College Research Ethics Policy

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[1] 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.

[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-Principle for Research has overall responsibility for research ethics and integrity at Royal Holloway. The Senior Vice-Principle 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
- 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 Universal Declaration of Human Rights 1948 (see http://www.un.org/en/documents/udhr/
- 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

Policy Owner *(usually Director-level)*	Sue Starbuck
Operational Owner *(where different to policy owner)*	Katherine Poole / Leisha Wickham
Approving Body	Academic Board
Approved on	TBC (16 March 2022)
To be reviewed before	December 2024

Version History		
Version (newest to oldest)	Date of approval	Summary of changes
1.3	June 2025	Updates to links in Related College policies and processes.
1.2	March 2024	Annex A: updated to reflect current processes in addition to style modifications. Annex B: updated to included revised framework and revisions to timelines. Annex C: updated to include additional approved protocols. Annex D: updated to include modifications to style of annex. Annex E: Expired links updated and modifications to style of annex.
1.1	January 2024	Updated Annex B following a review and amendments to the risk review framework
1	TBC (16 March 2022)	N/A

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,

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,
c) 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 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) provides a favourable opinion of the application, b) provides a favourable opinion of 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 an academic peer reviewer/s providing a favourable opinion, Research & Innovation sends the application to a 'Chair-delegate' to provide concluding favourable opinion for the application. When the research ethics application has been provided with a favourable opinion approved by the Chair-delegate, a notification will be triggered through the Online Ethics System to the researcher that informs them of the outcome of their application and that they may commence their research.

3. ***Reviewing against the framework***

- The review process is to be guided by a greater emphasis upon a risk-based approach
- 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).
- All applications – for Undergraduate, Postgraduate Taught, Postgraduate Research and Staff projects – will be reviewed using the new risk-based review framework (Annex B).

4. Triaging Structure

Responsibility for reviewing routine class-based research and Undergraduate and Postgraduate Taught research to remain with Schools and Departments. Reviewers of all research ethics applications (Undergraduate and Postgraduate Taught students, and Postgraduate Research students and Staff). are to review against the Risk-based review framework. Postgraduate Research students and Staff applicants will retain responsibility for deciding whether to Self Certify applications or submit for Full Review. Medium Risk Postgraduate Research Student and Staff research will, as with High Risk research, be reviewed through the REC. 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

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

Risk Level	Review Stage	Review Process
Low Risk	1	1 Review and Approval by Research & Innovation, with consultation of REC reviewers should a project be deemed at the boundary of Low Risk and Medium Risk.
Medium Risk	1	1 Review by Research & Innovation (to identify whether a project has the materials that enable reviews by REC reviewers to take place)
	2	1 Review –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).
	3	1 Approval by Research Ethics Committee Chair / Chair-delegate
High Risk	1	1 Review by Research & Innovation

	2	2 Reviews – conducted by REC reviewers
	3	1 Approval by Research Ethics Committee Chair / Chair-delegate

6. 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 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.
Amendment requests should be completed:

1. Where a change to the project affects the ethics of a project which has received a favourable opinion from the REC
2. Where changes alter the project in a manner where it no longer resembles the project that had received a favourable opinion.

It is important to note that whilst amendments may not impact the ethics of a project, you may need to complete other processes or notify other professional services to address changes that impact your research activity. Should you require changes to any supplementary documents (information sheets, consent forms, debrief sheets) please provide a copy of each document in .docx format with track changes enabled. This will make it much easier for the reviewer to identify the amendments being requested and how they change the documents.

Approval must be received prior to the commencement or continuation of the project. Amendments are distinguished between Minor and Major Amendments. Minor amendments are reviewed approved by the Research Ethics Officer and can take up to a week. If the Research Ethics Officer decides that an amendment request constitutes a Major Amendment, it will need to be reviewed and approved by the Chair of the REC, who are given three weeks to review.

Examples of 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 clarifications
- Changes in funding arrangements
- 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.

Examples of 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 Review Framework which 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 year.

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.

Risk	**Suggested Risk Level**
1. Research with risks to researchers or research collaborators:	
1.1. If involves:	
• Research into literature and imagery that has the potential to generate secondary trauma in the researcher. • 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 & Safety Co-ordinator) • Research that blurs the line between the researcher's identity as researcher and an identity as participant in social media (Twitter, Facebook, Reddit, etc.)	Medium
1.2. If also includes:	
• Significant risks to the physical safety (as determined by Risk assessment produced with Department or School-based Health & Safety Co-ordinator) • 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 based on identity (for example trolling, racism, misogynism, political views), and which may lead to the researcher receiving unsolicited negative attention. • Substantial risk of negative attention due to research outputs.	High
2. Research involving 'at risk' participants:	
2.1. Involving infants or children under 16 years of age	
2.1.1.If limited to: • Research that implements approved mitigations (for e.g., opt-out consent for research in schools)	Low
2.1.2.If includes: • Research that goes beyond approved mitigations	Medium

• 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	
2.1.3. If research activity goes beyond risks detailed above?	High
2.2. Other 'at risk' participants:	
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.	Medium
2.2.2. 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.	
2.2.3. Participants who may not be able to exercise unfettered informed consent due to specific circumstances, such as members of the armed forces, young offenders, prisoners, asylum seekers.	
2.2.4. Participants who are at risk of criminal prosecution	High
3. All other research involving participants	
3.1. Data Management	
3.1.1.; Data is anonymised at the early ages of collection and identifiable data is destroyed	Low
3.1.2. Consent details management of data and include consent for future use of anonymised data	
3.1.3. Consent forms are kept in a secure safe space on campus	
3.1.4. Collect, manage or received anonymised data that is: • Safely secured. • Collected in the UK and EU. • Stored on servers in the UK and EU.	
3.1.5. Third party sources or software has been appropriately vetted	
3.1.6. Data shared will be anonymised	
3.1.7. Withdrawal process is compliant with data protection legislation personal, identifiable, sensitive, and special category data	
3.1.8. Identifiable data destroyed after transcription.	
3.1.9. Identifiable data for the purpose of withdrawn remains on campus throughout the research lifecycle and is destroyed once withdraw is no longer possible.	
3.1.10. If data has been pseudonymised by a third party but you are in receipt of only anonymised data and cannot reidentify the participants.	
3.1.11. Data is pseudonymised, identifiable data is kept separate to participant responses. Access to reidentifying data is limited to research leads (note: this risk can be reduced to low if researchers provide evidence that they have followed data management guidance in the researchers' guidance document)	Medium
3.1.12. Collect, manage or received pseudonymised, data that is: • Safely secured. • Collected in the UK. • Stored on servers in the UK.	
3.1.13. Collect, manage or received personal, identifiable, sensitive, and special category data is collected that is: • Safely secured.	

• Collected in the UK. • Stored on servers in the UK.	
3.1.14. Retaining identifiable data after transcription, which will be secured safety and not shared.	
3.1.15. Collect, manage or received personal, identifiable, sensitive, and special category data is: • shared with a third party. • collected outside of the UK. • shared outside of the UK. • 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
3.1.16. Data collected includes or references illegal or highly sensitive activities.	
3.1.17. In receipt of identifiable data from a third party	
3.1.18. Identifiable data can be linked to responses	
3.1.19. The 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)	
3.1.20. Identifiable data retained for the purpose of future use.	
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
3.3.2. Research that scrapes identifiable data from social media (Twitter/X, Facebook, Tiktok, etc). Although in the public domain, it is doubtable 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.	Medium
3.3.3. If the data goes through the mitigating process of anonymisation/pseudonymisation	
3.3.4. Research into social media content that: • Evidences illegal activities or the possibility of conducting illegal activities. • Evidences the targeting of individuals based on identity (for example trolling, racism, misogyny, political views).	High
3.4. Does the research involve deception?	
3.4.1. Very unlikely to lead to discomfort, anger or objections from the participants.	Low

3.4.2. Could lead to discomfort, anger or objections from the participants.	Medium
3.4.3. Highly likely to lead to discomfort, anger or objections from the participants.	High
3.5. Other potential consequences for participants:	
3.5.1. Labelling': Research that may lead to the 'labelling' of participants, if shared or revealed outside of the research team or published	Medium/High
3.5.2. 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
3.5.3. Invasive interventions (such as the administration of drugs or other substances, vigorous physical exercise or techniques such as, hypnosis) that would not usually be encountered during everyday life.	High
3.6. Indirect impact on others	
There is a possibility that during the course of the research activity a consenting research participant may reference or expose individuals who are not aware of nor have consented to participate in the research activity	Medium
3.7. With significant power relations that are involved in recruitment as part of the research process (for e.g., parent/guardian and child, teacher and pupil, employer and employee, lecturer and student).	
3.7.1. The research participants rights are upheld in line with good research practice and the principles pf the concordat to support research integrity, participants should be informed that: • participation is voluntary. • participants are not pressured into participating, • Participants are not coerced or motivated by financial inducements, marked assessments course credits etc. • Participants have the right to decline their participation. • Participants can withdraw their data during an appropriate timeframe.	Medium
3.7.2. The research participants rights are not upheld in line with good research practice and the principles pf the concordat to support research integrity	High
4. 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:	
4.1.1. The researcher is accessing data in an archive from a recognised source such as the British Library	Low
4.1.2. The archival source has completed a screening process to remove data that may expose or identify a third party who did not consent to participate in the activity	
4.1.3. The researcher can confirm that the participant gave consent for re-use and the intended use of the data is in line with the consent provided.	
4.1.4. If in receipt data which has been anonymised.	

4.1.5. Has the potential to expose researchers and Royal Holloway to accusations of complicity with research that was collected in an unethical manner.	Medium
4.1.6. 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)	
4.1.7. 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	
4.2. Research Involving the Dark web, terrorism or extremism	
4.2.1. Research which involves observations of activity on the dark web, where the content and imagery that has the potential to generate secondary trauma in the researcher.	Medium
4.2.2. Research which involves direct activity (e.g., contributions to forums) via the dark web	High
4.2.3. Research which involves observations and sensitive subject areas such as terrorism and extremism	
4.3. 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
4.4. 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
4.5. Private or Government Property:	
Research undertaken on private or government property without permission.	High
4.6. Animals:	
Research involving animals needs to be discussed with Royal Holloway's Named Animal Care and Welfare Officer, via 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
4.7. Human Tissue:	
Research involving human tissue needs to be discussed with the Institutional 'Designated Individual' to ensure compliance with the Human Tissue Act. Contact 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

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.

Each protocols 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.

AMP01 Parent-Guardian Opt-Out Consent Protocol for Research in Schools and Other Childcare Settings

AMP02 Magnetic Resonance Imaging Unit

AMP03 Data Management Mitigation Protocols

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 1717 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.