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# HUMAN RESEARCH ETHICS POLICY

# VERSION CONTROL

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# PURPOSE AND SCOPE

# 1.1 Cardiff University is committed to protecting the safety, security, rights, and dignity of all those involved in research and to fostering an environment where research is conducted to the highest ethical standards.

# 1.2 This Policy is designed to support this commitment and to ensure that Human Research is conducted to the highest ethical standards. This Policy provides clarity on:

# the role and responsibilities of individuals, teams, and committees in ensuring the ethical conduct of Human Research at Cardiff University;

# the key principles that must underpin all Human Research; and

# the University’s requirements for the ethical review of Human Research projects.

# 1.3 This Policy also supports the University in adhering to the UK Concordat to Support Research Integrity, together with the terms and conditions of many research funders, which require employers of researchers to have clear policies on ethical review.

# 1.4 For the avoidance of doubt, the University is committed to rigorous and objective inquiry and supports its staff and students to pursue research in an environment that affirms academic freedom. This Policy is not intended to limit academic freedom and does not require the avoidance of potentially high-risk research. Instead, this Policy aims to ensure that proper consideration is given to the ethical issues and risks arising from Human Research and to ensure that these are managed appropriately.

# 1.5 This Policy applies to anyone planning or conducting Human Research under the auspices of the University. This includes, but is not limited to, members of staff and students planning or conducting Human Research at the University, including those conducting Human Research outside the University (but as part of their University role).

# 1.6 This Policy also applies to any persons not employed by the University but with permission to carry out Human Research within, or on behalf of, the University.

# All persons falling within the scope of this Policy (as set out above) are referred to hereafter as ‘Researcher’ or ‘Researchers’.

# DEFINITIONS

# 2.1 Human Research: For the purposes of this Policy, “Human Research” means Research involving Human Participants, Human Material or Human Data (as defined below).

# Research:

# The primary objective of research is the deepening and broadening of knowledge and understanding by expert, responsible and professional means, including the dissemination of results through a range of tailored outputs appropriate for the targeted audience.

# For the purposes of this Policy, any project which attempts to derive generalisable new knowledge or to transfer existing knowledge to new applications (including studies that aim to generate hypotheses, as well as studies that aim to test them) must be considered ‘Research’.

# The University acknowledges that it may sometimes be difficult to determine whether a specific activity is ‘Research’, particularly in light of the abundance of definitions used across the sector and the way in which a specific activity is funded or labelled locally. Pending the development of University-level definitions and guidance in this area, Researchers should seek advice from their School (Directors of Research are advisable) if they are unclear on whether a particular activity is ‘Research’.

# ‘Service Evaluation’ and/or ‘Audit’ activities will not usually constitute ‘Research’ for the purposes of this Policy. However, Research Ethics Committees may exercise their discretion to require that such activities are subject to ethical review, where appropriate.

# ‘Service Evaluation’ is an activity which seeks to assess how well an existing service is performing. The activity is designed and conducted with the sole purpose of defining or judging a current service. ‘Audit’ is an activity which usually involves a quality improvement cycle that measures performance against predetermined standards and recommends specific actions to improve performance.

# Human Participants

# For the purposes of this Policy, ‘Human Participants’ means:

* + 1. People who have been actively recruited to participate in (or have otherwise chosen to participate in) the Research and have provided their informed consent to do so. Examples include survey/questionnaire respondents, focus group and interview attendees, people who agree to be observed and people who undergo a test or procedure; and
		2. People who are the subjects of the research, regardless of whether they have provided informed consent and/or are aware that they have been part of a Research project (sometimes referred to as ‘Human Subjects’). Examples include ethnographic or observational studies and covert research where the people being observed/taking part might not realise and might not have provided informed consent.

# Human Material:

# For the purposes of this Policy, ‘Human Material’ means material that comes from the human body including:

# ‘Relevant Material’ for the purposes of the Human Tissue Act 2004 i.e. material that comes from the human body and contains or consists of human cells, including bodily fluids (e.g. saliva, blood and urine), waste products and solid sections of tissue;

# Other material not considered ‘Relevant Material’ but which has (or is being) collected directly from a human (alive or deceased); and

# Archaeological human remains[[1]](#footnote-2), including osteological material (whole or part skeletons, individual bones or fragments of bone and teeth), soft tissue, including organs and skin, embryos and slide preparations of human tissue.

# Human Data

# For the purposes of this Policy, ‘Human Data’ means:

# ‘Personal Data’ as defined by UK data protection legislation, namely any information relating to an identified or identifiable natural person i.e. a person who can be identified directly or indirectly by reference to an identifier such as a name, identification number, location data, online identifier or one or more factors specific to that person i.e. their physical, psychological, genetic, mental, economic, cultural, or social identity; and/or

# Other information collected directly from, or relating to, a specific human regardless of whether the information is anonymised;

# Notwithstanding the above definition, Research involving secondary or publicly available anonymised data only may be exempt from the University’s requirements for ethical review. Please see Section 4 for further detail. Even where ethical review is not required, Researchers proposing to conduct Research involving Human Data must still abide by the key principles of this Policy (see Section 3);

# Researchers need to be mindful of situations where their perceived use of anonymised data may actually amount to processing of ‘Personal Data’. For example, data will be considered Personal Data where Researchers have, or will likely gain access to, a key, or other means, that would enable re-identification of the individual to whom the data relates. Researchers will be deemed to have ‘access’ where the key to identify the individual(s) is held anywhere within Cardiff University. Further guidance on what constitutes ‘Personal Data’ is contained in the University’s ‘[Guide to GDPR and Research](https://intranet.cardiff.ac.uk/intranet/students/documents/Guide-to-GDPR-and-Research.pdf)’.

# 3. POLICY: KEY ETHICAL PRINCIPLES

# 3.1 For all Human Research, the safety, security, rights, and dignity of the participant must be the primary concern. This section confirms the overriding ethical principles that must underpin all Human Research, followed by a list of specific ethical considerations that Researchers must reflect on (where relevant to their project).

# Researchers must ensure that any Human Research they are proposing adheres to these overriding principles and has been designed with these principles (and the list of specific ethical considerations) in mind.

# SRECs are expected to scrutinise Human Research projects against these overriding principles (where ethical review of the project is required, or otherwise conducted).

# Overriding Principles

# Beneficence - The benefits of the Research must outweigh the risks; Research must be designed in a way that ensures the maximum benefit whilst minimising risk.

# Non-maleficence - Harm to those involved in, or affected by, Research must be avoided or minimised wherever possible. Researchers must conduct an appropriate risk assessment to identify and manage the risks posed to participants, and others involved in the Research.

# Autonomy – Participants must be treated as autonomous individuals and provided with an opportunity to give free and informed consent to participate in Research wherever possible. Any departure from this rule must be justified. As a general rule, participation in Research must be voluntary and participants must be free to withdraw their participation at any time without giving a reason, and without adverse consequences. Participants must be fully informed of what will happen to any data already collected from (or about) them if they choose to withdraw their participation; in some circumstances it will not be possible for Researchers to remove data already provided/collected, particularly if the data has been anonymised and/or published. It is therefore imperative that participants are given clear information about whether or not they can withdraw their data following participation and any limitations surrounding this.

# Confidentiality - The information given by participants must be respected and Personal Data must be processed in accordance with data protection legislation and as notified to the participant. Whilst anonymisation of Personal Data is encouraged where possible, this does not guarantee privacy and consequently all data must be stored securely and destroyed securely after the expiry of the relevant retention period set out in the University’s [Research Records Retention Schedules](https://www.cardiff.ac.uk/public-information/policies-and-procedures/record-management-policy-and-retention-schedules).

# Integrity – Researchers must be open about the way Research is conducted and must meet recognised ethical standards. The independence of Research must be maintained, and conflicts of interest must be declared and managed (please see guidance contained in our [Research Integrity and Governance Code of Practice](https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/research-integrity-and-governance)).

# Specific ethical considerations

# Due to the diverse nature of Research, it is not possible to list all ethical considerations that might be relevant to a specific Human Research project. Researchers are ultimately responsible for identifying and assessing all ethical considerations and risks of relevance.

# Notwithstanding the above, there are some ethical consideration areas that are key and/or common to many Human Research projects. These are listed below. Researchers must reflect on the extent to which these areas are relevant to their project. If relevant, Researchers must ensure they reflect on, and address, any ethical issues relating to the area in the design of their project (further guidance on these areas is contained [here](https://intranet.cardiff.ac.uk/staff/supporting-your-work/research-support/research-integrity-and-governance/research-ethics), unless stated otherwise below):

1. The recruitment of Human Participants;
2. Obtaining informed consent from Human Participants;
3. Dealing with identifiable information;

**Note: In addition to ethical matters, Researchers must adhere to Data Protection legislation and to the University’s related policies in this area, where relevant.**

1. Respecting confidentiality;
2. Research involving children (those under the age of 18) and/or ‘at risk’ (vulnerable) adults or groups;

**Note: In addition to ethical matters, Researchers must adhere to Safeguarding legislation, the University’s related policies in this area, and the Mental Capacity Act 2005, where relevant**.

1. Using Social Media data (or similar internet-based data). The University’s expectations (and further guidance) on this specific area are contained within the University’s ‘Framework for the ethical review of Research using Secondary Data or Publicly Available information only’;
2. Research involving sensitive topics or sensitive research questions;
3. Offering payment and/or an incentive for participation;
4. Publishing the research – the ethical perspective;
5. Informing participants of the results of research;
6. Risk of harm to participants or groups;
7. Risk of harm to the Researcher; and
8. Conducting Human Research overseas.

**4. ETHICAL REVIEW REQUIREMENTS**

# 4.1 The University requires that all Human Research conducted by its Researchers be subject to ethical review by an independent, competent, and properly constituted ethics committee, unless a specific exemption applies. The requirements of ethics review at the University are designed to demonstrate that Researchers have given due consideration to the ethical issues surrounding the design and conduct of their Research.

# 4.2 For all Human Research conducted by Researchers at Cardiff University, the University requires that the Research is subject to ethical review by the relevant SREC unless the Research:

# falls within the remit of an external ethics committee which is required to conduct ethical review of the project e.g. an NHS REC (see Appendix 1 for examples of Research requiring review by an external ethics committee). Where an external ethics committee is responsible for conducting ethical review, neither the SREC nor ORIEC is empowered to provide a favourable ethical opinion for the Research. Researchers must adhere to the procedures and requirements of the external ethics committee.

# is exempt from ethical review under the University’s 'Framework for the Ethical Review of research using Secondary Data or Publicly Available information only’. This framework allows certain research projects using secondary data and/or publicly available information only to proceed without ethical review by a SREC provided certain conditions are met.

# is exempt from ethical review under another framework or process approved by ORIEC and piloted by Schools from time to time (as part of the University’s continued effort to streamline ethical review processes and to introduce greater proportionality, by facilitating responsible risk-based decision making).

# only involves the use of Human Data and/or human tissue that has already been collected with appropriate consent and that has been given a favourable ethical opinion (from either a UK ethics committee, a biobank with generic NHS REC approval, or an ethics committee based in a country with similar standards of research ethics) and will only be used within the terms of the original consent.

# is being led by another university or institution that has undertaken (or will undertake) ethical review of the Research in accordance with its own procedures. Where this applies, Researchers are required to submit evidence of the ethical review conducted to the SREC before the Research commences. This evidence must include the ethical review outcome letter/communication and, where considered necessary by the SREC, a copy of the ethical review policy of the institution. If the Researcher or SREC has reason to believe that the ethical review procedures of the external university or institution are not of an equivalent (or higher) standard to our own, the SREC must conduct ethical review of the project. Unless the Researcher or SREC have reason for a specific concern, other UK Universities are presumed to have appropriate ethical review standards for the purposes of this Policy.

# Where ethical review is required, a Researcher is not permitted to commence Human Research activity and must not recruit any participants until they have received a favourable ethical opinion from the relevant ethics committee. Please see Section 4.6 below for further information about what this means in a SREC context.

# Research involving more than one Academic School should normally be reviewed by the SREC of the School where the lead/principal investigator is based. It may occasionally be more appropriate for the SREC of the School where a co-investigator is based to review the Research (if that SREC has expertise in the subject area/methodology of the Research). If a Researcher is unsure if ethical review is required, or if a Researcher is unsure to which ethics committee they must apply, they should contact their School Ethics Officer. A list of School Ethics Officers is available [here](https://intranet.cardiff.ac.uk/staff/research-support/integrity-and-governance/research-ethics/ethical-review/school-research-ethics-committees-srecs)[[2]](#footnote-3).

# 4.5 SREC application process and procedures:

# 4.5.1 Unless a School-specific deviation is approved by ORIEC (available in exceptional cases), all Cardiff University SRECs are required to operate in accordance with a set of ORIEC-approved template procedures which are finalised and published locally. These procedures confirm the Terms of Reference and Membership of the SREC, together with information about the application procedure (how a Researcher makes an application and how this is reviewed by the SREC). In the majority of cases, a Researcher will be required to submit an individual application for ethical review to the SREC. However, some Schools also operate a Group Application process and/or a Module-wide application process to cover UG/PGT projects. Familiarity with local SREC Procedures is therefore key.

# 4.5.2 Researchers who are only proposing to use secondary data and/or publicly available information must adhere to the University’s 'Framework for the Ethical Review of research using Secondary Data or Publicly Available information only’.

# 4.5.3 All Researchers must adhere to the SREC procedures, engage with the process, and follow any instruction provided by the SREC in relation to the ethical conduct of their Human Research project. Mutual respect is expected in all interactions between Researchers and SRECs.

# 4.6 SREC Decisions

# 4.6.1 Cardiff University SRECs are empowered to make four kinds of decision, following review of an ethics application. The SREC can grant:

# A ‘Favourable’ ethical opinion

# A ‘Favourable, with conditions’ ethical opinion (this is still considered a ‘favourable’ opinion for the purposes of this Policy *provided* (and once) all specified conditions are met by the Researcher. The Researcher must not commence the Human Research and cannot recruit participants (where relevant) until all conditions have been met)

# A ‘Provisional’ (or ‘Pending’) opinion (this is not considered a ‘favourable opinion’ and requires the Researcher to submit further information and/or revised documents to the SREC, to enable the SREC to re-consider whether it can issue a favourable, or favourable with conditions opinion)

# Unfavourable opinion (project rejected)

# 4.6.2 The decision of the SREC will be confirmed to the Researcher in writing and, where applicable, will be accompanied by feedback. Where a ‘favourable, with conditions’ or ‘provisional’ opinion has been granted, the SREC decision communication will confirm what steps must be taken by the Researcher prior to commencing their Human Research. The Researcher must retain a copy of the SREC decision communication with their Research records.

# 4.6.3 Retrospective ethical review is not permitted at Cardiff University, in keeping with sector-wide best practice. SRECs are not authorised to grant a favourable ethical opinion retrospectively. Any discovery of Human Research commencing prior to receipt of a favourable ethical opinion must be notified to the Head of School and School Ethics Officer within which the lead Researcher/PI is based. The Head of School and School Ethics Officer are responsible for reporting all such cases, including any action taken to remedy the failure by the Researcher to obtain ethical review, to ORIEC as part of the annual ethics reporting process.

# 4.6.4 Researchers must note that a favourable (or favourable, with conditions) decision by a SREC should not be taken to imply an expert assessment of all possible dangers or risks involved with the Research. SRECs address themselves to ethical matters. They are not experts in legal matters and are dependent upon information supplied by the Researcher. It is, therefore, the responsibility of Researchers to ensure that the information provided to SRECs is complete and accurate.

# 4.7 Action following a Favourable Ethical Opinion

# 4.7.1 Once a favourable ethical opinion is obtained, Researchers must act in accordance with the opinion provided and comply with any conditions or reporting/monitoring requirements of the relevant ethics committee.

# 4.7.2 Any proposed changes to the Research must be actioned in accordance with the procedures of the relevant committee.

# 4.8 Other Review, Approval and/or Registration Processes

# 4.8.1 Researchers must carefully consider whether other forms of review, approval and/or registration of the Research may be required, in addition to ethical review, before the Research commences. For example:

# Research involving the collection or use of human tissue (including saliva and other bodily fluids) must initially be reviewed by the University’s Human Tissue Act Compliance Team prior to submission to an ethics committee. This is still the case where the material will be rendered acellular immediately.

# Research falling within the scope of the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)/Research involving the NHS will usually require:

# Sponsorship from the University’s Research Governance Team (further details are available [here](https://intranet.cardiff.ac.uk/staff/research-support/research-projects/conducting-research-in-the-nhs/applying-for-sponsorship)[[3]](#footnote-4));

# Approval from the Health Research Authority/Health and Care Research Wales; and

# Local NHS site approval (capability and capacity review, previously known as ‘R&D approval’).

# Research involving prisoners may require approval from the National Offenders Management Service, the Scottish Prison Service or the Northern Ireland Prison Service.

# Health-related research involving access to Personal Data without consent will require approval from the Confidentiality Advisory Group.

# Research involving investigational medicinal products or medical devices will require Sponsorship from the University’s Research Governance Team and approval from the Medicines and Healthcare products Regulatory Agency.

# Research in the areas of terrorism, extremism and/or radicalisation (or research involving access to materials of such a nature) must be registered with the University in accordance with the [Security-sensitive Research Policy](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/security-sensitive-research).

# Research requiring security clearances or Disclosure and Barring Service (‘DBS’) checks;

# Research requiring the completion and/or authorisation of a Data Protection Impact Assessment due to the nature of Personal Data processing taking place;

# Research which has a *potential* military-related application (often referred to as ‘dual-use’ risk), should be notified to RIGE and may require specific licences and authorisations, particularly if the Research involves international partners or any transfer of sensitive or controlled items or information overseas. This is mostly relevant to STEM-related Research involving international partners.

# 5. ROLES AND RESPONSIBILITIES

# 5.1 This section confirms the role and responsibilities of specific individuals, teams, and committees in ensuring the ethical conduct of Human Research at the University. However, for the avoidance of doubt, everyone involved in conducting or supporting Human Research at Cardiff University is expected to abide by the highest ethical standards and to promote ethical and responsible practice in all Research activity.

# 5.2 Researchers (including Research Supervisors)

# Researchers are ultimately responsible for ensuring that their Research is conducted to the highest ethical standards. In respect of Human Research specifically, this includes taking personal responsibility for:

# 5.2.1 adhering to this Policy, and the related policies and procedures stated in Section 8;

# 5.2.2 identifying the ethical issues arising from their Research, giving particular attention to the matters stated in [Section](#_GUIDING_PRINCIPLES_IN) 3;

# 5.2.3 submitting an application for ethical review to the appropriate research ethics committee (where required), ensuring that all information provided within the application is complete and accurate (see [Section](#_ETHICAL_REVIEW_REQUIREMENTS) 4);

# 5.2.4 ensuring that the Research has obtained a favourable ethical opinion (where required), from an appropriate ethics committee, before the Research commences (see [Section](#_ETHICAL_REVIEW_REQUIREMENTS) 4);

# 5.2.5 undertaking appropriate training in research ethics and reflecting on whether such training and/or past experience enables them to evaluate the ethical implications of their Research;

# 5.2.6 keeping the ethical issues arising from the Research under regular review, amending project documents and seeking ethical review of such amendments (where required);

# 5.2.7 ensuring that all Research activity is within the scope of the favourable ethical opinion obtained, where applicable;

# 5.2.8 acting in accordance with all other relevant University, funder and professional body policies, procedures and guidance in relation to the ethical conduct of Research; and

# 5.2.9 ensuring adherence to any laws or regulations that are relevant to the Research and/or provide participants with certain rights or protections. This includes but is not limited to: Data Protection legislation; the Human Tissue Act 2004; the Mental Capacity Act 2005.

Researchers must ensure they are familiar with, and adhere to, any legislation that applies to their Research. This Policy is not intended to address areas of legal compliance, but some specific pieces of legislation are signposted. It is not the role of Research Ethics Committees to ensure legal compliance.

# 5.3 Schools/Head of School

# 5.3.1 Schools are responsible for establishing and maintaining a School Research Ethics Committee (SREC) which must operate in accordance with Section 5.4. Schools are expected to allocate an appropriate workload tariff to individuals acting as Chair of a SREC, or as a SREC Member.

# 5.3.2 In exceptional cases, a School may be exempted from establishing and maintaining a SREC. All exemptions must be approved by the University’s Open Research Integrity and Ethics Committee (ORIEC). Where an exemption is granted, the Head of School will be required to provide an annual written declaration to ORIEC (containing various assurance statements) to ensure that any Human Research arising in the School is subject to ethical review in accordance with this Policy. This declaration process is managed through an annual reporting cycle (from Schools to ORIEC), whereby all Schools provide data, information and documentation relating to its SREC operations for audit and oversight purposes.

# 5.3.3 In accordance with the University’s Template Procedures for School Research Ethics Committees, the Head of School is responsible for referring appeals and/or matters requiring advice and guidance (referrals) from the SREC to ORIEC.

# 5.4 School Research Ethics Committees

# 5.4.1 SRECs play a vital role in helping to maintain ethical standards and in supporting the practical implementation of the key principles and expectations contained in this Policy. SRECs are primarily concerned with protecting the safety, security, rights, and dignity of Human Participants, but they also play an important role in considering the interests of others involved in the Research. SRECs aim to facilitate, not hinder, valuable Human Research that is ethically sound and defensible.

# 5.4.2 SRECs are responsible for reviewing applications for ethical review for all Human Research proposed by Researchers within the School unless ethical review falls within the remit of a mandatory external ethics committee, or a specific exemption applies (see Section 4 and Appendix 1). The role of the SREC is to review the information provided, to consider the ethical implications of what is being proposed, and to ensure that the Research complies with relevant ethical standards and protects participants from unnecessary harm. The SREC is ultimately responsible for providing an ethical opinion on the Research.

# 5.4.3 Unless a School-specific deviation is approved by ORIEC (available in exceptional cases), SRECs operate in accordance with a procedural framework (entitled *‘Cardiff University Template Procedures for School Research Ethics Committees’*) issued by ORIEC. The framework comprises a template procedure for adoption by the SREC and contains a set of minimum standards, alongside confirmation of the areas where the SREC has discretion to adopt bespoke/discipline-specific measures. As such, the SREC is responsible for publishing and managing its procedures for the ethical review of Human Research conducted within the School.

# 5.5 School Ethics Officer

# Each School has appointed a School Ethics Officer (SEO) who is responsible for:

# ensuring there are effective mechanisms via the SREC or School Board (as appropriate) to bring any policy, guidelines or procedures developed with or through the ORIEC and the SREC to the attention of staff and students for whom the School is responsible. These mechanisms must make it clear that it is a University requirement that these policies, guidelines and procedures are followed;

# keeping School research ethics matters under review;

# managing and monitoring the School’s ethics procedures in practice;

# ensuring that appropriate records of applications, decisions and practices are made and retained by the School;

# reporting to the Head of School, as appropriate;

# reporting to the School through an appropriate forum, such as the School Board;

# reporting to ORIEC on an annual basis on behalf of the School; and

# conducting a three yearly review of School ethical procedures and reporting to ORIEC on behalf of the School.

# 5.6 Open Research Integrity and Ethics Committee

# 5.6.1 ORIEC is responsible for oversight of the University’s approach to good research practice (Research Integrity) and ensuring that the University meets the requirements of the [Concordat to Support Research Integrity](https://www.universitiesuk.ac.uk/sites/default/files/field/downloads/2021-08/Updated%20FINAL-the-concordat-to-support-research-integrity.pdf). This includes, but is not limited to, ensuring that Research is conducted to the highest ethical standards. ORIEC’s function is predominantly one of oversight, strategy and policy review/development. In relation to research ethics specifically, ORIEC is responsible for:

# Maintaining and reviewing this Policy, the template SREC procedures and associated documents;

1. Oversight of the annual SREC reporting process, including approval of the annual report template, and reviewing the annual reports submitted by SRECs; and
2. Considering appeals and referrals submitted by SRECs via the Head of School, in accordance with the template SREC procedures.

# 5.6.2 ORIEC’s Terms of Reference and Membership are publicly available on the Cardiff University internet pages[[4]](#footnote-5).

# 5.7 Pro Vice-Chancellor for Research, Innovation and Enterprise (PVC-RIE)

# Given the nature of this Policy, and pursuant to their role as Chair of ORIEC, the PVC-RIE is the UEB Sponsor for this Policy.

# 5.8 Research and Innovation Services (RIS)

# 5.8.1 RIS is the owner of this Policy. The Research Integrity, Governance and Ethics Team (RIGE), who are based within RIS, administer the Policy, oversees its review and revision, and provides general advice on its operation.

# 5.8.2 The Head of RIGE is Secretary to ORIEC and prepares the agenda and minutes for each ORIEC meeting. RIGE works closely with ORIEC to provide assurance that the University has appropriate systems in place to ensure that Research is conducted to the highest ethical standards.

# 5.8.3 In addition, RIGE has specific responsibility for helping Researchers to secure compliance with the rules that govern clinical research, including supporting Researchers to obtain ethical review by an NHS Research Ethics Committee, together with other local NHS approvals.

5.9 Human Tissue Act Compliance Team

5.9.1 The Human Tissue Act (HTA) Compliance Team (based in the College of Biomedical and Life Sciences) is responsible for providing and maintaining a robust system of governance and ensuring Researchers have the framework to adhere to the HTA. The HTA Compliance Team has administrative responsibility for the University’s Code of Practice for Human Tissue Research and the associated SOPs.

5.9.2 In addition, the HTA Compliance Team has a specific responsibility to review all SREC applications that involve the collection or use of relevant material prior to submission to the SREC. This review is not limited to Schools within the College of Biomedical and Life Sciences; it includes any SREC application involving relevant material in the College of Arts, Humanities and Social Sciences and the College of Physical Sciences and Engineering.

# 6. MONITORING AND REVIEW OF THIS POLICY

This Policy will be subject to review at least every three years. The Policy is primarily monitored through the annual reporting process from Schools (administered by SRECs) to ORIEC (administered by RIGE).

Any queries on this Policy should be directed to RIGE via resgov@cardiff.ac.uk.

# 7. BREACH OF THIS POLICY

# 7.1 A failure by a member of staff to comply with the requirements of this Policy, including a failure to obtain a favourable ethical opinion for Human Research where required, may be grounds for disciplinary action and/or may amount to [Academic Research Misconduct](https://www.cardiff.ac.uk/public-information/policies-and-procedures/academic-research-misconduct), depending on the nature and severity of the breach.

# 7.2 A failure by a student to comply with the requirements of this Policy, including a failure to obtain a favourable ethical opinion for Human Research where required, may amount to Academic Misconduct, and may result in sanctions, depending on the nature and severity of the breach. Please refer to the University’s Academic Integrity Policy and Academic Misconduct Procedures, as contained in the University’s [Academic Regulations](https://www.cardiff.ac.uk/public-information/policies-and-procedures/academic-regulations)).

# 8. RELATED POLICIES AND PROCEDURES

8.1 This Policy must be read in conjunction with:

8.1.1 the University’s ‘[Research Integrity and Governance Code of Practice](https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/research-integrity-and-governance)’ which comprises a framework for the responsible conduct of research at Cardiff University; and

8.1.2 the University’s ‘[Framework for the ethical review of research using Secondary Data or Publicly Available information ONLY](https://intranet.cardiff.ac.uk/staff/supporting-your-work/research-support/research-integrity-and-governance/research-ethics)’ which is considered a sub-policy of this Policy. Researchers conducting projects that only involve the use of secondary data or publicly available information must read and adhere to this Framework.

8.2 This Policy is supported by [Human Research Ethical Guidelines](https://intranet.cardiff.ac.uk/staff/supporting-your-work/research-support/research-integrity-and-governance/research-ethics) which all Researchers conducting Human Research must read.

**APPENDIX 1**

**Research requiring review by an external ethics committee.**

1. The following types of Research must be referred to **an NHS Research Ethics Committee** (NHS REC) for review and approval:

Research involving:

* 1. patients and users of the NHS i.e. individuals identified as potential participants from, or because of their past or present use of, NHS services (including services provided under contract with the private or voluntary sector);
	2. individuals identified as potential participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
	3. collection of, or access to, data, tissue or other bodily material from patients or users of the NHS, as defined above;
	4. the storage of ‘Relevant Material’ from the living or deceased on premises in the UK (excluding Scotland) without an appropriate licence from the Human Tissue Authority;
	5. the storage or use of Relevant Material from the living, collected on or after 01 September 2006, where appropriate consent for the research is not in place from or on behalf of the donors;
	6. the analysis of human DNA in cellular material, where appropriate consent for the research is not in place from or on behalf of the person whose body manufactured the DNA;
	7. a clinical trial of an investigational medicinal product;
	8. a clinical trial involving the participation of practising midwives;
	9. a non-CE marked medical device, or a device which has been modified or is being used outside of its CE mark intended purpose. A definition of a ‘medical device’ can be found at the www. gov.uk[[5]](#footnote-6);
	10. exposure to ionising radiation;
	11. the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent;
	12. intrusive procedures (refer to the Human Research Ethical Guidelines for a definition of intrusive) with adults who lack capacity to consent for themselves, including participants retained in a project following the loss of capacity;
	13. prisoners in the custody of the National Offenders Management Service, the Scottish Prison Service or the Northern Ireland Prison Service, where the research is health-related; and
	14. xenotransplantation (putting living cells, organs, or tissue from animals into humans).
1. Social care research funded by the Department of Health must be referred to **the Social Care Research Ethics Committee** (now managed through the Health Research Authority, alongside the NHS RECs).
2. Any Human Research funded or sponsored by the Ministry of Defence (MOD) must be referred to **the MOD Research Ethics Committee**.

#### **CHANGE HISTORY RECORD**

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| **Version** | **Approval Body/Officer and date** |
| 1.0 | University Research Integrity and Ethics Committee (09 October 2018). |
| 2.0 | Open Research Integrity and Ethics Committee (20 May 2021).Council (07 July 2021). |
| 3.0 | Open Research Integrity and Ethics Committee (14 May 2024)Council (10 July 2024) |

1. For further information refer to <https://www.britishmuseum.org/pdf/DCMS%20Guide.pdf> [↑](#footnote-ref-2)
2. Student link: <https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics/ethical-review/school-research-ethics-committees-srecs> [↑](#footnote-ref-3)
3. Student link: <https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/conducting-research-in-the-nhs/applying-for-sponsorship> [↑](#footnote-ref-4)
4. Terms of Reference link - <https://www.cardiff.ac.uk/about/organisation/governance/charter-statutes-ordinances>

Membership link - <https://www.cardiff.ac.uk/public-information/corporate-information/committees> [↑](#footnote-ref-5)
5. <https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device> [↑](#footnote-ref-6)