

UNIVERSITY OF PLYMOUTH

University of Plymouth

Research Ethics Policy

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Disclaimer:

Please ensure that you are using the most up to date version by checking on the University website. This Policy must be read in conjunction with other University Policies, Standard Operating Procedures, or Codes of Practice as well as regulatory documents listed in the reference section.

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Introduction

Research at the University of Plymouth is conducted according to the principles of **integrity, academic excellence, accountability, inclusiveness and professionalism**. All research must follow appropriate ethical, legal and professional frameworks, obligations and standards. The Research Ethics Policy and the Code of Good Research Practice have been drawn up to conform with the principles laid out in other relevant policies, guidelines and codes of conduct, including those of funding bodies such as the Research Councils and the [Universities UK's Concordat to Support Research Integrity](#)¹.

The **Research Ethics Policy** describes the principles underpinning the ethical conduct of research and defines the process and principles for the objective and rigorous ethical review of research which falls within its scope.

It is expected that all research undertaken at the University will be conducted in compliance with the [Code of Good Research Practice](#)², which sets out the University's commitment to research integrity.

This policy applies to **all employees, students and visiting researchers** of the University, including persons holding honorary University appointments and students on placements, who conduct research within, or on behalf of, the University.

All **members of the University are individually responsible** for ensuring that their work is conducted in accordance with the University values and with all policies that form part of the terms and conditions of employment or study. Disregard for this policy may lead to the failure of assessed work; the suspension of study/research projects, and/or funding from research sponsors; or to the inability to publish. Work conducted without the appropriate ethical approval (where required) or in deliberate contravention of the decisions of the FREIC (UREIC) would not be covered by the University's indemnity arrangements.

The following research is subject to additional regulations and requires review through the appropriate research ethics committee/process and to be formally approved before it is undertaken:

- [research involving human participants](#);
- [research involving NHS patients, staff or resources](#);
- [research involving human tissue](#);
- [research involving non-human live organisms](#).

Research that may raise other significant ethical issues or pose a reputational risk to researchers or the institution should also be referred for advice and/or review from the

¹The Universities UK Concordat to Support Research Integrity (2012) is available from: <http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf> (accessed 28th November 2017)

²University of Plymouth (2019) *Code of Good Research Practice*. Available from: https://www.plymouth.ac.uk/uploads/production/document/path/12/12338/Code_of_Good_Research_Practice_final_draft_V1.0_.pdf

appropriate Faculty Research Ethics and Integrity (FREIC) Chair or the University's Research Ethics and Integrity Committee (UREIC) Secretary.

The purpose of ethical review is not to discourage controversial or high-risk research, but rather, to recognise and manage potential harms and risks related to the pursuit area of research.

Additionally, the University [Research Data Policy](#)³ provides guidelines for good practice in research data management and open access to research data as an integral part of high-quality research.

For the purpose of this policy, **research** is defined as original investigation undertaken in order to acquire knowledge and understanding. This would include:

- the invention and generation of ideas, images, performances, artefacts including design, leading to new or substantially improved insights;
- work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors;
- scholarship such as the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines (e.g., dictionaries, catalogues and research databases);
- the use of existing knowledge and experimentation to develop new or substantially improved materials, devices, products and processes, including design and construction.

Research would **not** normally include:

- routine audit and evaluation, such as the routine evaluation of teaching, as distinct from the development of new analytical techniques;
- the development of teaching materials and activities that do not involve original research;
- purely documentary research on sources that are already in the public domain such as historical, literary, and theoretical research;
- routine testing and analysis of materials and processes.

The Research Ethics Policy and the Code of Good Research Practice is reviewed and updated annually by the University Research Ethics and Integrity Committee (UREIC). Any substantive changes are subject to approval by the University Research and Innovation Committee.

³ University of Plymouth (2018). *Research Data Policy*. Available from: https://www.plymouth.ac.uk/uploads/production/document/path/6/6913/Research_Data_Policy.pdf

Part 1: Human ethics in research

1.1 Background to human ethics in research

The University requires that human participation in research, on any level, from on-line surveys, through focus group participation, dissemination or public engagement activities, to clinical trials, is ethical with appropriate consideration of risks.

Historical developments in research ethics with humans have informed the University's requirements of its researchers. In brief, these cover; voluntary and informed participation (Nuremberg 1947), protection from harm, protection of participants' rights and independent review (Helsinki 1964), and beneficence in research and equality for participants (Belmont 1979). These principles must inform all research with human participants.

There are numerous research sector and regulatory guidelines (see most recent resources in appendix) that inform the University principles of ethical research. The following policy is drawn from [Research Councils UK](#)⁴ (including Economic and Social Research Council - ESRC and Medical Research Council - MRC), and [British Psychological Society \(BPS\)](#)⁵.

1.2 Purpose and scope

This Ethics Policy sets out the University's approach and structures for protecting human participants in research by using ethical review and guidance. This document explains what the University is doing to meet key sector principles in research with humans, promote consistency in quality and demonstrate sector and legal compliance. It outlines what is in place, such as codes, structures, systems, processes, guidance, training and monitoring to support researchers and therefore, must be read in conjunction with other relevant University policies, codes and procedures.

This is a policy for research staff, postgraduate researchers, and those supporting them. It does not apply to Undergraduate students (governed by **Teaching & Learning Quality Assurance**) although may inform the supervision of some Undergraduate research dissertations or placements. Undergraduate research projects involving the National Health Service (NHS), however, must follow guidelines set down by the [Health Research Authority \(HRA\)](#).⁶ Undergraduate research projects involving other external organizations (such as Her Majesty's Prison & Probation Service), likewise, must follow guidelines set down by the relevant external organization.

⁴ RCUK Policy and Guidelines on Governance of Good Research Conduct (2015). Available from: <https://www.ukri.org/files/legacy/reviews/grc/rcuk-grp-policy-and-guidelines-updated-apr-17-2-pdf/> (accessed 24th October 2019)

⁵ The British Psychological Society (2010) *Code of Human Research Ethics*. Available from: http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf (accessed 28th November 2017)

For research under the remit of the [Health Research Authority \(HRA\)](#)⁶ (for example those researchers accessing National Health Service (NHS) patients, their tissue or data), Part 3 of the Ethics Policy explains the University's responsibility as a study Sponsor and the interaction of different ethical committees and application processes.

1.3 The principles

Ethical research practices are based on fundamental principles of research integrity. The University expects all researchers to follow the University Code of Good Research Practice to maintain the highest standard, quality and robustness of research. Additionally, in all research involving human participants, researchers must address the following four principles:

- **Autonomous, informed consent**
- **Openness and honesty**
- **Protection from harm**
- **Confidentiality and data protection**

These principles are described in detail below.

1.4 Guidance for researchers

1.4.1 Autonomous, informed consent

The researcher should, where possible, inform participants in advance of any aspects of the research that might reasonably be expected to influence a person's willingness to take part in the study.

Where the research topic is sensitive, the ethical protocol should **include verbatim instructions** for the informed consent procedure. Where possible, consent should be obtained in writing and kept.

If there is a possibility of a **duty of care or legal reason for confidence to be broken** then this should be explained as part of informed consent (see also Protection and Safeguarding).

Coercion: It is important that the participant is not coerced during recruitment. Coercion is an issue if **incentives for participants** go beyond compensating for participants' out of pocket expenses or their time. In medical research, this is a very sensitive area where often a patient's altruism is the reason for their participation. Questionnaires and lower risk types of research have a more lenient approach so it is important to adhere to the sector guidelines in the specific area of research.

⁶The Health Research Authority (2017) *UK Policy Framework for Health and Social Care Research*. Available from: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research> (accessed 12th April 2018)

Children: Children (under 16 years old⁷) should be involved in the decision-making process and give informed consent to participation in research wherever possible. It is important to ensure that children receive information about research that is understandable to them. Children must be given the time and opportunity to access support in their informed consent, for example, to discuss the research with a trusted adult.

Where children are concerned, it is mandatory (unless special circumstances) to secure permission from **parents or teachers acting in loco parentis**, in addition to the child's informed consent. With sensitive research topics, written informed consent may be obtained from both parents.

In some circumstances, children might object to involving their parents in the decision-making process or it might jeopardise the research (for example, in research into teenage sexuality or psychoactive substance use). In such circumstances, the researcher needs to have regard to the potential risk to the participants as a priority.

Vulnerable groups: where research involves potentially vulnerable groups, for example, older persons, young adults (16-18 years old) or adults with disabilities, members of marginalised groups, or those in disadvantageous power relationships within personal and professional roles, every effort should be made **to secure freely given informed consent** that participants have actively provided.

Where adults with a **cognitive impairment**⁸ are concerned, researchers should assume that a person has capacity to make a decision, unless there is evidence that they do not have capacity to make a specific decision. Prospective participants must receive support to try to help them make their own decision. Where appropriate, carers or gatekeepers might make a decision on behalf of the participant. The participant has the right to disagree with such decision.

For a **researcher in a position of trust**, where their professional role brings them into contact with potential participants, an independent **gatekeeper** is required as a mediator so that the participants do not feel coerced into taking part. There may be a **conflict in interest** here in the researcher's role as a professional and a researcher.

Right to withdraw: Where possible, participants should be informed at the outset of the study that they have the right to withdraw at any time, without penalty. (See confidentiality and data protection guidance at section 2.4.4 on appropriate use of initial data already gathered.)

⁷ The age of 16 refers to regulations in England. There are different rules, regulations and guidelines regarding the participation of children in research in different countries, in particular concerning ethics approval and informed consent. The overview of EU regulations and relevant policies is available from: <https://fra.europa.eu/en/publication/2014/child-participation-research> (accessed 24th October 2019)

⁸ Mental Capacity Act 2005, available from: <https://www.legislation.gov.uk/ukpga/2005/9/contents> (accessed 30th January 2018).

In the case of children, **the children** themselves, or those acting in **loco parentis (if children are not** of sufficient understanding), shall be informed of the right to withdraw from participation in the study.

1.4.2 Openness and honesty

As far as possible, researchers should be open and honest about the research, its purpose and potential applications. This includes declaring any conflicts of interest, the funding source and how the results might be used.

Clarity of language: all effort, within reason, must be made to ensure **inclusivity**, for example the use of translated material, interpreters or illustrations.

Deception: Some types of research require deception in order to achieve their scientific purpose. Deception will be approved only if the following conditions are met:

- Deception is **completely unavoidable** if the purpose of the research is to be achieved.
- The research objective has **strong scientific merit**.
- Any potential harm arising from the proposed deception can be effectively **neutralised or reversed** by the proposed debriefing procedures.

Failing to inform participants of the **specific purpose of the study** at the outset is not normally considered to be deception, provided that adequate informed consent and debriefing procedures are proposed.

Covert research: Covert observation may be a legitimate method of research when it is impossible to use other methods to obtain essential data. Covert research must observe current legislation on **privacy**. If informed consent has not been obtained prior to the covert research in non-public settings, it should be obtained *post hoc* wherever possible.

Debriefing: Researchers should, where possible, provide an account of the purpose of the study as well as its procedures. If this is not possible at the outset, then it should be provided on completion of the study.

1.4.3 Protection from harm and safeguarding

Safety responsibilities: It is the Principal Investigator's (PI's) responsibility to ensure that all relevant safety procedures are in place to assess and minimise risk to participants, the research team or the general public and the environment. This will include reviewing risk assessments, referring to lone working guidelines, updating training and appropriate certification.⁹

⁹ For detailed guidelines, refer to Research Ethics Handbook available from: <http://www.ethicsguidebook.ac.uk/Assessing-risk-and-harm-21> (accessed 28th November 2017)

Protection from Harm: Researchers must protect participants from physical and/or psychological harm at all times during the research.

Note that where stressful or hazardous procedures are concerned, the essential **informed consent** does not absolve the researcher from responsibility for protecting the participants. In such cases, the research protocol must specify the means by which participants will be protected, e.g. by the availability of qualified medical or non-medical assistance.

Where physical or mental harm nevertheless does result from research procedures, investigators are obliged to take action to remedy such harm.

Equality: Participants should not be disadvantaged by their involvement in research (i.e., removed or excluded from treatment or education). They should be given opportunity of the alternative treatment or education to be consistent.

Beneficence: It is expected that although altruistic participation is considered the ideal, participants should not be disadvantaged by their willingness to participate in research. Out of pocket expenses and compensation for time (in some cases) are acceptable and not considered as coercive.

Right to complain: The information provided to participants about the study must clearly state the procedure for them to complain if they are not satisfied. Ideally, an **independent contact** should be provided to allow participants to report their dissatisfaction with the study if they are not able to address it with their study team contact. The procedure should be outlined with initial information about the study, so that instances of unethical behaviour or allegations of research misconduct can be addressed.

Any **safeguarding concerns involving vulnerable participants** must be reported to the University Safeguarding Officer. The safeguarding officer will be able to follow procedures and make appropriate contacts directly and in a timely manner.

1.4.4 Confidentiality and data management

Confidentiality: Except with explicit consent of the participant, researchers are required to ensure confidentiality of the **participant's identity and personal identifiable data** throughout the conduct and reporting of the research.

To support the right of a participant to withdraw from a study and **control how their data is used** the information form should clearly explain what happens to their data, in terms of what research data will be kept, how their personally identifiable information will be anonymised and what data will be publically available (open data). The form may have to state a **caveat** that, due to some data already being incorporated, irretrievable or already used in producing results, their discontinuation may only be possible after a certain point.

Research **protocols need to specify procedures for how confidentiality will be achieved**. For example, transcriptions of interviews may be encoded such that no written record of the participant's name and data exist side by side¹⁰.

Research data: Researchers must ensure appropriate storage and protection of research data. Where records are stored digitally, or within log or lab books - the [Information Security Classification Policy](#)¹¹ and the [Research Data Policy](#)³ apply

Open data policy: Researchers must ensure appropriate open access to research data resulting from publicly funded research after its current use in research. Data relating to identifiable individuals must be held in accordance with the principles of data confidentiality legislation and any guarantees given to participants. Such data must be anonymised¹⁰ before it is made publicly available. Researchers must restrict access when anonymity and confidentiality cannot be guaranteed.

¹⁰ Comprehensive guidance for anonymisation of personal data is included in Information Commissioner's Office (2012) *Anonymisation: managing data protection risk code of practice*. Available from: <https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf> (accessed 13th December 1017)

¹¹ Information Security Classification Policy is available from: <https://www.plymouth.ac.uk/uploads/production/document/path/6/6015/EIM-POL-001 - Information Security Classification Policy v1.1.pdf> (accessed 13th December 1017)

Part 2: Research involving NHS patients, staff or resources

2.1 Background

For research, governed by the Health Research Authority (HRA) and under the remit of the HRA UK Policy Framework for Health & Social Care (for example National Health Service (NHS) patients, their tissue or data), applications are made for approval by HRA and in most cases by an external NHS research ethics committee (REC) termed a National Research Ethics Service (NRES REC) Committee¹².

Review by a NRES REC Committee is required by law in certain situations:

- Adults lacking capacity to consent for themselves
- Disclosure of protected information from HFEA Register
- Exposure to ionising radiation
- Human tissue
- Investigational medical devices
- Investigational medicinal products
- Practising midwives
- Private and voluntary health care
- Processing confidential patient information without consent
- Residential care homes
- Nursing Homes
- Independent Health Care Clinics

This Policy explains the University's responsibility as a study Sponsor and the interaction of different ethical committees and application processes to support compliance with the HRA and NRES policy framework.

2.2 Ethical review of research that relates to areas of responsibility of the UK Health Departments.

The [HRA UK Policy Framework for Health & Social Care](#)¹³ sets out **principles of good practice** in the management and conduct of health and social care research in the UK. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-

¹² NRES head office is accountable to the UK Health Departments and United Kingdom Ethics Committee Authority (UKECA) which is the statutory body responsible for establishing, recognising and monitoring ethics committees in the UK. It is independent of the researchers, the organisations funding the research and the organisations where the research will take place. UKECA utilises Standard Operating Procedures (SOPs) and Governance Arrangements for Research Ethics Committees (GAfREC) to audit RES committees

¹³ Health Research Authority's HRA UK Policy Framework for Health & Social Care is available from: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/> (accessed on 1st February 2018).

based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

It is expected that implementation of these principles is achieved by organisations using existing [‘national operational policies and guidance, standard operating procedures \(SOPs\) and operational platforms’](#)¹⁴ and only supplementing these with their own guidelines and processes for local arrangements when necessary.

2.2.1 Health Research Authority (HRA) review and approval process

The Health Research Authority (HRA) reviewing process for health and social care research involves a) ‘initial assessment’ (to confirm the proposed study meets legal requirements, including ‘capability and capacity’ arrangements), b) where applicable, validation for submission to a National Research Ethics Service (NRES) research ethics committee (REC), to obtain ‘favourable opinion’, c) final ‘HRA approval’ d) review by the local Trust research and development (R&D) committee to provide local capability and capacity approval.

2.2.2 Health Research Authority (HRA) requirements before a study begins

The University or NHS Sponsor for the study is only able to confirm that a study can go ahead once it is satisfied that; HRA approval, NRES REC ‘favourable opinion’, R&D capability and capacity approval and/or University faculty ethical review (FREIC) is in place. If required, appropriate access arrangements with the site Trust should be made (e.g. research passport) if the researcher does not already have an employment contract with that Trust.

2.2.3 Summary of Sponsor responsibilities under the HRA UK Policy Framework for Health and Social Care

The sponsor has overall responsibility for the research, ensuring;

- a. quality of research proposals, protocols and applications
- b. suitability of the investigators, research team and research sites
- c. roles and responsibilities agreed and documented
- d. insurance or indemnity in place
- e. appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards,
- f. relevant approval in place before study starts
- g. verifying that regulatory and practical arrangements are in place
- h. adequate finance and management of the research project (including its competent risk management and data management)
- i. effective procedures and arrangements in place and adhered to for reporting (e.g., progress reports, safety reports) and for monitoring the research,

¹⁴For detailed policies guidelines, refer to HRA UK, available from: <https://www.hra.nhs.uk/planning-and-improving-research> (access 1st February 2018)

including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

The Research Governance Specialist (acting as University Sponsor Representative) follows the principles – giving advice and support to researchers and students, co-ordinating a governance process and authorising submissions for HRA approval. The Research Governance Specialist also liaises with the University and the Faculty Research Ethics and Integrity Committees (UREIC and FREICs) who provide internal ethical review, training and monitoring.

Governance process at the University for NHS ethical review: The Research Governance Specialist reviews and manages all applications from University researchers and students that are submitted to HRA for assessment and (if applicable) independent ethical review by HRA Research Ethics Committee (REC). The Research Governance Specialist authorises applications on behalf of the University and ensures that the University and NHS sites can meet the capability and capacity requirements proposed by the research.

Internal ethical review: Where studies are assessed by HRA as not requiring independent, UKECA approved, ethical review (via NRES) they will still need to be fully reviewed by the University Faculty Research Ethics and Integrity Committee (FREIC). If the study has been given HRA NRES REC, favourable opinion the researcher is required by the University to submit their study and approval documentation to the FREIC for expedited review or Chair's action.

Audit: The FREIC reports annually on the number of studies that have undergone external review to UREIC. Studies approved by HRA will be subject to regular audits by the Sponsor Representative and Principal Investigators must comply with this requirement.

2.3 Data management

Confidentiality: In case of studies involving NHS patients, staff or resources, **no personally identifiable information** should be stored at the University beyond the end of the study except for signed consent forms.

Storage: Researchers must ensure appropriate storage and protection of research data for a period of 10 years. Where records are stored digitally, or within log or lab books the Information [Security Classification Policy](#)¹⁵ and the [Research Data Policy](#)³ also apply. Post study storage arrangements for data need to be agreed with the Research Governance Specialist (sponsor representative).

Open data policy: Researchers must ensure appropriate open access to research data resulting from publicly funded research after its current use in research. Data relating to

¹⁵ Information Security Classification Policy is available from:
https://www.plymouth.ac.uk/uploads/production/document/path/6/6015/EIM-POL-001_-_Information_Security_Classification_Policy_v1.1.pdf (accessed 13th December 2017)

personally identifiable information related to human tissue must be held in accordance with the principles of data confidentiality legislation and any guarantees given to participants. Such data must be [anonymised](#)¹⁶ before it is made publicly available. Researchers **must restrict** access when anonymity and confidentiality cannot be guaranteed.

¹⁶Comprehensive guidance for anonymisation of data is included in Information Commissioner's Office (2012) *Anonymisation: managing data protection risk code of practice*. Available from: <https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf> (accessed 13th December 1017)

Part 3: Research involving human tissue

3.1 Background to research ethics involving human tissue

The governance of research involving human tissue at the University is regulated under the **Human Tissue Act (2004)**¹⁷ and works to standards set by the **Human Tissue Authority (HTA)** in the **Codes of Practice and Standards**¹⁸. It must meet the requirements of the **University HTA Licence**.

The University is licensed by the **Human Tissue Authority (HTA)**¹⁹ specifically for the storage of human 'relevant material' for bio-medical research under the Human Tissue Act.

Human tissue governance at the University ensures that research involving human tissue or 'relevant material' is conducted to the highest professional standards, consent is appropriate to the research purpose, confidentiality protected, material is handled with dignity and respect, and stored with care to ensure its integrity.

3.2 Human Tissue Research Governance

The University Human Tissue Governance Committee oversees this area of research reporting to the University Research Ethics and Integrity Committee (UREIC). It delivers training and continued improvements in the quality management of human tissue research by monitoring practices (such as record keeping) and updating procedures. It monitors sample collections and has regular audits on the traceability of samples, appropriate storage and consent.

The University's **HTA Quality Manual**²⁰ sets out a framework for conducting human tissue research and includes policy statements on human tissue research and guidance on the use of the University's **Human Tissue Core Standard Operating Procedures**.

The University requires that staff working with human tissue for research, are appropriately trained and that they are aware of their obligations. Human tissue training is mandatory for those working under the licence and is available to all staff through the University Staff Development Programme.

¹⁷Human Tissue Act 2004. Available from: <https://www.legislation.gov.uk/ukpga/2004/30> (accessed 26th February 2018)

¹⁸Human Tissue Authority (2017) *Codes of Practice and Standards*. Available from: <https://www.hta.gov.uk/hta-codes-practice-and-standards> (accessed 26th February 2018)

¹⁹Human Tissue Authority, the regulator for human tissue and organs. Details available from: <https://www.hta.gov.uk> (accessed 26th February 2018)

²⁰Plymouth University (2014) *HTA Quality Manual*. Available from: <https://www.plymouth.ac.uk/research/human/tissue> (accessed 9th March 2018)

3.3 Informed consent

The University procedures and audits ensure compliance under Human Tissue Act (2004), where all human tissue, used and stored for research, **must** have appropriate consent for storage and the proposed research study. Researchers should refer to the [HTA Code of Practice A \(Consent\)](#)¹⁸, the University HT CoreSOP 1: Consent or contact the [University's HTA Designated Individual](#)²² for advice.

In exceptional cases where appropriate consent is not available, the material is from a living donor and it is completely anonymised, approval may be sought from a **recognised Research Ethics Committee (REC)**²³.

The Human Tissue Act (2004) governs the use of DNA in research. There is a legal requirement that the use of DNA for research is appropriately consented by the donor.

3.4 Ethical review

Studies using **human tissue defined as 'relevant material'** in the Human Tissue Act (2004) that is received from NHS patients, **must** always have regulatory assessment approval from the Health Research Authority (HRA)²⁴ and ethical approval from the NHS Research Ethics Service ([NHS RES](#))²⁵. Upon receiving a favourable opinion by the **NHS RES Research Ethics Committee**, this information should be passed to the University's FREIC for chair's acknowledgment.

When the NHS RES committee approval date **has expired** any remaining tissue samples must be destroyed or if appropriately consented booked in under the University's HTA licence by contacting the [University's HTA Designated Individual](#)²².

Studies that are using human tissue from **non-NHS patients** (i.e., students or people not recruited via NHS) or those that obtain material from a **research tissue Biobank** or from any other source, including from outside of the UK, will submit their proposal for the FREIC approval before commencing their study. Research tissue biobanks, in some cases, can provide material with appropriate recognised or NHS RES committee generic ethical approval. In these cases, researchers are still required to submit an application to the University FREIC for review.

²² More information about the procedures involving research with human tissue are available from: <https://www.plymouth.ac.uk/research/human/tissue> (accessed 2nd March 2018)

²³ For the purposes of the Human Tissue Act (2004), **recognised RECs** include all RECs within the Research Ethics Service of the four UK countries (Please refer to HTA Code of Practice E: Research, section 65).

²⁴ Details about the ethical review process under HRA are included at the University policy on [The Research Involving NHS Patients, Staff or Resources](#).

²⁵ See NHS RES webpage: <https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs> for guidance. Apply for NHS RES ethical approval through the Integrated Research Application System available through: <https://www.myresearchproject.org.uk> (accessed 2nd March 2018)

The Designated Individual for the University's HTA licence will be informed in all cases to ensure that the study meets HTA standards and that the researcher has received the appropriate training.

Storage and use of human tissue without approval from a recognised REC: In some cases, e.g., when the human tissue is not from NHS patients, the material can be stored and used for research without approval from a recognised REC, with approval from the Designated Individual and the appropriate FREIC. In these cases the human tissue **must** be registered with the Designated Individual and be stored under the University HTA Licence.

3.5 Data management and confidentiality

In the case of studies using human tissue originated from NHS patients, **no personally identifiable information** or samples should be stored at the University. Human Tissue samples **must** be coded such that they do not include any information that would enable identification of a tissue donor from a stored sample. NHS data security is overseen by the [NHS Trust Caldicott Guardian](#)²⁶ who ensures appropriate protection for patient records. The University HT CoreSOPs detail appropriate record keeping and labelling for human tissue samples and personal information.

Research data: Researchers must ensure appropriate storage and protection of research data. Where records are stored digitally, or within log or lab books - the Information [Security Classification Policy](#)²⁷ and the [Research Data Policy](#)³ apply in addition to the HT CoreSOPs.

Open data policy: Researchers must ensure appropriate open access to research data resulting from publicly funded research after its current use in research. Data relating to personally identifiable information associated with human tissue must be held in accordance with the principles of data confidentiality legislation and any guarantees given to participants. Such data must be [anonymised](#)²⁸ before it is made publicly available. Researchers **must restrict** access when anonymity and confidentiality cannot be guaranteed.

²⁶ See the Caldicott principles for professional standards of managing patient data: <https://www.ukcgic.uk/manual/principles> (accessed 2nd March 2018)

²⁷ Information Security Classification Policy is available from: https://www.plymouth.ac.uk/uploads/production/document/path/6/6015/EIM-POL-001_-_Information_Security_Classification_Policy_v1.1.pdf (accessed 13th December 2017)

²⁸ Comprehensive guidance for anonymisation of data is included in Information Commissioner's Office (2012) *Anonymisation: managing data protection risk code of practice*. Available from: <https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf> (accessed 13th December 2017)

Part 4: Research involving non-human live organisms

4.1 Research involving animals regulated under the Animal (Scientific Procedures) Act 1986 (ASPA)

Research on animals included in the [Animals \(Scientific Procedures\) Act \(1986\) / EU Directive 2010/63/EU](#)²⁹ (currently all non-human vertebrates and cephalopods) is regulated through a stringent licensing system, operated by the [Home Office](#)³⁰, controlling what can be done, where and by whom. Individuals must check, prior to any commencement of work, what permissions and licences are required.

The University holds a **Home Office establishment licence** and all researchers carrying out work regulated by [ASPA](#)²⁹ are required to hold a personal and/or project licence in order to carry out research involving these organisms. Once the project (or the researcher's post) is finished, the licence holder must contact the Home Office and request revocation/transfer of any active personal or project licence if not immediately required.

The University is a signatory of the [UK Concordat on Openness on Animal Research](#)³¹ that sets the commitments for clear, proactive communication with the public and reporting about when, how and why animals are used in research.

The University uses alternatives to animals wherever possible, such as computer modelling, tissue culture, cell and molecular biology, and research with human participants.

The University Governance Board and Animal Welfare and Ethical Review Board overview and support compliant research activities by providing advice and training for all research regulated under ASPA²⁹.

4.2 Ethical review of research involving animals³²

All projects involving animal research are underpinned by a commitment to [the principles of the 3Rs: replace, reduce, refine](#)³³; and are subject to the University's ethical review process prior to authorisation by the Home Office.

Permission to carry out a specific research project is granted only if the potential benefits to humankind or other animals are judged to outweigh any likely animal suffering. Compliance with legislation is monitored closely through the University Animal Welfare and Ethical

²⁹ The Animals (Scientific Procedures) Act (1986) is available from:

<http://www.legislation.gov.uk/ukpga/1986/14> (access 2nd February 2018)

³⁰ For guidance on how to carry out scientific research and testing using animals, and how to apply for licences from the Home Office, please, refer to: <https://www.gov.uk/guidance/research-and-testing-using-animals> (access 2nd February 2018)

³¹ The UK Concordat on Openness on Animal Research is available from: <http://concordatopenness.org.uk> (access 2nd February 2018)

³² For details about Use of Animal in Research and Ethical Review process at Plymouth University, please, refer to: <https://www.plymouth.ac.uk/research/animals> (access 2nd February 2018)

³³ For details, please, refer to: <https://www.nc3rs.org.uk/> (access 1st February 2018)

Review Board which reports directly to the Home Office and the Office of the Vice-Chancellor. It is monitored by the Home Office through its Inspectors who make regular visits, some of which are unannounced.

The Animal Welfare and Ethical Review Board includes lay representation as well as veterinary and animal care expertise as is required by law. The ethical review process also ensures that high standards of animal care, welfare and accommodation are maintained, and that persons working under the ASPA receive appropriate guidance and training.

4.3 Research on organisms not covered by ASPA

A wide range of potential research projects may involve living organisms that are not regulated under ASPA. However, the principles of the 3Rs and our responsibility to formally consider the justification of such work, and at all times work with consideration, respect for the living world, and to cause least harm, remains. This includes a very broad range of scenarios, including, for example, instances of sampling tissue from live organisms in the field, the collection of organisms from the field for laboratory experiments, observation of organisms, or the physical alteration of the environment as a result of research activities.

In all cases, an ethical review form should be completed for any research work where any potential harm may be caused to individual organisms and their surrounding environment. These will be reviewed initially by a nominated local ethical review panel, and where relevant, passed to either the relevant Faculty Ethics and Integrity Committee, or to the AWERB for further scrutiny.

Part 5: University research governance

5.1 University Research Ethics and Integrity Committee (UREIC)

The University Research Ethics and Integrity Committee ensures and monitors the integrity of research, the ethical review of research involving human participants, their tissue and research involving non-human live organisms, and environmental awareness by co-ordinating the activity of its Faculty sub-committees and regulatory committees. It promotes the general principles of **honesty, scientific rigour, transparency and open communication, and care and respect**, expressing the commitment to the [Universities UK Concordat to Support Research Integrity](#)³⁴.

The UREIC is primarily concerned with the activities of research staff and students. It steers the development, review, implementation, monitoring and evaluation of procedures, policies and guidelines to facilitate the process of research governance and review of research application and projects in relation to ethics and integrity.

The UREIC is responsible for approving the terms of reference, membership, procedures and annual reports of Faculty Research Ethics and Integrity Committees (FREICs) and giving guidance to FREICs as required.

UREIC oversees the FREICs, develops ethics and integrity training for staff and reviewers, monitors research, implements safeguarding measures, deals with FREIC appeals, participant complaints that are unresolved by FREIC and takes steps to prevent research misconduct.

The UREIC will consider specific ethical matters on an *ad hoc* basis, for example, in the case of high-risk studies or if a FREIC is unable to reach a decision on a research proposal for whatever reason or if a researcher wishes to appeal against the decision of a FREIC. In addition, it will undertake an annual audit of decisions taken by Committees, particularly those decisions taken by expedited review.

The UREIC committee reports to the Research and Innovation Committee and provides an annual report to Senate. Research governance for research integrity, human research ethics and animal research ethics is undertaken through the University Research Ethics and Integrity Committee and reporting to it, Faculty Research Ethics and Integrity Committees, Human Tissues Governance Group, and Animal Welfare Ethical Review Board (Figure 6.1).

³⁴The Universities UK Concordat to Support Research Integrity (2012) is available from: <http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf> (access 28th November 2017)

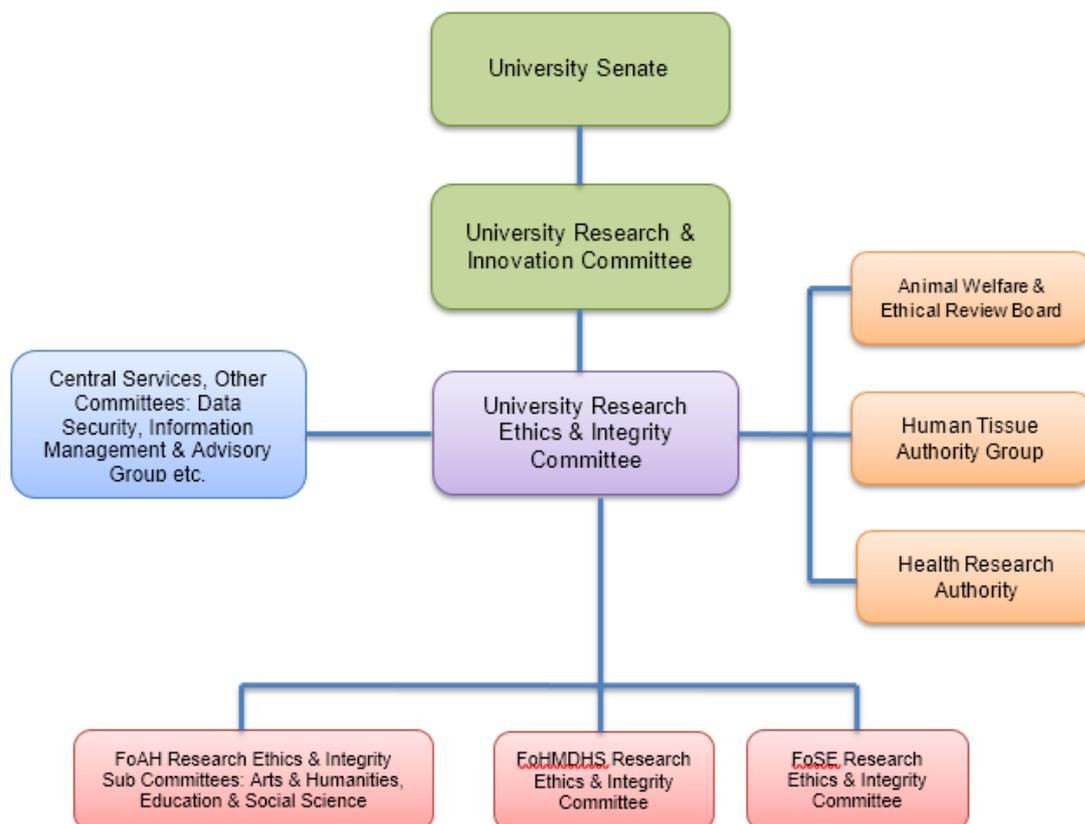


Figure 6.1 Research Integrity and Governance Structure

5.2 Faculty Research and Integrity Committees (FREICs)

To comply with the sector standards in research ethics and integrity the FREICs implement the ethical and data management review process, facilitate training, provide information and guidance, monitor studies and research misconduct allegations, assess their own practices and review their documentation regularly. The FREICs work with the Faculty Research Committees and UREIC to define and mitigate levels of risk.

Review processes vary between FREICs but the University requires them all to meet minimum standards of expertise and ethical review.

Applicants can appeal the decision made by the FREIC in which case it is submitted to the UREIC Secretary for investigation.

Where external regulatory bodies are involved the FREICs are notified and will assist by recording the studies for monitoring. Co-ordination with responsible officers for regulated activities provides assurance of compliance with sector requirements.

5.3 Externally Regulated Research at the University

Where research is externally regulated, for example under the Human Tissue Act 2004, there are additional, specific University policies, procedures and committees in place. These work independently from the FREICs with named representatives and as specialist committees with their own reporting lines.

Part 6: Guidance and Process for University Ethical Review

6.1 The process of Ethical Review

Researchers have a responsibility to review their projects in advance to identify issues of relevance to the Ethics and Integrity policies and take appropriate actions, including a submission of the research proposal for ethical review when required.

Faculty Research Ethics and Integrity Committees (FREICs): Faculty review committees apply the fundamental principles outlined in University of Plymouth Research Ethics Policy and standards of their professional bodies when approving and advising on projects for research by University researchers.

The University Research Ethics and Integrity Committee (UREIC) has overall responsibility for the development, implementation and monitoring of research ethics policies and reports to the Research & Innovation Committee.

Appeal: Applicants can appeal the decision made by the FREIC in which case it is submitted to the UREIC Secretary for investigation.

External regulations: Where external regulatory bodies are involved the FREICs are notified and will assist by registering the studies for monitoring. Co-ordination with responsible officers for regulated activities provides assurance of compliance.

Research studies cannot begin until ethical approval has been obtained.

6.2 Principles for reviewers - (from AREC 2013)

The University applies the four principles of governance for research ethics committees: independence, competence, facilitation, openness. They are set out by the Association of Research Ethics Committees (AREC, 2013) to describe what is expected of Committees and how they function:

A-Independence

- Conflicts of interest must be declared by reviewers and/or mitigated
- Consistent standards maintained across committees and documents
- Accountable reporting - ratification and audit of decisions
- Process for appeal/intervention on outcome (on process and/or judgement?)
- Presence of lay person or cross disciplinary representative

B-Competence

- Expertise and systematic development through training
- Up to date -procedures reviewed annually or in light of current sector changes
- Standard Operating Procedures for fair and consistent opinion
- Coherent information and communication for sound judgement
- University acknowledgement of review contribution

- Continuing review - closer monitoring of high risk studies

C-Facilitation

- Efficient and clear process
- Guidance on good research conduct
- Constructive criticism and standard decision outcomes/opinions
- Timely and proportionate – expedited review possible for low risk studies
- Local processes
- Information and training for researchers

D - Openness

- Public expects transparency on reviewed projects and research ethics committees opinions (with due attention to appropriate confidentiality and intellectual property rights)
- Published governance arrangements for public accountability
- Regular review planning and implementation
- Self-review and development to maintain efficiency and expertise
- Responsible - Annual reporting on changes to procedures, membership and documentation.

6.3 Appeals process

Researchers can appeal against the decisions taken by a FREIC either to reject or require significant modifications to research. Initially the appeal should be to the FREIC taking the decision. If this is not successful the researcher can request the appeal be considered by the UREIC.

Appeals referred by a FREIC to the UREIC will be considered by a sub-committee. This sub-committee will comprise all UREIC members with the exception of the FREIC Chair referring the appeal for consideration.

The sub-committee will receive verbal statements from the relevant FREIC Chair and the project researcher.

The relevant FREIC Chair and project researcher will subsequently be informed in writing of the sub-committee's decision.