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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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 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.

*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:
  o 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.
  o 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.
  o 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.
  o 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

<table>
<thead>
<tr>
<th>Policy Owner <em>(usually Director-level)</em></th>
<th>Sue Starbuck</th>
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<tbody>
<tr>
<td>Operational Owner <em>(where different to policy owner)</em></td>
<td>Sue Starbuck / Leisha Wickham / John Francis</td>
</tr>
<tr>
<td>Approving Body</td>
<td>Academic Board</td>
</tr>
<tr>
<td>Approved on</td>
<td>TBC (16 March 2022)</td>
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<tr>
<td>To be reviewed before</td>
<td>December 2024</td>
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**Version History**

<table>
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<tr>
<th>Version (newest to oldest)</th>
<th>Date of approval</th>
<th>Summary of changes</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>TBC (16 March 2022)</td>
<td>N/A</td>
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Annex A: Review Process

Research Ethics at Royal Holloway are reviewed through internal and external review processes. This annex describes Royal Holloway’s current internal research ethics review processes, updates that are to be implemented by September 2022, and references to updates that have been planned for a project to revise Royal Holloway’s research ethics review processes and systems (between 2022 and September 2024). The review processes were initially proposed by a Task & Finish group review into research ethics review processes at Royal Holloway that convened and reported in 2021 and which have been subsequently developed through meetings of the Research Ethics Committee (REC).

1. Research Ethics Review of Undergraduate and Postgraduate Taught Student Research Ethics

It is the responsibility of Departments and Schools to review and record the research ethics applications of Undergraduate and Postgraduate Taught students. The REC provides guidance to Departments and Schools upon request, for instance when projects are above the Low / Medium Risk threshold, and Research & 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.

2. Research Ethics Review of Postgraduate Research Student and Staff Research Ethics

It is the responsibility of the College Research Ethics Committee to review and record the research ethics applications of Postgraduate Research Students and Staff projects.

Researchers are required to submit research ethics applications via Royal Holloway's browser-based Online Ethics System. Upon entering the online system researchers are faced with compulsory questions, and depending upon how they answer these questions they will either be given the option to:

- Receive a ‘Self Assessment’ form for their research, or;
- Be directed to a second page where more detailed questions are presented.

At the conclusion of this page researchers are presented with an option to either:

- ‘Self Certify’ their application; or,
- Send their application for ‘Full Review’ by Royal Holloway’s Research Ethics Committee.

2.1. Self Certified Applications

Self certified projects are not forwarded for review by either Research & Innovation or academic reviewers. 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 at the termly Research Ethics Committee meetings to mitigate the risk that effective research ethics protocols and risk mitigations have not been put in place. The Committee reaches out to the researcher if an application has not:

a) indicated that it has considered the risks involved with the research;

b) put in place robust mitigations for those risks; or,

- included the appropriate supplementary documentation.

The applications and documentation for self-certified research should therefore be of a very high standard. If a researcher is unsure as to whether their application can be self certified it is recommended that they submit their application for full review.

2.2. Fully Reviewed Applications

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

1. Initial Review by Research & Innovation: A request for full review via the Online Ethics System triggers a notification to Royal Holloway’s research ethics mailbox. Research & Innovation undertake an initial review to identify whether research complies with essential Royal Holloway compliance commitments to safeguarding, health and safety, and data management, and whether there is sufficient information for academic peer review. When Research & Innovation
conclude that an application is ready it is then forwarded through the Online Ethics System to an academic peer reviewer (preferably with expertise in the field of the researcher). In addition, Research & Innovation ask the reviewer to use their expertise to state whether the research is of a risk level that warrants a second review from an additional academic reviewer.

2. **Academic Peer Review**: An academic peer reviewer reviews the application and either (a) signs off on the application, (b) signs off on the application but requests an additional reviewer, or (c) provides feedback that requests that the applicant update the application prior to (a) or (b). If the reviewer provides feedback that requests updates to the project prior to being signed off, Research & Innovation liaises with the applicant to update the application, maintaining the anonymity of the reviewer.

3. **Research Ethics Committee Approval**: Upon sign off by academic peer reviewer(s), Research & Innovation sends the application to a 'Chair-delegate' to provide final approval for the application. When the research ethics application has been approved by the Chair-delegate, a notification will be triggered through the Online Ethics System to the researcher that informs them that their application has been approved and that they may commence their research.

3. **Updates to be implemented 1 September 2022**

i. The review process is to be guided by a greater emphasis upon a risk-based approach

ii. The adoption of the below new review triaging structure for the reviewing of applications submitted for Full Review to the Online Ethics System by Postgraduate Research Student and Staff. (Applications submitted to the Online Ethics System by Postgraduate Research Student and Staff via the Self Certify route will remain outside the scope of a risk-based approach to review).

iii. All applications – for Undergraduate, Postgraduate Taught, Postgraduate Research and Staff projects – will be reviewed using the new risk-based review framework (Annex B).

**New Review Triaging Structure**

The 2021 Task and Finish group proposed the implementation of review processes that would be underpinned by a risk-based review framework. The review triaging structure will be implemented through a phased approach during the project to revise Royal Holloway’s research ethics review processes and systems (2022-2024). A project is currently underway to assess the implications of the review processes that were proposed and, as such, a new review triaging structure will be implemented without the following recommendations from 1 September 2022:

i. The recommended review process for routine class-based research.

ii. The incorporation of the review of Undergraduate and Postgraduate Taught research within a College-wide system, and reviewing of Low Risk research by supervisors.

iii. Schools based review processes for Medium Risk research, facilitated by Schools-based Ethics Officers.

iv. The removal of the option to Self Certify applications.

To accommodate the absence of these components the following temporary measures are to be implemented:

i. Responsibility for reviewing routine class-based research and Undergraduate and Postgraduate Taught research to remain with Schools and Departments

ii. Risk-based review framework to be communicated to reviewers of all research ethics applications (Undergraduate and Postgraduate Taught students, and Postgraduate Research students and Staff).

iii. Postgraduate Research students and Staff applicants will retain responsibility for deciding whether to Self Certify applications or submit for Full Review.

iv. Medium Risk Postgraduate Research Student and Staff research will, as with High Risk research, be reviewed through the REC.
From 1 September the processes for reviewing Medium and High Risk research will therefore remain essentially the same (see below). This distinction between Medium and High Risk is to be implemented, however for the reasons that justify the role of the risk-based review framework (Annex B). Namely, to:

i. help to characterise the level of risk of a research project.
ii. implement more proportionate, efficient and timely review processes; and

4. Supplement research ethics application audit data with the category of risk.

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Review Stage</th>
<th>Review Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td>1</td>
<td>1 Review and Approval by Research &amp; Innovation, with consultation of REC reviewers should a project be deemed at the boundary of Low Risk and Medium Risk.</td>
</tr>
<tr>
<td>Medium Risk</td>
<td>1</td>
<td>1 Review by Research &amp; Innovation (to identify whether a project has the materials that enable reviews by REC reviewers to take place)</td>
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<td></td>
<td>2</td>
<td>1-2 Reviews –conducted by REC reviewers. (See Annex C – the implementation of Approved Mitigation Protocols. That, if implemented, Approved Mitigation Protocols may justify the reduction of the number of REC reviewers deemed necessary from two to one).</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>1 Approval by Research Ethics Committee Chair / Chair-delegate</td>
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<tr>
<td>High Risk</td>
<td>1</td>
<td>1 Review by Research &amp; Innovation</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>2 Reviews – conducted by REC reviewers</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>1 Approval by Research Ethics Committee Chair / Chair-delegate</td>
</tr>
</tbody>
</table>

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

The Research Ethics Committee encourages researchers to reflect upon the effectiveness and appropriateness of their research methods after it has commenced. However, as with new research ethics applications it is important that any changes are appropriately and proportionality reviewed.

Royal Holloway stipulates that postgraduate research students and staff researchers are required to complete an ‘amendment request form’ and email this to Research & Innovation via ethics@rhul.ac.uk. This design of the amendment request form is intended to describe and justify the proposed amendments in sufficient detail. If any supplementary documents need to be amended (for example participant documents), these need to be submitted with track changes, so that these can be easily identified by the reviewer. As with ethics applications, amendment requests must be approved before researchers can use their updated research methods or materials.

To facilitate the approval of amendment requests in a proportionate 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 reviewed by an academic peer reviewer or Chair-delegate. 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**

a) Amendment to research methods that mean that the project operates at the same or lower level of risk
b) Minor textual errors, e.g. correcting errors, updating contact points, minor clarification
c) changes in funding arrangement
d) changes to contact details for the chief/principal investigator or other study staff
e) extension of the study beyond the period specified in the application form
f) 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
Annex B: Research Ethics Review Framework

This annex describes a proposed Research Ethics Risk Framework that is to be implemented in September 2022. This annex was developed by an academic-led Task & Finish group review into research ethics review processes at Royal Holloway that convened and reported in 2021.

The Task & Finish group acknowledged that it is impossible to anticipate all the risks associated with research. Nonetheless, the group identified the potential of a risk-based review framework to:

i) help to characterise the level of risk of research projects.
ii) implement more proportionate, efficient and timely review processes; and
iii) supplement research ethics application audit data with the category of risk.

This framework was created in consultation with guidance from professional bodies and processes adopted by other Higher Education Institutions but, as with those guidance and standards, it was written as an iterative document that is to be subject to ongoing review. The REC subsequently decided that the framework, once implemented on 1 September 2022, will be subject to review every six months.

This framework makes reference to 'Mitigation Protocols' that may lower the risk attributed to a project should they be implemented by researchers, some of which are labelled 'TBC'. For further information about the Research Ethics Committee’s plans for developing Mitigation Protocols see Annex C.

<table>
<thead>
<tr>
<th>Risk</th>
<th>Suggested Risk Level</th>
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**Research with risks to researchers or research collaborators:**

<table>
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<tr>
<th>1.1.</th>
<th>Medium</th>
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<tr>
<td>If involves:</td>
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<tr>
<td>• Research into literature and imagery that has the potential to generate secondary trauma in the researcher.</td>
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<tr>
<td>• Fieldwork or lab-based work that is at the lower threshold of health and safety risk (as determined by Risk assessment produced with Department or School-based Health &amp; Safety Co-ordinator)</td>
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<tr>
<td>• Research that blurs the line between the researcher’s identity as researcher and an identity as participant in social media (Twitter, Facebook, Reddit, etc.)</td>
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<tr>
<th>1.2.</th>
<th>High</th>
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<tr>
<td>If also includes:</td>
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<tr>
<td>• Significant risks to the physical safety (as determined by Risk assessment produced with Department or School-based Health &amp; Safety Co-ordinator)</td>
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<tr>
<td>• Interacts with social media forums that have evidenced illegal activities or the possibility of conducting illegal activities, thus posing legal implications for the researcher; and evidenced the targeting of individuals on the basis of identity (for example trolling, racism, misogyny, political views), and which may lead to the researcher receiving unsolicited negative attention.</td>
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<tr>
<td>• Substantial risk of negative attention due to research outputs.</td>
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**Research involving ‘at risk’ participants:**

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<thead>
<tr>
<th>Involving infants or children under 16 years of age</th>
<th>2.1.1.</th>
<th>Medium</th>
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<tbody>
<tr>
<td>If limited to:</td>
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<tr>
<td>• Research that implements approved mitigations (for e.g. opt-out consent for research in schools)</td>
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2.1.2. If includes:
- Research that goes beyond approved mitigations
- Research that takes place outside of school, e.g. children’s’ homes, or RHUL laboratories
- Tasks that children would not do as part of normal everyday activities

<table>
<thead>
<tr>
<th>2.2. Other ‘at risk’ participants:</th>
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<tbody>
<tr>
<td>2.2.1. Participants who may not be able to provide informed consent, may be at risk of losing the ability to provide informed consent, or have a fluctuating ability to provide informed consent.</td>
</tr>
<tr>
<td>2.2.2. Participants who have from mental health conditions that would mean that they have an ability or fluctuating capacity to provide informed consent may fluctuate.</td>
</tr>
<tr>
<td>2.2.3. Participants who may have only a basic or elementary knowledge of the language in which the research is being conducted, and when there is a strong possibility that individuals will be unfamiliar with their rights as research participants and ethical research.</td>
</tr>
<tr>
<td>2.2.4. Participants who are at risk of criminal prosecution.</td>
</tr>
<tr>
<td>2.2.5. Participants who may not be in a position to exercise unfettered informed consent due to social conditions, such as members of the armed forces, young offenders, prisoners, asylum seekers.</td>
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</table>

All other research involving participants

<table>
<thead>
<tr>
<th>3.1. Data Management</th>
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<tbody>
<tr>
<td>3.1.1. Includes the management, however brief, of personal or identifiable data (name, identification number; location data; and an online identifier), or special category GDPR data as determined by the Information Commissioner’s Office (ICO). UK GDPR defines special category data as:</td>
</tr>
<tr>
<td>- personal data revealing racial or ethnic origin</td>
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<td>- personal data revealing political opinions</td>
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<tr>
<td>- personal data revealing religious or philosophical beliefs</td>
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<td>- personal data revealing trade union membership</td>
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<tr>
<td>- genetic data</td>
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<tr>
<td>- biometric data (where used for identification purposes)</td>
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<td>- data concerning health</td>
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<tr>
<td>- data concerning a person’s sex life</td>
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<tr>
<td>- data concerning a person’s sexual orientation</td>
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</table>
In addition to managing identifiable data or special category data, poses the additional risk of significant negative ramifications for participants (e.g. data about personal circumstances, of an employer, discussion of commercially sensitive information, discussion of patient with clinicians) | High

| 3.2. Observation | Research involving observation, either in person (fieldwork, such as museums) or online (social media), but which does not collect or manage personal or identifiable data, or special category GDPR data, as determined by the Information Commissioner’s Office (ICO). | Low |

| 3.3. Internet-mediated research | **3.3.1.** Research that scrapes identifiable data from the social media posts of public figures (politicians, civic actors, prominent profiles in the media, celebrities), who might be assumed to have a greater awareness of the dissemination of the content that they produce. | Low |

|  | Research that scrapes identifiable data from social media (Twitter, Facebook, Tiktok, etc). Although in the public domain, it is doubtful that the individual would expect or wish their identifiable data to be viewed and disseminated without their consent (for example, the posts are posted by private figures). In addition, the data that is scraped are content deleted by the individual but stored elsewhere, or ‘fleets’, posted via Snapchat, Facebook, Instagram. | Borderline Medium/High |

|  | If the data goes through the mitigating process of anonymisation/pseudonymisation the project may be assessed as Medium risk (Mitigation TBC). | Borderline Medium/High |

| 3.3.4. | Research into social media content that: | High |

|  | • Evidences illegal activities or the possibility of conducting illegal activities. | |

|  | • Evidences the targeting of individuals on the basis of identity (for example trolling, racism, misogyny, political views). | |

| 3.4. Does the research involve deception? | **3.4.1.** Very unlikely to lead to adverse effects for participants and/or researchers | Low |

|  | 3.4.2. Could possibly lead to adverse effects for participants and/or researchers | Medium |

| 3.4.3. | Likely to lead to adverse effects for participants and/or researchers | High |

| 3.5. Other potential consequences for participants: | 'Labelling': Research that may lead to the ‘labelling’ of participants, either by the researcher (e.g. categorisation), or by the participant themselves (e.g. ‘I am stupid’, ‘I am not normal’). Review may also be dependent upon implementation of approved mitigations (Mitigations TBC). | Borderline Medium/High |
### 3.5.1. Psychological stress, anxiety or humiliation or cause more than minimal pain, at any stage of participation or after (e.g. repetitive or prolonged testing).

**High**

### 3.5.2. Invasive interventions (such as the administration of drugs or other substances, vigorous physical exercise or techniques such as fMRI, hypnosis) that would not usually be encountered during everyday life.

**High**

### 3.6. With family members

| e.g. sociology, oral history, creative arts. | Medium |

### 3.7. With significant power relations that are in addition to the research process (for e.g. parent/guardian and child, teacher and pupil).

#### 3.7.1. Research that implements approved mitigations (Mitigations TBC).

**Medium**

#### 3.7.2. Research that goes beyond approved mitigations (Mitigations TBC).

**Borderline Medium/High**

### Other Research Aspects

#### 4.1. Secondary Data Analyses: Research with third party datasets can be more sensitive upon closer inspection. Research with third-party datasets, including publicly accessible datasets:

- Has the potential to expose researchers and Royal Holloway to accusations of complicity with research that was collected in an unethical manner.
- May involve restrictions upon the how these datasets can be engaged with. For instance, that subjects had consented to the use of their data for specific purposes, researchers, and organisations, and that it may not be deemed reasonable that they had consented to their data being used for the new research (hence requiring additional consent).

May require data sharing agreements to be in place before these datasets can be accessed (e.g. IP considerations), with failure to do so potentially leading to significant legal and reputational consequences for the researchers, collaborators, and Royal Holloway.

**Medium**

#### 4.2. Cultural, heritage, or archaeological consequences: Research that removes, can potentially affect cultural or archaeological artefacts, or have cultural ramifications for a community (for e.g. Cultural insensitivities)

**High**

#### 4.3. Environmental consequences: Research that poses risks to the environment or to a community living in the researched environment. For e.g., research that affects an environment, or removes geological or sedimentological samples.

**High**
| 4.4. | **Private or Government Property:** Research undertaken on private or government property without permission. | High |
| 4.5. | **Animals:** Research involving animals needs to be discussed with Royal Holloway’s Named Animal Care and Welfare Officer, via [NACWO@rhul.ac.uk](mailto:NACWO@rhul.ac.uk), to ensure your proposed work fully complies with the Animals (Scientific Procedures) Act 1986, including required licensing and scrutiny procedures. | High Contact NACWO |
| 4.6. | **Human Tissue.** Research involving human tissue needs to be discussed with the ‘Designated Individual’ at College to ensure compliance with the Human Tissue Act. Contact [bso@rhul.ac.uk](mailto:bso@rhul.ac.uk) | High Contact D.I. |
Annex C: Mitigating Risks

Guidance for Mitigating Risks

As with Annex B, the risk-based review framework, it is impossible to predict all mitigations for the risks associated with research but recommended guidance on mitigating risks can help to:

a) communicate best practice to mitigate risks associated with research;
b) provide researchers with guidance that can help them to consider and describe the risks of their research and the mitigations for those risks within their research ethics applications;
c) provide a more efficient research ethics review process.

As such, Research & Innovation and the Research Ethics Committee commits to proactively developing mitigation guidance and publishing via appropriate channels (the Research Ethics intranet page, training, and other communications).

Approved Mitigation Protocols for Medium to High Risk Research

Research & Innovation and the Research Ethics Committee are committed to creating Approved Mitigation Protocols. These protocols are intended to:

a) facilitate institutional approval for research that would otherwise raise prohibitive risks for researchers, collaborators, research participants, and Royal Holloway by stipulating the implementation of certain mitigations;
b) reduce the level of risk attributed to a research project, making for a more efficient review process;
c) reduce the number of academic peer reviewers deemed necessary for a review process.

At present one Approved Mitigation Protocol has been established, Approved Mitigation Protocol 01 (AMP01). This protocol a) stipulates mitigations that researchers agree to implement in order to use Opt-Out consent with children; b) lowers the level of risk attributed to the project to Medium Risk; and c) lowers the number of academic peer reviewers deemed necessary from two to one.
Annex D: Research Conducted with the NHS

HRA Approval

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. The HRA have created a decision tool and a student-specific research toolkit to help researchers confirm whether they need to pursue NHS REC. For most applicants to the HRA, review by the NHS Research Ethics Committees forms part of the overall HRA Approval process.

For projects that do not require NHS REC approval, once you have obtained an NHS approval number, please submit an application via the online ethics system and upload copies of the submitted forms and approval confirmation.

NHS REC Review

If researchers 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.

Once you have obtained an NHS REC approval, please submit an application via the online ethics system and upload copies of the submitted IRAS forms and approval confirmation.

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.

Please note that Royal Holloway provides sponsorship for these projects but not ethical review, Institutional ethical review may still be required.

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 2004.

Institutional process

For any project involving human tissue, in the first instance researchers are required to seek guidance from the Designated Individual (College employee responsible for oversight of compliance with the terms of the licence, who is also the Biological Safety Advisor, BSO@rhul.ac.uk). The Biological Safety Officer (BSO) will require a summary of your project and will advise on what steps need to be taken.

Researchers will need to seek ethical approval for each research project via the NHS HRA (Health Research Authority) and via the online ethics system.

Human Tissue Act licence

The College has a licence from the HTA to store human tissue samples for research purposes. An HTA licence on its own does not permit the ‘use of tissue for research or approve an individual research project or clinical trial’. The situation is complex. For example, 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. However, we need to ensure that such material is stored and destroyed appropriately. It is essential that the BSO is consulted before any such project starts to advise on measures to be taken.

Further guidance

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

When an application submitted via the online ethics indicates that the project involves animals a notification is sent to Royal Holloway's delegated Named Animal Care & Welfare Officer (NACWO).

If you have not made a submission via the online system, you must contact the NACWO directly.

Researchers will asked to provide a summary of their project, where an assessment will be made whether a Home Office licence is required under the Animals (Scientific Procedures) Act, 1986.

The Animal Welfare Ethical Review Board (AWERB) discusses and authorises as appropriate. Non-regulated research is logged in the College register of non-regulated animal research. Regulated research on protected species undergoes AWERB and Home Office review. Deliberations take place at AWERB meetings and by e-mail exchange between meetings, and deliberations and decisions are logged in meeting minutes.

Once you have obtained approval from AWERB and or a Home Office licence, completed forms should be sent to ethics@rhul.ac.uk, to be uploaded to your approved online submission.