloway, to manage research ethics record keeping and reporting, and to deliver training in research ethics.
7. Related Documents

Related College policies and processes
- Data protection policy
- Data management Policy
- Code of Good Research Practice
- Code of misconduct
- Safeguarding
- Statement of expectations
- Guidelines on relationships involving staff, students & others
- Health and Safety – Risk Assessment
- Whistleblowing
- Disciplinary Policy

Related external legislation, codes and policies (selected)
- Human Rights Act 1998
- Equality Act 2010
- Mental Capacity Act 2005
- Health and Safety at Work Act 1974
- Human Tissue Act 2004
- Animals (Scientific Procedures) Act 1986 (amended 2012)
- Data Protection Act 1998 (from 25th May 2018 the European Data Protection Regulation will apply).
- The Declaration of Helsinki; Ethical Principles for Medical Research Involving Human Subjects (see http://www.wma.net/en/30publications/10policies/b3/)

8. Monitoring and Compliance

Further information on the interpretation and application of this policy may be obtained from ethics@rhul.ac.uk

Non-compliance and issues arising from Research
If anyone considers that this policy has not been followed, in the first instance they should raise the matter with the secretary to the Ethics Committee at ethics@rhul.ac.uk

If issues arising from research projects need to be reported, or participants have concerns that they wish to raise with Royal Holloway, the secretary to the Ethics Committee should be contacted at ethics@rhul.ac.uk

Where research gains press attention for ethical matters this should be raised immediately with the Director of Communications and the Chair of the Ethics committee, via the secretary at ethics@rhul.ac.uk

Misconduct
Non-compliance with the Research Ethics Policy may be considered research misconduct, please see Code of Research Misconduct and its associated procedures for more information.
9. Document Control Information

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Annex A: Current Review Process

Research Ethics at Royal Holloway are reviewed by internal and external review processes. This annex covers internal Royal Holloway's internal research ethics review processes.

Research Ethics Review and Amendment Requests for Undergraduate and Postgraduate Taught Student Research Projects

Responsibility for reviewing research undertaken by undergraduates and postgraduate taught students is delegated to Royal Holloway Departments and Schools. Royal Holloway Research and Innovation have provided a template ethics application form to facilitate the review of Undergraduate and Postgraduate Taught research ethics, but Departments and Schools can implement their own bespoke ethics application review forms, procedures, and systems. In addition, Departments and Schools are delegated responsibility for maintaining records of ethics applications and amendments, so that Royal Holloway can comply with its obligations to the Concordat to Support Research Integrity (2019).

Research Ethics Review for Postgraduate Research Student and Staff Research Projects

Postgraduate Research and Staff projects are reviewed by the College Research Ethics Committee. This is facilitated by a browser-based online ethics system that also maintains records of research ethics approvals. Upon entering the online system researchers are faced with the first of potentially two system webpages of questions that solicit binary tick box answers formulated upon a risk-based approach to research ethics.

Depending upon the answers that are given by the researcher, the online system may determine that the project is of a risk level that requires no further information beyond the first page. Subsequently, the system will offer the researcher the option to finish their involvement with the system and sign a ‘Self Assessment’ form for their research. However, the researcher's answers may indicate to the system that further information is required. As such, a second system webpage with additional, more detailed questions will be generated.

This second system webpage includes additional binary tick-box questions as well as text boxes to provide information about how the researcher plans to mitigate the risks associated with their research. After completing the second system webpage the researcher is asked to provide any relevant supplementary documentation (participant documents, data management plans, data sharing agreements, health and safety risk assessments), and to choose whether they wish to 'Self Certify' their research ethics, or submit for full review by Royal Holloway's Research Ethics Committee.

Self certified projects are not reviewed by parties other than the researcher and their supervisor (if the researcher is a postgraduate research student). If the researcher chooses to 'self certify' their project they can therefore commence their project immediately after doing so. However, self certify projects are subject to audits during the termly Research Ethics Committee meetings, to mitigate the risk that effective research ethics protocols and risk mitigations have not been put in place. If it is identified that a project does not have effective research ethics protocols and risk mitigations in place, the Committee reaches out to the researcher to advise how the project can be amended. Self-certified research should therefore have detailed descriptions of the risks involved in the research, should detail effective strategies for mitigating those risks, should include the right supplementary documentation, and should therefore operate in the spirit of the Concordat to Support Research Integrity (2019).

If the researcher decides to submit their research ethics application there is a multistage process to review:

1. Research & Innovation: The request for full review triggers a notification to Royal Holloway's research ethics mailbox that indicates that a project has been submitted for review. A member of Research & Innovation delegated the role of Ethics Secretary to the Research Ethics Committee monitors the research ethics mailbox and undertakes initial reviews of research ethics applications. They identify whether the research complies with Royal Holloway compliance commitments to safeguarding, health and safety, and data management, and whether there is sufficient information for academic peer reviewers to provide a review. This
includes information within the application itself and additional documents. The ethics secretary then forwards the application to academic reviewers through the online ethics system when they believe that the application is ready to be reviewed. This may mean that they liaise with the researcher to update their application before doing so.

2. Academic Peer Review: The member of Research & Innovation forwards the research project to an academic peer reviewer (preferably with expertise in the field of the researcher). The reviewer is provided with the option to provide feedback and/or sign off, and is asked whether the project is of a risk level that warrants a second reviewer. If the reviewer provides feedback that requests updates to the project prior to being signed off, the ethics secretary liaises with the researcher to update the application and return to the first reviewer, all the time maintaining the anonymity of the reviewer to the researcher. If the first reviewer indicates that they are happy with the project they will then either sign off or sign off and pass to a second reviewer. The process of review will then be repeated with the second reviewer.

3. Research Ethics Committee Approval: When a project has been approved by the academic peer reviewer/s, the ethics secretary will then send to a ‘Chair-delegate’, delegated responsibility for approving ethics applications. When the research ethics application has been approved by the Chair-delegate, the researcher will receive a notification through the online ethics system informing them of this.

Research Ethics Amendment Requests for Postgraduate Research Student and Staff Research Projects

The Research Ethics Committee recognises that projects may need to change, and it encourages researchers to reflect upon their design of their research once it has commenced. However, it is important for Royal Holloway that there is review process and method of recording these changes.

To request an amendment, postgraduate research students and staff researchers are required to complete an amendment request form and email to Research and Innovation via the research ethics inbox. This document amendment request form needs to detail each proposed change, and if any supplementary documents (such as participant documents) need to be changes, these need to be submitted with track changes, so that the reviewer can identify the proposed changes. Researchers are also required to justify the changes. As with ethics applications, amendment requests must be approved before researchers can use their updated research design or materials.

To facilitate the approval of amendment requests in the most effective manner, minor and major amendments are distinguished. Minor amendments are reviewed and approved by Research and Innovation and can take up to three working days, whereas major amendments are forwarded by Research and Innovation to the Chair of the REC. As with ethics application approves, the timeframe for approving major amendment requests is up to three weeks. Minor and major amendments are distinguished according to the following:

Minor Amendments

- Amendment to research methods that mean that the project operates at the same or lower level of risk
- Minor textual errors, e.g. correcting errors, updating contact points, minor clarification
- changes in funding arrangement
- changes to contact details for the chief/principal investigator or other study staff
- extension of the study beyond the period specified in the application form
- changes to the research team (excluding the Principal Investigator), subject to confirmation of additional researchers having undertaken appropriate training in research ethics

Major Amendments

- changes to the design or methodology of the study, or to background information affecting its academic value (including addition of participants)
- changes to the procedures undertaken by, or other requirements expected of, participants (including any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study)
• significant changes to study documentation such as protocol, participant information sheets, consent forms, questionnaires, letters of invitation, information sheets for relatives or carers
• appointment of a new chief/principal investigator
• change of territory for international studies
• temporary halt of a study to protect participants from harm (or resulting from a concern or complaint made), and the planned restart of a study following a temporary halt
• any other significant change to the terms of the REC application
Proposed Phased Updates to Annex A

**Phase 1: Now – Term 1 (September) 2023**

- The implementation of the research ethics risk framework recommended by 2021 Task & Finish group.
- The implementation of the following triage system, on the basis of the recommendation of the 2021 Task & Finish group:

| Triage System Proposed by 2021 Task & Finish Group |
|---------------------------------|--------------------------------------------------|
| Low Risk                         |                                                   |
| UG/PGT Research                  | 1 Review/Approval by Academic (Dissertation Supervisor / Module Convener, etc., with School Ethics Officer Providing Support) |
| PGR/Staff Research               | 1 Review/Approval by College Research Ethics & Integrity Manager |
| Medium Risk                      |                                                   |
| All Researchers                  | 1 Review by College Research Ethics & Integrity Manager |
|                                  | 1-2 Reviews by REC reviewers (Depending upon use of Approved Mitigations) |
|                                  | 1 Approval by Research Ethics Committee Chair / Chair-delegate |
| High Risk                        |                                                   |
| All Researchers                  | 1 Review by College Research Ethics & Integrity Manager |
|                                  | 2 Reviews by REC reviewers |
|                                  | 1 Approval by Research Ethics Committee Chair / Chair-delegate |

- Greater steer from College in recommending that undergraduate and postgraduate taught research should be low risk.
- Scope of routine class-based research determined in advance by class convener as suggested by the 2021 Task & Finish Group.

**Phase 2: Term 1 (September) 2023 – Term 1 (September) 2024**

- Removal of option to Self Certify.
Annex D: Research Conducted with the NHS

Research involving NHS patients, staff, premises, resources (pharmacy, radiology or laboratories) or data/tissue in England is required to go through the Health Research Authority’s (HRA) approval process. Royal Holloway provides sponsorship for these projects but not ethical review.

The HRA have created a decision tool and a student-specific research toolkit to help researchers confirm whether they need to pursue NHS REC approval, and this is communicated to researchers via the ethics intranet page. If researchers do require NHS REC approval they are required to complete an application using the Integrated Research Application System (IRAS). The HRA provides detailed guidance on the process and how to apply.

NHS REC Review

For most applicants to the HRA, review by NHS Research Ethics Committees form part of the overall HRA Approval process. For some projects that do not require HRA Approval NHS REC review may still be required.

Royal Holloway Sponsorship

The HRA stipulates for its approval process that research should have a sponsor, taking on overall responsibility for proportionate, effective arrangements to be in place to set up, run and report a research project. Researchers are required to request sponsorship from Royal Holloway by submitting their HRA and/or NHS REC ethics documents, plus a completed Royal Holloway confirmation form, to Research and Innovation. Confirmation of sponsorship will be returned in the form of an email. For research involving a clinical trial of an investigational medicinal product (CTIMP), the UK Policy Framework requires that there should be a designated UK legal representative of the lead sponsor (or any co-sponsor). The sponsor is responsible for ensuring that a clinical trial complies with the legislation and GCP.

If amendments need to be made to a research project, Royal Holloway will need to again confirm sponsorship of the amended project.

Research passports

To acquire a research passport, PhD researchers are to contact the doctoral school and staff researchers are to contact HR.

Doctorate in Clinical Psychology (DClinPsy)

For students undertaking work with the NHS for the Doctorate in Clinical Psychology (DClinPsy), sponsorship is signed off by the programme’s Research Director.
Annex E: Human Tissue Act Process

The Human Tissue Act 2004 repealed and replaced the Human Tissue Act 1961 (in England and Wales). The Act makes it unlawful to remove, store or use human tissue from the living or deceased without consent to do so for specified health-related purposes or public display, and is punishable by a fine and/or 3 years' imprisonment. In addition, there are a number of activities in the Act that require a license from the Human Tissue Authority before they can be lawfully undertaken.

The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes (such as research, transplantation, and education and training) set out in the Human Tissue Act. In order to carry out research that leads to human benefit, Royal Holloway and New Bedford College uses and stores tissue that falls within the remit of the HTA. The College therefore has obligations under the Human Tissue Act.

The definition of relevant material in the Human Tissue Act 2004 (excluding human application) is:

**Section 53: Relevant Material:**

1. *In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.*

2. *In this Act, references to relevant material from a human body do not include:*

   (a) embryos outside the human body, or
   (b) hair and nail from the body of a living person. (Human Tissue Authority)

To supplement the HTA's broader policy framework on relevant material, a list has been produced to provide stakeholders with guidance on whether specific materials fall within the definition of relevant material under the Human Tissue Act. Please see the supplementary list of materials for the purposes of the Human Tissue Act.

The College has a licence from the HTA to store human tissue samples for research purposes. However, you are still required to seek ethical approval for each project via the NHS HRA (Health Research Authority) REC (Research Ethics Committee) and to keep the College Ethics Committee informed as this progresses by seeking College approval in parallel. An HTA licence on its own does not permit the 'use of tissue for research or approve an individual research project or clinical trial'.

Not all human tissue requires a licence. If the tissue comes from living people and there is project specific approval from a recognised REC, then you are allowed to store the material for the duration of that specific project. Material (tissue or primary cells) not used must be appropriately destroyed at the end of the project.

In either case, seek guidance from the Designated Individual (College employee responsible for oversight of compliance with the terms of the licence, BSO@rhul.ac.uk)

**Further guidance**

- HTA legislation
- HTA guiding principles
- Post-mortem examinations
- Research
- Human Tissue Act 2004
Annex F: Research Involving Animals

Information on projects involving animals is relayed from Royal Holloway’s delegated Named Animal Care & Welfare Officer (NACWO) to the national Animal Welfare and Ethical Review Body (AWERB). The AWERB discusses and authorises as appropriate. Non-regulated research is logged in the College register of non-regulated animal research. Research on protected animals undergoes AWERB and Home Office review. Deliberations take place at AWERB meetings by e-mail exchange between meetings, and deliberations and decisions are logged in meeting minutes.