Research Integrity

A Policy Framework on Research Ethics & Governance
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FOREWORD

At Swansea University, we are very proud of our reputation for excellent research, and for the calibre, dedication, and professionalism of our research community. We understand that integrity must be an essential characteristic of all aspects of our research, and that as a University entrusted with undertaking research we must clearly and consistently demonstrate that the confidence placed in our research community is rightly deserved. The University therefore expects everyone engaged in research to adhere to the very highest standards of research integrity and to conduct themselves and their research activities accordingly. This Framework clearly lays out those expectations, and systematically sets out how the University will seek to ensure that they are met in all of our research activity. The Framework is fully aligned with the Universities UK’s *Concordat to Support Research Integrity*, whose five key commitments we share and wholly endorse:

- We are committed to maintaining the highest standards of rigour and integrity in all aspects of research;
- We are committed to ensuring that research is conducted according to appropriate ethical, legal, and professional frameworks, obligations, and standards;
- We are committed to supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers;
- We are committed to using transparent, robust, and fair processes to deal with allegations of research misconduct should they arise; and
- We are committed to working together to strengthen the integrity of research and to reviewing progress regularly and openly.

We all share the responsibility for understanding, upholding, and promoting research integrity and research excellence, and for ensuring that we continue to merit being entrusted with so many vitally important research projects across the full spectrum of our research portfolio, subject areas, and research community. This Framework demonstrates our determination to embed research integrity at the heart of all that we do.

Professor Hilary Lappin-Scott

Senior Pro Vice Chancellor
SCOPE

The document provides a framework for research ethics and governance at the University and applies to all academic disciplines. It is the central reference point for matters relating to research governance and should be used and referred to accordingly by research staff and students.

The framework is a ‘live document’ and is reviewed annually by the University Research Ethics and Governance Sub-Committee to reflect ‘best practice,’ and legislation, where applicable, within research.

The aim of the framework is to set standards and expectations that enhance research quality, integrity and compliance and safeguard both the public and researchers. Research principles and standards set out in the framework apply to all stages of a research project and provide information on what research requires ethical approval.

Research involves information gathering, and research ethics concerns the means (methods) used to gather and analyse that information as well as its presentation and publication. When the information to be gathered is:

- not in the public domain; and/or
- Involves using other human participants (e.g. in questionnaires or interview), human tissue, or animals, then some form of ethical review of that research is normally required.
  Research pursued by undergraduate and postgraduate students and staff that satisfies the above criteria will need some form of ethical review.

As per the Frascati manual, research is also defined as creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of humanity, culture and society, and the use of this stock of knowledge to devise new applications.

Researchers are defined as members of the University, including staff and postgraduate research students, and other students insofar as they are engaged in research, and those individuals who are not members of the University but who are conducting research on University premises or using University facilities.

The University requires all employees, students, independent contractors and consultants, visiting or emeritus staff, staff on joint clinical or honorary contracts, and anyone conducting research using institutional facilities or on institutional premises or under the auspices of the University to abide by and promote the principles highlighted in this Framework, irrespective of their source of funding and area of research.
EXECUTIVE SUMMARY

The *Research Integrity: A Policy Framework on Research Ethics and Governance* is an overarching document specifying standards, policies and procedures for implementing and ensuring ‘good research governance’ practices in all subject areas. It outlines the University’s approach to research integrity in relation to ethical approval, research misconduct, research funding, peer review, registration of research projects, and research data management.

The Framework has been developed in accordance with the guidelines of the *Concordat to Support Research Integrity*, *UK Research & Integrity Office Code of Practice* and *Research Governance Framework for Health & Social Care in Wales*.

Based on guidelines provided in this Framework, subject specific research ethics and governance policies and procedures are developed.

The Framework is owned, implemented, monitored and reviewed by the University Research Ethics and Governance Sub-Committee, with regular reporting to Committee for Research & Innovation (CRIS) and Senate.
1. INTRODUCTION

As an organisation conducting research, employing researchers, and as a signatory to the *Concordat to Support Research Integrity*, the University has a responsibility to demonstrate that appropriate mechanisms of ‘Research Integrity: Ethics and Governance’ are embedded in its practices.

The University seeks to conform with all applicable external research governance guidelines and codes of practice including those developed or adopted by major funding bodies.

2. RESPONSIBILITY AND ACCOUNTABILITY

Demonstrating evidence of good ‘research governance’ is a responsibility of all. Researchers should comply with all applicable laws and statutes relevant to the conduct of research, including the Data Protection Act 1998, the Human Tissue Act 2004, the Mental Capacity Act 2005, the Safeguarding Vulnerable Groups Act 2006, the Medicines for Human Use (Clinical Trials) Regulations 2004, the Animals (Scientific Procedures) Act 1986 and the International Committee on the Harmonisation of Good Clinical Practice (ICH GCP).

A commitment to research integrity should be reinforced through the research environment, research culture, research practices and the training of researchers. The University is responsible for:

- Maintaining the highest standards of rigour and integrity in all aspects of research;
- Compliance with all current health and safety legislation;
- Demonstrating clear codes of practice and a research governance framework;
- Ensuring that principal investigators, research staff and students, and anyone else conducting research using institutional facilities and on institutional premises, are aware of the research governance framework and comply with it;
- Ensuring that appropriate indemnity/insurance arrangements are in place for any authorised research activity;
- Discharging the role of a ‘sponsor’ in the management and monitoring of any research-related work;
- Demonstrating systems for continuous professional development of staff at all levels;
- Having agreements and systems to identify, protect, and exploit intellectual property;
- Ensuring that processes are in place to enable individuals to seek redress if harmed as a result of whistleblowing on the part of the University’s research staff to research students, and others for whom the University is responsible;
- Ensuring that systems are in place to detect fraud and other forms of research misconduct;
- Ensuring that systems are in place to process, address and learn lessons from any errors or complaints brought against any University staff or students; and
• Ensuring that systems are in place for permitting and assisting with any statutory inspections, audits or investigations arising from errors or complaints associated with the research undertaken by University staff or students.

3. RESEARCH GOVERNANCE

Research Governance requires well defined quality and risk-management policies and procedures that:

• Define clear standards;
• Ensure that standards are met; and
• Ensure that arrangements are in place to assess, monitor, manage and report adherence to the standards.

Research Governance aims continuously to improve standards by setting out principles, requirements, and mechanisms. It describes assessments and monitoring practices to ensure that:

• Rigour and integrity are maintained in all aspects of research;
• Research is conducted in accordance with appropriate ethical, legal and professional frameworks, obligations and standards;
• A culture of integrity and support is available to researchers;
• Decision-making processes are transparent, with clear allocation of responsibilities and effective monitoring arrangements;
• Robust and fair processes are in place to deal with allegations of research misconduct; and
• Regular auditing and reviewing of research practices are conducted.

Research Governance is applicable to all those who:

• Design research studies;
• Undertake research;
• Host research in their organisation;
• Fund research proposals or research infrastructure; and
• Undertake and manage research in all professional groups.

Staff and students undertaking research are expected to familiarise themselves with all relevant guidelines, be accountable for their actions and conduct, and observe the highest standards of integrity, honesty, professionalism, transparency and rigour in every aspect of their research work.

4. RESEARCH ETHICS

Research involves information gathering and research ethics concerns the means (i.e. methods) used to gather and analyse that information in addition to its presentation and publication. When the information to be gathered is not in the public domain, or where its collection involves using other human participants (e.g. in questionnaires or interviews or...
interventions), human tissue, or animals, then it is highly likely that some form of ethical review and approval of that research is required. The dignity, rights, safety, and well-being of participants should be the primary consideration of any research study. Informed consent should be at the heart of any ethical research involving human participants. Maintaining good ethical conduct lies, in the first instance, with researchers themselves. Ethical research is therefore a matter of being risk aware, and not necessarily of being risk averse.

5. RESEARCH PRINCIPLES

A glossary of important ethical terms and ideas is provided in Appendix 3 of this Framework.
Section A

SWANSEA UNIVERSITY’S RESEARCH GOVERNANCE STRUCTURE

A1. Institutional responsibility & arrangements for Research Ethics and Governance

The University has the organisational structure to ensure that research conducted meets the highest levels of integrity, including sponsorships, appropriate frameworks, research design, and that research findings are robust and defensible.

At the Institutional level the Research Ethics and Governance Sub-Committee has the overarching responsibility for managing the University’s research ethics and governance arrangements. This Sub-Committee is not responsible for conducting ethical reviews per se but for ensuring that the appropriate committees, groups, structures and processes are in place at College level in order for ethical reviews to be conducted to whatever point necessary on all relevant research.

The Research Ethics and Governance Sub-Committee provides policy direction and ethical oversight to Colleges in relation to arrangements for ethical reviews and quality assurance. Any exceptional cases/issues that cannot be dealt with by College level Research Ethics Committees are dealt with by the Institutional level Research Ethics and Governance Sub-Committee.

The Sub-Committee provides progress reports to the Committee for Research & Innovation Strategy (CRIS) and Senate (if required).

A2. University Research Ethics and Governance Sub-Committee
(Reports to the Committee for Research & Innovation Strategy (CRIS) and its terms of reference and membership are as follows):

Terms of Reference

- Own and Implement the Policy Framework on ‘Research Integrity: Ethics & Governance’;
- Oversee the work of University committees with particular responsibility of research governance matters, including College Research Ethics & Governance Committees, Research Misconduct Screening & Investigation Panels, Sponsorship Review and Approval Committee, Joint Scientific Review Committee, Animal Welfare and Ethical Review process group, and any Subject or Area specific Oversight Groups.
- Monitor compliance with internal ethical policies/procedures and external regulations/legislation relating to research ethics and governance;
- Monitor, review, and where necessary update policies and procedures relating to research integrity: ethics & governance;
- Maintain oversight of research misconduct cases, including providing guidance to institutional screening and investigation panels.
- Provide assistance and guidance to Colleges to ensure that appropriate mechanisms and structures are developed at Colleges for the management of research ethics and
governance. Ensuring that research ethics and governance is a standing agenda item for the College Research Committees;

- Ensure that research risk is managed appropriately and risks are mitigated for business continuity and emergency planning.
- Promote best practice and encourage consistency in matters of research integrity: ethics and governance across the University through training and raising awareness;
- Ensure oversight and compliance of sponsorship requirements, audits and inspections by external bodies (e.g. MHRA, HTA, RCUK, IAU)
- Update and disseminate all institutional research-governance related documentation with a view to ensuring that stakeholders awareness of the processes relating to research governance and ethical approval; and
- Approve and review periodically subject-specific research ethics and governance frameworks produced by the College Research Ethics & Governance Committees.

**Membership**
- Academic Lead - Research and Integrity (Chair)
- Deputy Academic Lead – Research Integrity (Deputy Chair)
- Chairs of College Research Ethics & Governance Committees
- Director of Swansea Trials Unit
- Director of the Institute of Research Ethics & Law

**In Attendance:**
- Professional Staff representatives from Research, Engagement & Innovation Services (REIS)
- Professional staff representative from Development & Training Services (DTS).
- University Risk Administrator
- Representative from Procurement & Finance
- Representative from ISS
- Research Integrity Compliance Officer (Secretary to the Committee)
- Lay member(s)
- Student representative(s)

**Frequency of meetings**

- Normally once a term with the option of special meetings being held as and when required.

**A3. College Research Ethics & Governance Committees**

Each College has a single College Research Ethics & Governance Committee that reports to the College Research Committee. If a single Research Ethics & Governance Committee is insufficient for the needs of the College’s research community, then the additional capacity is configured as sub-committees or oversight groups. All College sub committees and oversight groups report to the College Research Ethics & Governance Committee.

Chairs of College Research Ethics & Governance committees and any sub-committees/oversight groups have competence in the ethical review of research. It is recommended practice that College committees involve a lay member to ensure some
independence of judgement and to help avoid conflicts of interest. College Research Ethics & Governance committees and any sub-committees/oversight group should foster a culture in which research integrity is recognised as integral to research excellence. College Research Ethics & Governance committees and any sub-committees should also be aware of when it needs to refer out to external ethics committees such as the NHS ethics review or AWERB (Animal Research Review Board).

To ensure that all research undertaken by staff and students at Swansea University embodies high standards of research ethics and governance, each College is expected to produce a research ethics and governance framework for its subject area(s) and community of researchers. These frameworks should accord with appropriate disciplinary, professional, regulatory, and legislative requirements, and be aligned with the University Framework. Each of the College frameworks is approved and reviewed by the University Research Ethics and Governance Sub-Committee on a regular basis.

The College framework should provide guidance on research integrity to staff and students within the College, including the requirements and procedures for undertaking ethical review and securing ethical approval, which may, where appropriate, be differentiated according to the particular needs of the College (e.g. discipline-specific ethical review procedures; provision for light-touch reviews and expedited reviews as well as full ethical reviews; and approved protocols for commonly occurring research).

**A4. REPORTING STRUCTURE**

The College Research Ethics & Governance Committee (and any of its Sub-Committees/oversight groups) should meet regularly to undertake ethical reviews and assess ethical risks of research, and should report regularly to the College Research Committee, and to the College Management Boards as appropriate.

The College Research Ethics & Governance Committee should provide a report **once per term**, to the University Research Ethics and Governance Sub-Committee with oversight information on ethical reviews, data on high risk research and its monitoring, and identifying any difficulties encountered in the process of ethical reviews.

It is expected that cases of disagreement for ethical approval in College Research Ethics & Governance Committees would be referred to the University Research Ethics and Governance Sub-Committee. More broadly, the University Research Ethics and Governance Sub-Committee should seek to resolve any problems that cannot be dealt with at College level and provide advice to Chairs of College Research Ethics Committees, where appropriate.

The College website should include links to relevant information on its research ethics and governance framework (e.g. College Research Ethics & Governance Committees and Sub-Committees/oversight groups; their terms of reference, membership, and meeting dates; research guidelines; procedures for obtaining ethical approval; and links to relevant external websites). The Chair of the College Research Ethics & Governance Committees should be a member of the College Research Committee.
Colleges are expected to bring to the attention of the Registrar & Chief Operating Officer or the Research Integrity Compliance Officer any cases of alleged research misconduct should they arise by emailing: researchmisconduct@swansea.ac.uk

College and subject-specific ethics information and policies can be accessed by the following links:

- College of Arts & Humanities
  [http://www.swansea.ac.uk/riah/research-ethics/](http://www.swansea.ac.uk/riah/research-ethics/)

- College of Engineering
  [https://www.swansea.ac.uk/engineering/research/research-ethics-committee/#guidance-on-applying=expanded&application-form-and-guidance-notes=expanded&terms-of-reference=expanded&committee-membership=expanded&meetings=expanded&research-governance-and-research-conduct-complaints=expanded](https://www.swansea.ac.uk/engineering/research/research-ethics-committee/#guidance-on-applying=expanded&application-form-and-guidance-notes=expanded&terms-of-reference=expanded&committee-membership=expanded&meetings=expanded&research-governance-and-research-conduct-complaints=expanded)

- College of Human & Health Sciences.
  [http://www.swansea.ac.uk/humanandhealthsciences/research/research-ethics-committee/](http://www.swansea.ac.uk/humanandhealthsciences/research/research-ethics-committee/)

- College of Law & Criminology
  [http://www.swansea.ac.uk/law/research/researchethics/](http://www.swansea.ac.uk/law/research/researchethics/)

- School of Management
  [http://www.swansea.ac.uk/som/research/researchethics/](http://www.swansea.ac.uk/som/research/researchethics/)

- Swansea University School of Medicine (SUMS)
  [http://www.swansea.ac.uk/medicine/research/researchethicsandgovernancecommittee/](http://www.swansea.ac.uk/medicine/research/researchethicsandgovernancecommittee/)

- College of Science.
  [http://www.swansea.ac.uk/science/research/](http://www.swansea.ac.uk/science/research/)

A5. COMPLIANCE REQUIREMENTS

- **Compliance with NHS ethics policies**: The Framework is designed to complement the National Health Service (NHS) ethics review system.

- **Compliance with research funding body ethics policies**: Research funding bodies may have their own research ethics policies and requirements. In such cases it is expected that the researcher will observe these policies and requirements, and the conditions of receiving funding will be considered alongside University policies. It is always advisable to observe the University policies and associated procedures as an additional layer of research ethics governance.

- **Compliance with external stakeholder ethics policies**: Professional bodies and learned societies may also have their own ethics policies, guidelines, and requirements. Whilst these should be followed where it is appropriate so to do, researchers must also adhere to the University’s Framework.
College Research Ethics & Governance Committees

(A Key Responsibility: Ethical approval of staff and student research)

1. College of Arts & Humanities
2. College of Engineering
3. College of Human & Health Sciences
4. College of Law
5. School of Management
6. College of Medicine
7. College of Science

Research area & subject specific Oversight groups


_______Reporting lines.  __________communication lines.
Section B

POLICY ON ETHICAL APPROVAL

B1. Ethical standards

Upholding high ethical standards in the conduct of research means accepting and respecting principles of integrity, honesty and openness. Conducting research with integrity means embracing intellectual honesty and accepting personal responsibility for one’s own actions.

Prior to, during, and following the completion of research activities, researchers are expected to consider the ethical implications of their research depending on its nature and context.

Researchers should always consider their research from the perspective(s) of all interested parties.

B2. Assessing research risks and determining whether ethical approval is required

If research involves data that are not in the public domain, and/or involves using other human participants (e.g. in questionnaires, interventions or interviews) human tissue, or animals, then some form of ethical review of the research would normally be required. Where there are no explicit legislative or regulatory requirements for ethical approval, there are a number of questions that should be taken into account when determining the level of ethical approval required for a research proposal. Such questions should include at least the following:

- Does the research involve vulnerable groups, such as children or people with cognitive impairment?
- Is there any risk that potential participants might feel pressured into agreeing to take part in the research? This could be the case, for example, where there is an imbalance of power between the researcher and the participants (e.g. doctor and patient, lecturer and student, line manager and employee).
- Will the study discuss sensitive topics (e.g. bereavement, sexuality or drug use)?
- Could the research compromise the anonymity of the participants (e.g. via use of email or the Internet)?
- Could the study cause embarrassment, anxiety or distress to participants?
- Would the research involve animals, organisms, human tissue, personal data or cause any harm to the environment?

(The above examples comprise the kinds of considerations that should be thought through, but by no means is an exhaustive list).

It will be the responsibility of the College Research Ethics and Governance Committees to determine the requirements for ethical approval and determine the level of ethical risk associated with the research project. Subject-specific checklists should be developed within Colleges to identify whether or not a full application for ethical approval should be submitted to the College Research Ethics committee. Any lead researcher or Principal Investigator (or the supervisor of student research) preparing an application should review the checklist and exercise appropriate professional judgement by way of good practice. If the answer is ‘yes’ to
any of the checklist’s questions, then ethical approval should be sought for their research proposal. If the answer is ‘no’ to all of the checklist’s questions, then confirmation should still be sought from the College Research Ethics Committee.

The College should retain all checklists and the documentation associated with ethical reviews and approvals for quality assurance and audit purposes, which may need to be made available at short notice (e.g. for external inspection).

**B3. Procedures on quality checks and assurance**

The University will give guidance to researchers, and will work to create and maintain a culture of research integrity that encourages and supports researchers by providing training to enable them to understand and meet their obligations.

The University will provide the following tools and training to enable compliance with this Policy Framework:

- A template risk assessment in the form of a research registration checklist to guide researchers through the regulations and to enable them to register their project and ensure that the correct approvals are obtained;
- Training and education in the regulations governing these areas of research through staff development, e-learning, and external training providers;
- Monitoring of research projects in accordance with University monitoring/audit procedures;
- Support of and engagement with internal and external audits and inspections of projects in the area of research; and
- An annual report to the University Committee for Research and Innovation (CRIS) and Senate.

**B4. Research Ethics review appeals:**

An appeal can be made in instances of procedural irregularities in the review process, or if bias or prejudice has impacted the decision of the committee. Any material relating to the case that was not brought to the attention of the College Research Ethics & Governance committee when the initial review decision was taken should be re-submitted for approval to relevant body with the updated information rather than as an appeal against the original decision.

- Researchers are encouraged to refer any ‘appeals’ on ethics approval to the Chair or Deputy Chair of the College Research Ethics & Governance Committees in the first instance.
- Issues that cannot be resolved by the College Committees due to the above body/persons being conflicted should be referred to the Chair of the University Research Ethics and Governance sub-committee.
- In the event that all of the above bodies/persons are conflicted, the matter must be referred either to the Registrar through the Secretary to the University Research Ethics & Governance sub-committee.
• Persons making appeals will be protected by the University policies on Whistleblowing, Victimisation and Harassment.

Procedure for making appeals:

• Researcher to notify the Secretary to the College Research Ethics & Governance committee, in writing, within 10 working days of having received the original committee decision.

• The appeals documentation should include the following details: Title of the research project, name of lead researcher or supervisor, date of the committee decision against which the appeal was being made, and grounds for appeal with any further supporting documentation.

• The Chair of the College Committee should screen the application and confirm in writing, if he/she is the most appropriate person to Chair the appeal committee.

• If the Chair is conflicted, then the appeal should be referred to either the Deputy Chair of the College Research Ethics & Governance Committee, Chair of the University Research Ethics & Governance sub-committee or the Chief Operating Officer as appropriate through the relevant committee secretary (College or the University).

• Where the appeal is based on valid ground, a suitable panel will be convened comprising of researchers with expertise in the area and an academic staff from a different area or an external lay member.

• The panel may meet virtually, or face to face, at the discretion of the Chair of the appeals panel.

• The panel will process the appeal as soon as possible and preferably within 4 working weeks from the receipt of the original appeal.

• The applicant will be informed in writing of the date of the meeting and the decision of the panel.

• The decision of the appeals panel will be final.

Records of appeals at College Research Ethics & Governance committees will be kept and included in the summary report to the University Research Ethics & Governance sub-committee.

Secretaries to both the College and University Research Ethics & Governance committees will ensure that institutional or contractual obligations in case of funded projects are identified with relevant staff in Research Engagement & Innovation Services (REIS).
Section C

POLICY ON HEALTHCARE RESEARCH

It is a requirement for some research to have a formal sponsor. The sponsorship responsibilities for health and social care research are documented within the Research Governance Framework for Health & Social Care in Wales (2nd Edition), 2009. Clinical Trials of Investigational Medicinal Products (CTIMP’s) are governed by the EU Clinical Trials Directive, and further clarified by the Good Clinical Practice (GCP) Directive 2005/28/EC. Other types of research may require a formal sponsor, with its own particular set of responsibilities.

NHS Research Ethics Committees (RECs) require evidence that a sponsor has accepted the role on submission of an application. The Medicines and Healthcare Products Regulatory Agency (MHRA) requires evidence that a sponsor has accepted the role before any Clinical or Device Trials are authorised.

The sponsor is the individual, organisation or partnership that takes on overall responsibility for appropriate arrangements being in place to set up, run and report a research project. All health and social care research must have a sponsor. The sponsor is normally expected to be the employer of the chief investigator/principal investigator in the case of non-commercial research, or the funder in the case of commercial research. The sponsor has overall responsibility for the design and management of the research, including:

a. verifying that everything is ready for the research to begin in a safe and timely manner;

b. putting and keeping in place arrangements to finance and manage the research project, including its competent risk management;

c. identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications;

d. ensuring that the research proposal or protocol is scientifically sound (e.g. through independent expert review, if appropriate) and that the investigators, research team and research sites are suitable;

e. satisfying itself that, where expected or required, the research has a favourable research ethics committee opinion and all relevant approvals before it begins;

f. satisfying itself that the chief investigator/principal investigator has made appropriate arrangements for making information about the research publicly available, normally before it starts, and for retaining and making accurate findings, data and tissue accessible, as appropriate, after it has finished;

g. ensuring that roles and responsibilities of the parties involved in the research are agreed and appropriately documented;
h. ensuring appropriate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project and any commercialisation of the findings; and

i. ensuring that appropriate, effective procedures and arrangements are kept in place and adhered to for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

The University will act as a ‘Sponsor’ only if it is satisfied that:

• the Project respects the dignity, rights, safety, and well-being of participants and the relationship with care professionals;
• an appropriate process of independent expert review demonstrates that the Project proposal is worthwhile, of high scientific quality, and represents good value for money;
• an appropriate Research Ethics Committee & Sponsorship Review and Approval Committee has reviewed the Project and has given a favourable opinion in writing;
• appropriate arrangements are in place for the registration of the trial or where appropriate other health-related research;
• the Principal Investigator/Chief investigator and other key researchers, including those at collaborating sites, have the necessary expertise and experience, and have access to the resources and support, needed to conduct the proposed Project successfully;
• the proposed arrangements and resources allow the collection and proper retention of high-quality data, and the proposed systems and resources are those required to allow appropriate data analysis and data protection;
• arrangements proposed for the Project are consistent with all applicable Regulations, statutes, and guidelines;
• organisations and individuals involved in the Project agree the division of responsibilities between them to ensure that:

  o satisfactory arrangements are in place for the management and monitoring of the Project, and that these are documented;
  o satisfactory arrangements are in place for the conclusion of the Project including appropriate plans for reporting the Project, disseminating the findings, archiving, data retention and destruction; and
  o the Trial Master File or study documentation includes copies of the following: the informed consent form; the Principal Investigator’s CV; the application to the relevant NHS REC, MHRA and the approval letters when received; the Protocol, and any approved amendments thereto; and

• there is agreement in writing on appropriate arrangements for:
  o recording, reporting and reviewing adverse events and any significant developments as the Project proceeds, particularly those that put the safety of individuals or the reputation of the University at risk;
  o approval of any modifications to the Project design;
  o a robust system to alert the University and other stakeholder organisations, including the NHS REC and MHRA, if significant developments occur as the Project progresses,
whether in relation to the safety of individuals or the scientific direction;
- ensuring that all members of the research team have appropriate contracts in place to fulfil their obligations in the Project and enable the Principal Investigator and the University as Sponsor to fulfil their obligations; and
- the University has put in place a service level agreement (SLA) to enable a delegated individual to undertake certain Sponsor responsibilities on its behalf for all University sponsored studies, regardless of where they are hosted.

Where projects are co-sponsored, formal arrangements should be put in place:

a) Between the Co-sponsors – so it is clear where all liabilities of fulfilling requirements lie. This should ideally be documented using a contract or a Memorandum of Understanding, either issued on a trial–by–trial basis or as an overarching master agreement for all clinical trials where two or more organisations are closely connected and often collaborate (e.g. NHS Trust and the University); and

b) Between sponsors and those delegated sponsor functions – to ensure all parties are aware of their delegated functions.

OBLIGATIONS OF THE CHIEF INVESTIGATOR

As a University employee or for a University sponsored CTIMP or Devices trial, the Principal Investigator of the project must ensure that they adhere to the following:

- the dignity, rights, safety, and well-being of research participants will be given priority at all times;
- the Protocol shall be strictly adhered to. However, adhering to the Protocol shall not override the Principal Investigator’s clinical judgement to use alternative measures if they believe these are needed to protect research participants for whom they are clinically responsible;
- the Principal Investigator has the necessary experience, suitable qualifications, training, and expertise to undertake the tasks associated with the Project;
- the Principal Investigator is responsible for ensuring that any research staff undertaking the project have suitable qualifications, necessary experience, training, and expertise to undertake tasks associated with the Project. For Clinical Trials Projects, the training should include Good Clinical Practice (GCP) and copies of the training should be included in the Trial Master File; and
- the Principal Investigator should ensure that students and research staff have adequate supervision, support, and training to undertake their roles in the project.

The University reserves the right to withdraw sponsorship and take whatever action is necessary to ensure the safety of research participants and its ability to act as sponsor if it believes the Principal Investigator is not fulfilling their obligations. In addition, non-compliance with the obligations by the Principal Investigator may lead to action under the University’s Staff Disciplinary Procedures and may invalidate the terms of any University Insurance for the trial.
POLICY ON HEALTH & SOCIAL CARE RESEARCH

The UK policy framework for health and social care research sets out principles of good practice in the management and conduct of health and social care research that take appropriate account of legal requirements and other standards. These principles protect and promote the interests of patients, services users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-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.

All forms of research involving human participants (including their tissue, organs or data) will follow the highest standards of research ethics, governance and relevant legislation, and will be conducted with the utmost care and respect for human welfare and rights.

Human participants in research must take part voluntarily and free of any coercion. Research involving humans will usually occur under informed consent. All research staff and participants would normally be fully informed of the purpose and methodologies of the research, the associated risks of participation and the proposed uses of the research data. Consent must be sought for any biological samples that might be used for future research.

Ethical consideration will be given to all research involving human participants or biological samples. Review by a relevant ethics committee (both internal and external to the University) will be undertaken as appropriate. Approval from other regulatory bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), Human Fertilisation and Embryology Authority (HFEA), the Gene Therapy Advisory Committee (GTAC), or Health and Social Care Information Centre (HSCIC), Human Tissue Authority (HTA) will also be sought where necessary. Researchers should ensure the confidentiality of personal information relating to the participants in research, and that the research fulfils any legal requirements such as those of the Data Protection Act 1998.

D1. Health and Social Care Research.

The Welsh Government’s Health & Care Research Wales (HCRW) sets out a clear framework for research governance and ethics for health and social care research in Wales. HCRW is responsible for developing research ethics policy in Wales.

NHS Research Ethics Committees act as part of an efficient, accountable and independent Research Ethics Service to protect the dignity, rights, safety and well-being of the people who take part in research.

D2. Research Governance Framework

Welsh Government’s Research Governance Framework second edition outlines the principles of good governance that apply to all research undertaken within the remit of the Minister for
Health and Social Services for Wales. In September 2009, the Wales Office of Research and Development for Health and Social Care (WORD) published the second edition of the Research Governance Framework, which reflected changes in research governance since 2001, including developments related to the introduction of the Medicines for Human Use (Clinical Trials) Regulations 2004, Human Tissue Act 2004 and Mental Capacity Act 2005. It also includes a number of updates that outline Wales’s position with regard to UK wide research governance initiatives.

Research governance is one of the core standards for healthcare organisations. The document identifies the responsibilities of:

- Research sponsors;
- Funders;
- Researchers;
- Employing organisations;
- Care organisations;
- Care professionals; and
- Participants.

All who have a part to play in ensuring that any research undertaken in the area of health and social care meets the standards.

Researchers working with the NHS should ensure compliance with NHS Research Governance Framework.

D3. NHS Research Ethics Committees

For Health and Social Care research, researchers must satisfy a Research Ethics Committee, that the research they propose will be ethical and worthwhile. The committee has to be assured that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society. A Research Ethics Committee is a group of people appointed to review research proposals to assess formally if the research is ethical. In Wales, there are 8 NHS Research Ethics Committees set up to provide ethical approval to research being conducted in the NHS. Four of these have been recognised by the United Kingdom Ethics Committee Authority to be able to review Clinical Trials of an Investigational Medicinal Product as required by The Medicines for Human Use (Clinical Trials) Regulations 2004. The other 4 Research Ethics Committees are authorised to review all other research applications except those relating to Clinical Trials of an Investigational Medicinal Product.

D4. The Human Tissue Authority

The Human Tissue Authority (HTA) licenses organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. In the College of Medicine there are designated individuals responsible for ensuring compliance with the relevant Human Tissue legislation for both research and teaching. For further information on HTA contacts in the University, visit:
D5. College of Medicine - The Secure Anonymised Information Linkage Databank

The Secure Anonymised Information Linkage (SAIL) Databank is a world-class, anonymous data linkage system that securely brings together the widest possible array of routinely-collected data for research, development and evaluation. Robust Governance arrangements underpin all areas of the work so that SAIL represents a valuable data resource, whilst complying with data protection legislation and confidentiality guidelines.

SAIL is committed to:

- robust Governance arrangements and Public Engagement to ensure that our work complies with the relevant legislative and regulatory frameworks and is in the public interest.
  - has an Advisory Board to provide strategic input from members of the public and leaders in the field of health information and research in Wales.
  - benefits from an active Consumer Panel to provide a public perspective on data linkage research.
  - has a Management Board that comprises of the SAIL Directors and Management Team, to oversee and direct operational arrangements.
  - has an Information Governance review Panel (IGRP) that provides independent advice on Information Governance and reviews all proposals to use SAIL data to ensure that they are appropriate and in the public interest.

The membership of the IGRP is comprised of representatives from: British Medical Association (BMA), National Research Ethics Service (NRES), Public Health Wales, NHS Wales Informatics Service (NWIS) and Consumer Panel.
POLICY ON RESEARCH INVOLVING THE USE OF ANIMALS

All research and teaching activities undertaken by staff and/or students at the University or in the field which involve interventions with live animals are subject to approval and monitoring by the University’s Animal Welfare & Ethical Review Board (AWERB). Members include a designated Animal Care and Welfare Officer, a Veterinary Surgeon and representatives from each College working in this area.

Certain categories of work in this area also require appropriate licences from the Home Office and are regulated by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012.

The University is committed to the principles of the 3Rs in the context of working with animals. The 3Rs relate to:

- **Replacing** the use of animals with alternative techniques, or avoiding the use of animals altogether.

- **Reducing** the number of animals used to a minimum, to obtain information from fewer animals or more information from the same number of animals.

- **Refining** the way experiments are carried out, to make sure animals suffer as little as possible. This includes better housing and improvements to procedures which minimise pain and suffering and/or improve animal welfare.

Queries relating to working with live animals should be directed to awerp@swansea.ac.uk

The University endorses the ARRIVE (Animal Research: Reporting of in Vivo Experiments) guidelines which were developed as part of an NC3Rs initiative to improve the design and reporting of animal research and are intended to ensure that studies are robust and reproducible and add fully to the knowledge base.

Subject to editorial policies, the University encourages all researchers to publish in line with the ARRIVE guidelines.

Further details on the range of available resources can be obtained from (www.nc3rs.org.uk/ARRIVEuniversities)
All research and teaching activities undertaken by staff and/or students, at the University or in the field, which involve a potential risk to the environment, such as the escape of invasive species or genetically modified organisms (GMO) or work involving human or animal pathogens, are required to notify the Chair of the University Research Ethics & Governance Sub-Committee, detailing how the risk will be managed. It is expected that appropriate contained-use facilities will be used, as detailed by the Health and Safety Executive (http://www.hse.gov.uk/biosafety/GMO/index.htm).

Knowledge and compliance with all existing regulations and law must be demonstrated. For the regulations involving the use of GMO the competent authority is the Health and Safety Executive (HSE) and the Secretary of State (represented by officials from DEFRA). In particular, the HSE Notification Team and Specialist Inspect Teams should have been contacted. Similarly, for research involving blood-borne viruses (BBV), compliance with the law must be demonstrated and appropriate risk assessment and risk reduction procedures must be in place, likely after having sought advice from the Advisory Committee on Dangerous Pathogens (http://www.hse.gov.uk/biosafety/blood-borne-viruses/index.htm).

Researchers and those with responsibility for the University estate should be mindful of the state of buildings and facilities in which work on animals and plants is undertaken and ensure that they are appropriate for the research being undertaken. In some instances, modification to buildings and facilities may be required, and/or regulations put in place, to avoid shared use and risks of contamination or escape. High-risk areas should be best placed outside main buildings, with a direct access for the delivery and elimination of the samples.
POLICY ON HANDLING ALLEGATIONS OF RESEARCH MISCONDUCT

(This section has been drafted with guidance from UKRIO and in consultation with RCUK and UKRIO procedures for investigating allegations of misconduct in research)

This policy and procedure on research misconduct will also be used to investigate and deal with allegations relating to misappropriation or misuse of research funds and equipment.

The University is able to receive and consider anonymous allegations.

(Please refer to Section H, for the University Policy on Whistleblowing)

G1 Definition of Research Misconduct

The Research Council UK definition of Research misconduct is fabrication, falsification, plagiarism or other serious deviation from commonly accepted practices in research for proposing, performing, or reviewing research, or in reporting research results.

Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

Misrepresentation including

• Misrepresentation of data, for example suppression of relevant findings and/or data, including the researchers own ideas, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data.

• Undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication.

• Misrepresentation of interests, including failure to declare material interests, either of the researcher or of the funder’s of the research.

• Misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held.

• Misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution (improper authorship).

Breach of duty of care, whether deliberately, recklessly or by gross negligence:

• Disclosing improperly the identity of individuals or groups involved in research without their consent, or other breach of confidentiality,

• Placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards
even with consent; this includes reputational danger where that can be anticipated.

• Not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly, explicitly and transparently.

• Not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment.

• Improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes.

Research misconduct does not include honest error or differences of opinion. Unlike poor research practice which needs to be identified and dealt with through training and mentoring, research misconduct needs to be investigated and dealt with appropriately through the disciplinary procedures.

G2 Terminology:

a) Named Person: The ‘Named Person’ is the individual in the University who is responsible for:
   • receiving any allegations of misconduct in research
   • initiating and supervising the procedure for investigating the allegations
   • maintaining information and records during the investigation and
   • taking decisions at key stages of the procedure, and working as an adjudicator when required.

Named person for Swansea University: Registrar & Chief Operating Officer.

b) Complainant: the Complainant is the person making the allegations of misconduct of research against one or more Respondents.

c) Respondent: the ‘Respondent’ is the person (s) against whom the allegations of misconduct in research have been made. He/she must be a present or past employee of the University.

d) Disciplinary process: The ‘Disciplinary process’ refers to the University’s mechanism for resolving disciplinary issues of staff.

e) Formal Investigation: The Formal Investigation is the procedure intended to examine the allegations of misconduct in research, hear and review the evidence, determine whether the alleged misconduct occurred and take a view on who was responsible.

f) Screening Stage: The Screening Stage is part of the procedure and intended to determine whether there is prima facie evidence of misconduct in research. The screening stage does not determine whether misconduct occurred or who might be responsible.

G3 Key Principles:

This policy and procedure on research misconduct will also be used to investigate and deal
with allegations relating to misappropriation or misuse of research funds and equipment.

The University is committed to operating on the following principles while investigating allegations of research misconduct:

- Misconduct in research is a serious matter.
- Investigation of allegations of misconduct in research will be conducted in accordance with the highest standards of integrity, accuracy and fairness.
- The University wishes to enable all stakeholders (including funders, sponsors, regulators, staff, scientific publishers, students, research participants and patients) to have confidence that high standards of research integrity are upheld by the University at all times, and that allegations of research misconduct are treated seriously and investigated as confidentially as is reasonably practicable.
- The University will ensure that those responsible for carrying out investigations of alleged misconduct in research will act with integrity and sensitivity at all times.
- The University will ensure that investigators of such cases will conform to the statutory obligations of the University and the rights of the employees according to current law along with any rights and obligations bestowed to employees by its ordinances and statutes.
- Anyone accused of misconduct in research is entitled to the presumption of innocence.
- It is acknowledged that allegations may be made for what appears to be malicious reasons.
- Where anyone is formally accused of misconduct in research, that person will be given full details of the allegations in writing, and will be given the opportunity to set out his/her case and respond to the allegations against him/her.
- The University is committed to protecting the reputation of those suspected of, or alleged to have engaged in, misconduct, when the allegations or suspicions are not confirmed.
- Staff undertaking research will be able to exercise their right to academic freedom under the University Statutes, but must also take responsibility in ensuring that the integrity of research is upheld, and that they are aware of the legal requirements that regulate their work.
- All employees and students and any individuals authorised to work in the University, its facilities or otherwise undertaking research on behalf of the University, are obliged and have a responsibility to report to the University any concerns about potential research misconduct, whether witnessed, or where there is reasonable belief that this is, has, or is likely to occur.
- Employees and students who raise such concerns in line with this policy will not be penalised or suffer detriment by the University for doing so, provided that they do so in confidence and reasonably believe that potential research misconduct is, has or is likely to occur.
- The basis for reaching a conclusion that an individual is responsible for misconduct in research relies on a judgment that there was an intention to commit the misconduct and/or negligence in the conduct of any aspect of research undertaken and that the burden of proof required is that of ‘on the balance of probabilities.’
- Where appropriate, issues may be resolved through informal discussions, advice, guidance, or agreed mediation, without the requirement for a formal investigation.
- If the route of investigation is undertaken, then depending upon the outcome of the investigation, other relevant formal procedures may be initiated including for example the University’s disciplinary or capability procedures.
• In such cases the information/findings of an investigation may be used in whole or in part, to form the investigation element of such procedures.
• All parties involved are under an obligation to inform the ‘Named Person’ (Registrar) immediately of any conflict of interest. In such circumstances, the Registrar should decide if a declared interest warrants exclusion from involvement in the investigation.
• In the case where the Registrar declares an interest his/her nominated alternate should decide if he/she should be excluded from involvement.

G4 Procedure:
The objective of the procedure outlined below is:
• to ensure that any allegations of research misconduct brought to the University as the organisation employing the individual against whom allegations are made, or brought to the University in its capacity as the host or sponsor of research, are dealt with agreed standard practices adopted nationally by other Universities and research organisations and
• to determine the truth of the allegations.

G5 Receiving allegations:
Any allegations of ‘misconduct in academic research’ should ideally be submitted to the Registrar in writing with supporting documentary evidence, though postal mail or email (researchmisconduct@swansea.ac.uk)
Any allegations received by the Registrar will be initially assessed to determine:
• whether it requires urgent and immediate action to prevent further risk or harm to staff or student participants or other persons or suffering to animals or negative environmental consequences; or
• whether the complaint relates to the University or should be directed to another organisation, external body or regulator; or
• whether the allegation falls within the scope of the research misconduct process or if another internal procedure, for example the disciplinary procedure needs to be used; or
• whether any immediate action needs to be taken, based on the concerns outlined in the allegation (i.e. to protect participants, or secure funds or evidence)

G6 Preliminary Stage:
Upon receipt of an allegation of misconduct in research, the Registrar will formally acknowledge receipt by letter or email (whichever appropriate), advising the complainant of the procedure to be followed.
If an allegation falls outside the definitions of ‘research misconduct’, the Registrar will communicate to the Complainant in writing:
• the reason why the allegations cannot be investigated using the University procedure;
• which process for dealing with complaints might be appropriate for handling the
allegations (if any); and

- to whom the allegations should be reported.

Where the allegation is **within** the definition of ‘misconduct in research’, the Registrar will inform the Vice Chancellor, Director of Human Resources, Pro Vice Chancellor for Research & Innovation and Director of Finance, details of the allegation in confidence, and would be investigated in accordance with University procedures. Details of all sources of internal and external funding and collaborators for the research in question would also be provided.

In a confidential meeting and in the presence of a representative from Human Resources, the Registrar will notify the ‘Respondent’, that an allegation of ‘research misconduct’ had been received against him/her. The ‘Respondent’ will be provided a redacted copy of the allegation, along with a copy of the University procedure to be followed and would be given the opportunity to respond to the allegations and set out their case at a later stage. The ‘Respondent’ can be accompanied to this meeting by a colleague, a Union representative or anyone else as specified by contractual rights.

If the allegations are made against more than one Respondent, the Registrar will inform all parties separately, without divulging any information on the identity of the other ‘Respondents’.

**Once initiated, the procedure will progress to the natural end-point irrespective of:**

- whether the Complainant has withdrawn the allegation;
- the Respondent admitting or having admitted the alleged misconduct, in full or in part and/or
- the Respondent or the Complainant resigning, or having already resigned, his/her post.

The University will aim to complete the Preliminary stage within 10 working days from the receipt of the allegations.

**G7 Screening stage:**

- The Registrar will carry out an initial investigation of the allegations to determine whether they are mistaken, frivolous, vexatious and/or malicious.
- If the allegations are categorised as any of the above, the Registrar will dismiss the allegations in writing, informing the Complainant, Respondent and all parties who had been informed initially.
- If the allegations were found to be frivolous, vexatious and/or malicious, the Registrar will consider recommending to the Human Resources Department that action be taken under the disciplinary procedures against the Complainant, and will take appropriate steps to support the reputation of the Respondent and the research project(s).
- Those making allegations in good faith will not be penalised and would be provided with support, including training if they are employees of the University.
- If the allegations cannot be entirely discounted by the Registrar, then a ‘**screening panel**’ would be set up to determine whether there is prima facie evidence of misconduct in research.
- The screening panel would consist of **at least** two people and would normally aim to
complete its work within **30 days** of being convened.

- A report from the screening panel would be made available to the Respondent and the Complainant for factual accuracy, and only in circumstances, where the report includes errors of fact will the screening panel modify the report.
- Where the allegations are considered mistaken, frivolous, vexatious and/or malicious, they will be dismissed and appropriate measures taken to protect the reputation of the Respondent and relevant research projects.
- Measures may include recommending to the appropriate authorities that action would be taken under the University’s disciplinary procedures.
- Where the allegations have some substance, but due to a lack of clear intent to deceive or due to their relatively minor nature, the matter will be addressed through the University’s competency, training and education or other non-disciplinary process, rather than through a formal investigation for a University employee.
- The Registrar would ensure that a programme of training or supervision is established in conjunction with the Respondent and his/her line manager.
- When the screening panel considers that the allegations are sufficiently serious and have sufficient substance to warrant recommending a Formal investigation, the Registrar would take immediate steps to set up a Formal investigation.

**G8 Formal Investigation:**

- Where the Screening panel recommends a formal investigation, the Registrar would take immediate steps to set up an investigation panel and would inform the Respondent, the Complaint or their representative that a formal investigation would take place.
- The Registrar would also inform the Vice Chancellor, Pro Vice Chancellor for Research & Innovation, Director of Human Resources, Director of Finance and any partner organisation with which either the Respondent and/or Complainant has an honorary contract of the case proceeding to a formal investigation.
- The Registrar would then convene a formal investigation panel with senior staff from the University with relevant expertise in the area, and if felt necessary would invite a member, external to the University to Chair the panel or be a member of the panel.
- The investigation panel would examine all evidence collected during the screening panel’s investigation following the original allegation and investigate further as required.
- During the Formal investigation, the investigation panel will interview the Respondent and the Complainant.
- The investigation panel will review all evidence and documentation to conclude whether the allegations of misconduct in research are upheld in full, upheld in part or not upheld.
- The standard of proof to be used by the Investigation panel will be that of ‘on the balance of probabilities’.
- The Investigation Panel may conclude that allegations are not upheld for reasons of being mistaken, frivolous, vexatious or malicious.
- During the investigation, should new evidence come to light regarding further, distinct instances of misconduct in research by the Respondent, unconnected to the allegations under investigation or of misconduct in research by another person/persons, then the investigation panel would submit the new allegations to the Registrar to be considered under the initial steps in the procedure.
- The investigation panel will be appointed within 30 working days of the submission of the screening panel’s report for recommending a formal investigation.
- The investigation panel will not work to a deadline or timetable but would aim to achieve completion of the investigation as quickly as possible without compromising the principles of the procedure.
- If the investigation takes a long time, the Chair of the panel would provide regular monthly updates to the Registrar who should provide appropriate information on the progress to the interested parties.
- On completion of the investigation, a draft report would be provided by the panel to the Registrar for forwarding to the Respondent and the Complainant for factual accuracy.
- Only when the report contains errors of fact and matters that have a bearing on the facts as indicated by the Respondent and/or the Complainant, and accepted by the Investigation Panel, should the report be modified (by Chair).
- The investigation panel should then produce a final report summarising the conduct of the investigation, stating their decision on the allegations of misconduct in research, making recommendations and addressing any procedural matters that have been brought to light during the investigation. The panel recommendations may include further action including retraction/correction of articles/papers and actions to inform or protect participants and patients, and where required reporting to regulators, funders, partner bodies or professional bodies.
- If all or any part of the allegations are upheld, the Registrar, the Director of Human Resources and another Senior Staff member (Pro Vice Chancellor or Head of College) should decide whether the matter should be referred to the University’s disciplinary process or for other formal actions.
- The Registrar would inform the Respondent and the Complainant (or their representatives) in writing of the conclusion of the formal investigation.
- The Registrar would also inform the Vice Chancellor, Pro Vice Chancellor for Research & Innovation and any other relevant personnel within the University along with any partner organisations, funding bodies and or regulatory or professional bodies.
- Should the allegations proceed to the University’s disciplinary procedure, the report of the investigation panel would form the basis of the evidence that the Disciplinary Panel receives.

G9 Appeals:

Where the formal investigation panel finds that the allegations have been substantiated in whole or in part but the nature of misconduct is such that it should be disposed of informally, for example, through an informal warning, the Respondent may appeal against the decision on one or more of the following grounds:

(a) that the allegation of misconduct was not heard in accordance to the above procedures; and/or
(b) that fresh evidence has become available which was not or could not have been made formally available to the panel before.

The intention to appeal against any decision should be made in writing by the Respondent to the Registrar within 28 days of the date of the notification of the panel’s decision. The notice should include all documentation relating to the grounds on which the appeal is being made.
Section H

POLICY ON PUBLIC DISCLOSURE (WHISTLEBLOWING)

H1. Introduction

Swansea University is committed to the highest standards of openness, probity and accountability. It seeks to conduct its affairs in a responsible manner taking into account the requirements of the funding bodies and the standards in public life set out in the reports of the Nolan Committee.

The Public Interest Disclosure Act 1998 gives legal protection to employees against being dismissed or penalised by their employers as a result of publicly disclosing certain concerns which are both serious and likely to be of wider public interest. It is a fundamental term of every contract of employment that an employee will faithfully serve his or her employer and not disclose confidential information about the employer’s affairs. However, where an individual discovers information which he/she believes shows malpractice/wrong-doing within an organisation then this information should be disclosed without fear of reprisal, and may be made independently of line management. The right of freedom of expression is a provision of the Human Rights Act 2000.

In addition to all staff, this policy and procedure may also be used by other members\(^1\) of the University, including the members of Council, the members of Court and students.

This policy is not intended to be used as a substitute for the University’s grievance procedure and any concern about an employee’s personal employment situation should be raised through the grievance procedure in the normal manner.

Members should not view this procedure as
\begin{itemize}
  \item an avenue to challenge or question business or financial decisions taken by the University;
  \item as an avenue of appeal to challenge decisions previously taken under other procedures of the University;
  \item or as a way of dealing with malpractice/wrongdoing of students.
\end{itemize}

H2. Scope of Policy

This policy is designed to allow members of the University both to raise concerns and to disclose information in circumstances which the individual believes shows malpractice.

In addition to this policy, the University has a number of other policies and procedures in place including grievance and complaints, harassment and discipline. This policy is intended to cover concerns which are in the public interest and may (in the first instance) be investigated separately but which might lead to the invocation of such procedures. Appropriate concerns to be addressed under this policy might include allegations of:

\(^1\) The members of the University are defined in the Ordinances
• fraud;
• financial malpractice and impropriety (including financial irregularities, corruption, bribery, dishonesty);
• commission of criminal offences;
• failure to comply with a legal obligation or with the Charter, the Statutes, the Ordinances and/or the Regulations of the University;
• miscarriages of justice;
• dangers to health and safety;
• dangers to the environment;
• unethical behaviour and improper conduct;¹
• academic, administrative or professional malpractice;
• attempts to conceal any of the above.

This list is not intended to be exhaustive, and members of the University are encouraged to utilise this policy on occasions where they believe they have discovered malpractice or impropriety.

H3. Safeguards

H3.1 Protection

This policy is designed to offer protection to those employees or other members of the University who disclose such concerns provided the disclosure is made in the reasonable belief of the individual making the disclosure that it shows malpractice.

The individual will only be protected if he/she makes the disclosure to an appropriate person/or body in accordance with the procedure set out in this policy. It is important to note that if employees/members of the University fail to utilise this procedure they will not be protected and this could in some circumstances result in their being the subject of disciplinary procedures where appropriate.

H3.2 Confidentiality

The University will treat all appropriate disclosures made in accordance with this policy in a confidential and sensitive manner. It will therefore endeavour to keep confidential the identity of the person who has raised the concern. However, it must be appreciated that the investigation process may reveal the source of the information and that a formal statement from the original complainant may be required as part of the investigative process.

The University will also take all reasonable steps to ensure that members of the University who have raised concerns under this procedure will not be victimised in any way by other members of the University.

Victimisation or other detrimental treatment of an employee, student or other member of

¹ The University has already approved a Protocol for the Investigation of Allegations of Misconduct in Research, and that Protocol would be used if the alleged malpractice related to research.
the University, as a result of that person raising concerns under this policy in good faith, will be treated as a serious disciplinary offence under the University’s disciplinary procedure.

H3.3 Anonymous Allegations

This policy is intended to encourage individuals to put their name to any disclosures they make. Concerns expressed anonymously are much less powerful, but they will be considered at the discretion of the University.

In exercising this discretion, the factors to be taken into account will include:
- the seriousness of the issues raised;
- the credibility of the concern; and
- the likelihood of confirming the allegation from attributable sources.

H3.4 Unfounded Allegations

If an individual makes an allegation in good faith, which is not confirmed by subsequent investigation, no action will be taken against that individual. If, however, an individual makes malicious or vexatious allegations, and particularly if he or she persists with making them, disciplinary action may be taken against the individual concerned.

H4. PROCEDURES

H4.1 Procedures for making a Disclosure

Step One

(i) The individual should make the disclosure in writing to the designated person, who would normally be the Registrar. The Registrar will keep the Vice-Chancellor informed of any disclosure but in cases involving financial malpractice the Registrar will act throughout in close consultation with the Vice-Chancellor, as the Accounting Officer for the University.

(ii) If the disclosure is about the Registrar then the disclosure should be made directly to the Vice-Chancellor.

(iii) If the disclosure concerns the Vice-Chancellor then it should be made to the Chair of Council.

(iv) If the individual does not wish to raise the matter with any of the above then he or she may raise it with the Chair of the Audit Committee, provided the issue falls within those matters ordinarily within the purview of that Committee, or if the matter is not within the purview of the Audit Committee, with the Chair of Council.

Step Two

(i) The designated person will consider the information made available to him/her and decide on the form of investigation to be undertaken. This may be:
   a) to investigate the matter internally;
   b) to refer the matter to the police;
   c) to call for an independent external inquiry.

(ii) If the decision is that investigations should be conducted by more than one of these means, the designated person should satisfy him/herself that such a course of action is
warranted. (iii) Where the matter is to be the subject of an internal inquiry, the designated person will then consider how to conclude whether there is a *prima facie* case to answer. This consideration will include determining:
   a) who should undertake the investigation;
   b) the procedure to be followed;
   c) the scope of the concluding report.

**Step Three**

(i) Normally, the Head of the Joint Internal Audit Unit, or when the case is of a non-financial nature, another independent officer of the University (normally a Pro-Vice-Chancellor) will undertake the internal investigation and will report his/her findings to the designated person. The investigation should not be carried out by the person who will have to reach a decision on the matter.

(ii) As a result of this investigation other internal procedures may be invoked by the designated person such as:
   a) disciplinary;
   b) grievance or complaints;
   c) harassment;
   d) Statutory procedures.
Reference to the police may also be made at this point in the procedure.

(iii) In some instances it might be necessary to refer the matter to an external authority for further investigation, e.g. the Higher Education Funding Council for Wales, or the bodies listed in Public Interest Disclosure Act.

**Step Four**

(i) The designated person will inform the individual making the disclosure of what action, if any, is to be taken. If no action is to be taken then the individual concerned should be informed of the reason for this and allowed the opportunity to remake the disclosure to another appropriate person (the designated reviewer) in accordance with the table below:

<table>
<thead>
<tr>
<th>Designated Person</th>
<th>Designated Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registrar &amp; Chief Operating Officer</td>
<td>Any other Designated Person</td>
</tr>
<tr>
<td>Vice-Chancellor</td>
<td>Any other Designated Person</td>
</tr>
<tr>
<td>Chair of the Audit Committee</td>
<td>Treasurer</td>
</tr>
<tr>
<td>Chair of Council</td>
<td>Chancellor</td>
</tr>
</tbody>
</table>

The *designated reviewer* will consider all the information presented, the procedures that were followed and the reasons for not taking any further action. The outcome of this will be either to confirm that no further action is required or that further investigation is required and will follow the procedures referred to in steps 2 and steps 3 above.
(ii) Where a disclosure is made the person or persons against whom the disclosure is made will be told of it, the evidence supporting it and will be allowed to respond before any investigation, or further action, is concluded.

**Step Five**

(i) A person who remains dissatisfied after all internal mechanisms for dealing with a complaint or concern have been exhausted may consider whether it is appropriate to petition the Visitor. Information on how this may be done is obtainable from the Registrar.

**Reporting of Outcomes**

(i) A report of all disclosures and any subsequent actions taken will be made by the designated person who will retain such reports for three years. In all cases a report of the outcomes of any investigation will be made to the Audit Committee, in detail where the issue falls within its purview, and in summary in other cases as a means of allowing the Committee to monitor the effectiveness of the procedure.

**H5. Abuse of Policy and Procedures**

As outlined above, employees and other members of the University will be protected by the University against any victimisation as a result of proper use of the procedures laid out in this policy. However, the University will take abuse of these procedures extremely seriously. If any member of the University abuses these procedures in order to make false or malicious allegations, this will be treated as a serious disciplinary offence under the University’s disciplinary regulations, which may result in appropriate action being taken against the member in question.

**Approval History:**

- UWS Council – 27 March 2000
- Revised (addressing change of title, officers and layout) – 11 July 2007
- Revised – October 2012
- Revised (UKRIO request regarding removal of previous requirement in H3.1, H3.2 and H3.4, that the allegation be made in “good faith”) – 7 June 2016
Section I

POLICY ON RESEARCH DATA PROTECTION

Research and the Data Protection Act 1998

Some of the research undertaken by the University uses information about identifiable living individuals and uses personal information which falls within the remit of the Data Protection Act. The Data Protection Act makes special provision for the use of personal data in research and other educational contexts, but this, in no way absolves users to treat data according to the terms of the Act.

The purpose of this guidance

This guidance is to raise awareness of the implications of the Data Protection Act for research data and to ensure that individuals are able to comply with the legislation. The specific areas where there are exemptions refer to:

- The purposes for which data are processed;
- The length of time for which data may be kept; and
- Subject access requests.

What is the Data Protection Act?

The Data Protection Act gives individuals (known as data subjects) rights regarding the personal data organisations hold about them and requires organisations and individuals to meet certain standards when gathering and using personal data. The Act states that:

- Research (including statistical or historical purposes) may legitimately involve further processing of personal data beyond the originally stated purposes, as long as the other conditions are respected. (One can imagine that data collected for one purpose in the course of an experiment or survey might later be seen to have other applications). Both this and other exemptions are very precise and all other conditions – including stating a purpose in the first place – must be respected;

- No processing of research data is allowed if the identity of a data subject is given away without consent or if the data are used to support decisions in respect of an individual or if there is likely to be substantial damage or distress.

- Personal data processed only for research purposes may be kept indefinitely;

- Personal data processed for research purposes are exempt from the rules regarding subject access requests as long as they are processed in line with all other conditions and as long as the published research does not identify individuals; and

- Statistics and anonymised data where information which might identify an individual has been removed are not considered personal data and are not covered by the Act.
Why should researchers be concerned with the Data Protection Act?

In many respects the Data Protection Act reinforces the good practices promoted by professional bodies via their codes of ethics and standards of practice. The legal concept of ‘personal data’ is complex and the penalties for not complying with the Data Protection Act can be very serious. If the University is shown to be in breach of the Act it can have reputational and legal implications. Information on the deceased is not protected by the Act, although in some situations there may be a common law duty of confidentiality to the estate of the deceased person (e.g. in regard to sensitive medical information).

What should a researcher do if they wish to use personal data for research?

To use personal data for research, researchers have two options:

1. to comply with the Data Protection Act. Or
2. to anonymise the data used so that it no longer falls within the Act’s definition of personal data.

Data are only completely anonymised if it is impossible to identify the individuals from the information plus any other information that the University holds or is likely to hold. A set of data is not anonymised if numbers are given to individual items and then a separate list is held which identifies the numbers to individuals.

Researcher’s Guide to the Data Protection Principles

The standards that individuals and organisations have to abide by are set out as eight data protection principles. There are additional requirements for sensitive personal data, about which the University must be particularly cautious.

- **First principle**: personal data must be gathered and used fairly and lawfully. Individuals must be provided with information about how data on them will be used, unless doing so would involve disproportionate effort. In addition, certain specific “fair processing” conditions set down in the Act have to be met whenever personal data is gathered or used.

- **Second principle**: personal data must not be used for any purpose which is incompatible with that for which it was originally gathered.

- **Third principle**: personal data must be adequate, relevant and not excessive in relation to the purpose for which it was gathered.

- **Fourth principle**: personal data shall be accurate and, where necessary, kept up-to-date.

- **Fifth principle**: personal data must not be kept for longer than is necessary for the purpose for which it was gathered.

- **Sixth principle**: personal data must be processed in accordance with the rights of individuals. These include the right to gain access to the information held about them; the right to prevent their data being used in a way which causes them substantial damage or
distress; and the right to have inaccurate data corrected.

- **Seventh principle:** appropriate security measures must be taken to prevent unauthorised access to personal data and accidental loss, destruction or damage to data.

- **Eighth principle:** Research often involves international collaboration. However the 8th data principle bans transfers of personal data outside the EEA\(^1\). Personal data must not be transferred outside the European Economic Area unless it is transferred to a country which provides an adequate level of data protection. These requirements are ultimately designed to protect individuals’ right to privacy under Article 8 of the European Convention on Human Rights, which has been incorporated into UK law as a result of the Human Rights Act.

The first data protection principle requires that personal data are processed fairly and lawfully. In order to process personal data, at least one of the conditions set out in Schedule 2 must be met, thus providing a legitimising reason to process personal data:
- consent of the data subject;
- contractual necessity;
- non-contractual legal obligation of the data controller;
- vital interests of the data subject;
- processing is necessary for administering justice, or for exercising statutory or governmental functions;
- legitimate interests of the Data Controller.

Where a researcher is seeking to use sensitive personal data, a valid Schedule 3 legitimate condition will also have to be met (in addition to at least one of the conditions set out in Schedule 2 above):
- explicit consent of the data subject;
- processing is necessary to comply with Employment Law;
- vital interests of the data subject or another person;
- processing is carried out by a not-for-profit organisation;
- the data subject has already made the information public;
- processing is necessary in relation to legal proceedings;
- processing is necessary for administering justice, or for exercising statutory or governmental functions;
- processing is necessary for medical purposes, and is undertaken by a health professional or by someone who is subject to an equivalent duty of confidentiality;
- processing is necessary for monitoring equality of opportunity, and is carried out with appropriate safeguards for the rights of individuals.

The data subject is not always required to give consent to the processing of their data, however in order to comply with the first principle of the Data Protection Act, one of the other

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\(^1\)EEA countries and countries which have an adequate level of protection are currently: Austria, Andora, Argentina, Belgium, Canada, Denmark, Finland, Faroe Island, France, Germany, Greece, Holland, Iceland, Ireland, Italy, Isle of Man, Israel, Jersey, Liechtenstein, Luxembourg, Norway, New Zealand, Portugal, Spain, Sweden, Switzerland, Uruguay, and the UK.
conditions relevant for the purposes of the fair and lawful processing of personal data will still be required.

The Data Protection Act recognizes that some types of personal data are more sensitive than others, and gives “sensitive personal data” additional protections. “Sensitive personal data” includes information on individuals’ ethnicity, race, political opinions, religious or similar beliefs, physical or mental health, sexual life, membership of a trade union, the commission or alleged commission of offences, and criminal proceedings against the individual. Particular care has to be taken when gathering and using data in these categories.

The Data Protection Act applies to the UK only. Personal data which is gathered and held overseas is not covered by the Act, but may be subject to equivalent local data protection or privacy laws. Once personal data is brought into the UK, it will be protected by the Act in the same way as data gathered in the UK. The Data Protection Principles will have to be met when importing the data into the UK and in any subsequent use of the data, including exporting the data from the UK.

Personal data should always be processed fairly and lawfully. Any research conducted by University Staff and Students must meet the requirements of the Data Protection Act and respect the right which it confers to individuals.

The Act gives individuals the right to sue for damages which they may suffer as a result of violations and the right to request an investigation by the Information Commissioner (the agency which regulates Data Protection).

Research funders increasingly require projects to have adequate protocols in place to protect personal data, and may refuse to give funding to institutions which have poor data protection practices. As high profile cases involving the loss of personal data indicate, inadequate data security can lead to bad publicity and serious reputational damage.

What is the role of consent?

Perhaps the most straightforward way to meet the requirements of the first, second and eighth Data Protection Principles is to ensure that information is gathered with the consent of research subjects. Consent requires that research subjects should fully understand the purpose, methods and intended possible uses of the research, and its implications for them (including any risks). Conducting research in an open way which respects the rights of research subjects and obtains their agreement is a crucial part of conducting research in an ethical manner.

To be meaningful, consent must be informed and must be freely given. “Informed” consent means that research subjects understand what they are consenting to and receive comprehensive information about the project and in a language and vocabulary with which they are familiar. While this information will vary from project to project, and will have to be tailored to the culture or society in which the research is being conducted, it is recommended that it should include:
• the name of the project, its purpose and its objectives;
• the identities of the organisations or individuals who have funded the research and any interests they may have in the research;
• why the information was being collected, and why it was necessary for the project;
• the name and contact details of the person who will be responsible for gathering the data for the project;
• names of individuals with access to the data, including any organisations or individuals outside the organisation who may be given access;
• special security measures that will be taken to protect the data;
• the countries to which the data may be transferred. Whether the data is gathered outside the UK and will be transferred into the UK and whether the data will be transferred outside the European Union;
• how the data will be published or made available, including whether research subjects will be identifiable in the published data, or whether the data will be published in anonymised form;
• steps which will be taken to archive the data;
• how the data will be used in future research projects; and
• how the research subject can withdraw their consent to participate in the project if they subsequently decide to do so.

Consideration should also be given to the extent to which the research subject is capable of giving consent. Every effort should be made to secure the informed consent of children and other vulnerable groups (e.g. adults with learning difficulties), although it is recognised that informed consent may also require the involvement of a parent, guardian or other person with a duty of care. Parental consent should normally be sought for children under the age of 16. Consent given “Freely” means that the individual should not be under duress: there should be no adverse consequences for them from refusing to participate in the project, and no coercion (actual or implied) to participate in the project. Researchers should recognise that informed and freely given consent requires an on-going dialogue with the research subject, and is not a one-off event.

Consent may need to be renegotiated, e.g. if the aims of the research or the methods of disseminating its results change. Research subjects have the right to retrospectively withdraw their consent at any point in the process, including after the completion of the research.

**How should consent be recorded?**

Recorded consent should be seen as a goal which researchers should always aim to achieve. Without a written record of the research subject’s consent, there is more likely to be uncertainty over whether a project has met the requirements of the Data Protection Act.

Data Protection Act requires consent to the handling of “sensitive” personal data. This is usually interpreted to mean that an individual’s consent should be captured in some form of written record authorised by them. The traditional and most straightforward way of recording
consent is through a paper consent form signed by the research subject. The form should record the research subject's consent to their data being used in the manner and for the purposes described in the information given to them. It should also give the project copyright permission to use the research subject's contribution.

In some fieldwork situations, where use of a written consent form may be impractical or even harmful to the relationship between the researcher and the research subject, researchers should concentrate on the objective of ensuring the research subject's informed participation, and adopt a method of achieving that which is appropriate to the project and the society where the research is taking place. Sensitivity should be shown to cultural differences in areas such as the concept of consent and the relationship between the individual and the group.

Any decision not to use written consent forms should take the following factors into account:

- There may be other, more suitable ways of directly recording the research subject's consent than a written consent form. For example, if data is gathered through audio visual recordings of interviews, the recording of the first interview could start with the researcher explaining the nature and purpose of the project and how the data will be used, and asking the interviewee to confirm that they agreed to participate in the project.

- A decision not to use a formalised method of recording consent does not remove the researcher's Data Protection and ethical obligations to provide research subjects with enough information for them to make a truly informed decision whether to participate. This should be done by whatever method is most appropriate in the research context. However, if research subjects are able to read, it would normally be expected that they should be provided with written information about the project so that they have a record of what they participated in. Where written consent forms are used, the research subject should be given a copy of the form to keep.

- The records of the project (e.g. project plan, field notes) should document the methods chosen by the researcher to obtain informed consent and how they were implemented. All documentation relating to the obtaining of consent (including consent forms and other written information provided to the research subject, where used) should be preserved for at least as long as the data is retained in non-anonymised form.

What does consent mean for audio-visual material and photographs?

Films, sound recordings and images will be personal data if they capture an individual with sufficient clarity to allow them to be identified. All of the considerations relating to consent outlined in the previous sections apply equally to AV material and photographs. Covert or “hidden camera” recording or photography (in which individuals are not aware that the process is taking place) raises serious ethical and legal concerns, and should only be undertaken after full ethical review of the proposed research according to the College Ethical review procedures. Consent for recording or photography may not always be necessary. In the UK, images of public spaces or public activities in which individuals are captured incidentally are not usually seen as raising privacy issues, or requiring consent. For example,
a photograph of a high street showing shoppers walking up and down, or news footage of a public demonstration. However, there are many legal uncertainties in this area; the courts have held that in some cases, individuals have a right to privacy in images of their activities carried out in public. Typically, this occurs where the image focuses on an individual, intrudes into their private life, is used without their consent, and there is no overriding public interest justification.

Researchers should also be wary of importing UK concepts of what is “private” and “non-private” into other cultural contexts. Activities performed by a group in its own group space may still be regarded as “hidden” or secret to the group, even if performed in the open. Researchers should always be transparent with research subjects about when recording or photography is taking place, and how the information will be used. When in doubt, following the recommendations for obtaining informed consent outlined above (see What is the role of consent? and How should consent be recorded?)

**What does consent mean for surveys?**

Surveys which are entirely anonymous (i.e. the researcher has no way of knowing the identity of the respondent) will not gather personal data in the sense of the Data Protection Act. Data Protection issues are not relevant, as there is no way of linking individuals to the data. However, it would still be good ethical research practice to provide respondents with information about the nature of the project and how their responses will be used. Survey data is personal data if respondents are identifiable, e.g. from information which they provide on the form or through other information which is available to the researcher. Respondents’ informed consent must be obtained. This is usually done through a Data Protection “fair collection” notice, which can be part of the survey form itself or in a separate information sheet provided alongside the form. The “fair collection” notice plays the same role as a consent form, and could be based on the model consent form. The ‘fair collection’ notice should explain who is gathering the data (the title of the project, identities project partners and funders, the nature and purposes of the research, and how the respondent’s data will be used.

The aim should be to cover, as far as possible, the points outlined in ‘what is the role of consent?’ The notice should also state that by completing the form, it will be assumed that the respondent consents to the use of their data for the purposes described. If a respondent will be contacted again (e.g. for a follow-up survey or to update them on the progress of the project), this should be explained, and the respondent told how they can opt out from future contact (e.g. by checking a box).

Signatures, while desirable as method of authentication, may be impractical in some situations (e.g. web based surveys). Fair collection notices can be used to give respondents a range of choices about how their data will be used, e.g. through check boxes. However, researchers should be wary of presenting respondents with too many options, as this may make it more difficult to manage the data.

**How much data should be gathered?**

The answer to this question will obviously depend on the goals and objectives of the research
project. However, researchers should remember that the third Data Protection Principle requires that personal data should be adequate, relevant and not excessive in relation to the purpose for which it was gathered. Avoid the temptation to collect more data about individuals than is necessary for the project: e.g. information which might possibly be of some use in the future, but for which no immediate use is envisaged.

**How to keep data secure?**

Good data security is an essential part of ethical research practice, and is a requirement of the Data Protection Act. Unauthorised access to personal data or accidental loss of data can have serious consequences for research subjects, and may damage Institutional reputation and that of the individual researcher. Research that involves the use of IT systems must conform with IT policies and procedures.

Where a project team involves more than one individual, one team member (usually the team leader) should be assigned responsibility for data security. The project team should agree and document the procedures which they will follow to keep data secure.

The appropriateness of data security procedures will depend on the sensitivity of the information. Not all personal data is equally sensitive. Information about individuals which has already been published or is publicly available may need little or no protection. Similarly, information about individuals’ public lives (e.g. their job title, office or rank, the identity of their employer) will generally be less sensitive than information about their private lives, and may not require extensive protection. Conversely, strong security measures will be necessary for sensitive personal data, personal financial information, or information whose disclosure might cause individuals loss or harm. As a rule of thumb, it should be assumed that harm could result from any unauthorised disclosure of information which relates to private life (e.g. home contact details, income, personal relationships or beliefs).

Anonymisation can play an important role in ensuring data security. As it is not personal data, an anonymised dataset can be used in a lower security environment than the version in which individuals are identifiable. Often, only the anonymised data is necessary for analysis purposes.

As far as possible, non-anonymised personal data should only be stored on Institutional server, where it will be backed up automatically and protected by security systems. Access should be restricted to those individuals who need access to the data for the purpose of the research project: for example, by restricting access to individual directories and/or password protecting individual files.

Most data security breaches occur when data is “on the move”. As many high profile cases demonstrate, laptops and storage devices such as data keys/flash drives, CDs/DVDs and portable hard drives are particularly vulnerable to theft and accidental loss. These devices should only be used to transport non-anonymised personal data where absolutely necessary. Where they are used, individual files containing personal data on research subjects should be password protected, and should be encrypted if the information includes sensitive personal data, financial information about individuals, or information whose disclosure could cause
harm or loss to individuals.

The transmission of personal data on research subjects should also be avoided, unless absolutely necessary. Where transmission is necessary, emailing encrypted attachments is preferable to the post as a method of sending personal data. Email attachments, containing non-anonymised personal data must be password protected, and must be encrypted if the information could cause harm or loss to individuals. Passwords or pass phrases must be communicated separately from the data (preferably by telephone). If the postal service has to be used to transfer personal data, the data should be sent by recorded delivery and the storage media must be protected through encryption as outlined above.

Data is vulnerable when it is being used at home, because of the increased risk of theft and unauthorised access.

To prevent accidental loss of data, researchers should regularly back up personal data which is not stored on the Institutional servers and are referred to the university’s Information Security policy:

**Encryption and Removable Media:** Removable media, such as USB keys, should be kept secure wherever possible and suitable encryption software used for sensitive or confidential data. If University data is held on personal laptops, home computers or mobiles devices it should be secured through password protection and encryption and a recent backup or synchronised copy stored on a University system in case of loss of device or password. TrueCrypt is a suitable open source encryption product, windows7 has built in encryption.

To ensure the security of personal data, the Data Protection Act imposes specific requirements where data is processed by one organisation on behalf of another (e.g. where the gathering and analysis of survey data is outsourced). The processing must be done under a contract which imposes security obligations on the data processor, and the organisation which commissions the processing must ensure that the data processor has adequate security measures in place.

Personal data in paper format (e.g. consent forms signed by research participants) should be kept in a secure area or a locked filing cabinet when not in use. Where more than one person has access to the information, a booking system should be used to keep track of files.

Personal data gathered in research projects should be disposed of securely when it is no longer needed. Data in paper format should be disposed of as confidential waste, or shredded on-site if highly sensitive. Electronic data should be deleted and emptied from the recycle bin. PCs and media used to store personal data should be securely wiped of data before disposal through the university’s disposal procedures.

**Publishing and disseminating data**

Research subjects should not be identified in published research results or in publicly available datasets, unless they have consented to being identified, or the information is already in the public domain. This applies equally to data obtained directly from the individuals, and
confidential personal data obtained from third parties. Anonymised data can be published, disseminated and deposited in publicly available data repositories.

Providing research subjects with a copy of the final research results or research publications, while not mandatory (or always practical), will support openness and transparency in research and should be seen as good practice. However, researchers should be cautious when entering into undertakings to allow research subjects to view or edit their contributions prior to publication. This may delay the publication of results, and create an expectation that the research subject has a right of veto. It may also increase the risk that the research subject will retrospectively withdraw consent. In any such arrangement, deadlines for comments should be set, and it should be agreed that editorial control remains with the researcher.

When can research data be transferred overseas?

Anonymised research data can be transferred outside the European Economic Area without contravening the eighth Data Protection Principle, as it has ceased to be personal data. Research data in which individuals are identified can be transferred to countries outside the EEA if the research subject consented to this when the data was gathered, as part of the consent process. Otherwise, the transfer of non-anonymised data outside the EEA will be restricted to a small number of countries which have been approved by the EU as having an adequate level of data protection, and to certain other specific situations (e.g. US companies registered under the Safe Harbor scheme). A data controller may only transfer personal data outside the EEA to a country whose data protection laws have not been approved by the European Commission as providing adequate level of protection for the rights of data subjects. The adequacy of the level of protection associated with a particular transfer may be ensured in a number of ways. The data controller may:

- Carry out his own assessment of the adequacy of the protection;
- Use contracts to ensure adequacy;
- Obtain commission approval for a set of Binding Corporate Rules governing intra-group data transfers;
- Rely on one of the exceptions to the prohibitions on transfers of personal data outside the EEA.

The eighth Data Protection Principal does not prevent the transfer of personal data to the UK, although this may be restricted by local laws in the country where the research has taken place. Once the data enters the UK, it will be subject to the Data Protection Act. To meet Data Protection and ethical requirements, research subjects should be informed that their data will be transferred to the UK, and should consent to this.

When is data anonymised?

Anonymising research data involves removing information which might lead to an individual being identified, either from the data itself or by combining the data with other information which a recipient of the data could be expected to have access to. Once the information is anonymised, it ceases to be personal data, and can be disseminated and published without
However, where a researcher produces an anonymised dataset but also retains the information which is necessary to identify an individual, the totality of the information held by the researcher (the anonymised dataset and the identifying information) will still be personal data, and will have to be managed in accordance with the Act. What the researcher holds will not cease to be personal data unless the researcher disposes of the identifying information and has no means of recovering it. For quantitative data, anonymisation may be as simple as removing variables which directly identify a research subject, such as name and home address. However, it is often necessary to do more than that to render a dataset truly anonymous. Variables may have to be removed or the data manipulated to deal with situations where an individual could be identified through combinations of variables, or by combining the data with other publicly available information. For example: full UK postcodes typically cover only a small number of delivery addresses, and can easily lead to identification of an individual or household when combined with other information.

To anonymise a dataset, it might be necessary to remove the postcode or to only include the element of the postcode which relates to a wider area. Anonymising qualitative data may involve the use of pseudonyms and editing the data to remove identifying information. Anonymisation of qualitative data can be problematic because of the risk of individuals being identified through contextual information, and the risk of the data being distorted by the anonymisation process. Anonymisation is a complex area.

Further guidance for researchers is available on the website of the UK Data Archive.

**How long should data be kept?**

The Data Protection Act sets down the general principle (in the fifth Data Protection Principle) that personal data should not be kept for any longer than is necessary for the purposes for which the data was gathered. This means that once data has ceased to have value for the purpose for which it was obtained, it should usually be destroyed: it should not be kept because it might conceivably be useful for some other purpose.

However, the Act contains an exemption which allows personal data to be retained indefinitely for research purposes, provided both of the following conditions are met:

- The data must not be used to “support measures or decisions with respect to particular individuals”. In other words, the information must be used solely for research purposes, and not in ways which directly affect individuals.

- Use of the data must not cause or be likely to cause substantial damage or substantial distress to any individual who is the subject of the data. This is likely to be met by ensuring that the data is only published and disseminated in anonymised form, by following strict data security procedures and by preventing public access to the original data during research subjects’ lifetimes.

These provisions allow personal data gathered in a research project to be retained for use in
future projects, without violating the second or fifth Data Protection Principles.

However, they do not remove the need to comply with the remaining Data Protection Principles, such as the need to keep data secure or the need for processing to be “fair” and “lawful”. For example: a research project which uses personal data gathered in an earlier project will have to provide research subjects with information about the new project and obtain their consent, unless they consented to the use of their data in future projects when the data was originally gathered or the conditions apply where the data can be used without consent. While the Data Protection Act means that research data should not be retained for any longer than it has research value, that value may persist for a considerable period of time after the completion of a project. Data should be kept for a reasonable period of time after the completion of research, to ensure that results can be verified and issues arising from the research addressed.

The JISC has produced Guidance for Managing Research Records, and its model retention schedule for HE institutions **recommend a retention period of 10 years from completion of the project for records relating to the conduct of research.**

Researchers are advised to follow the JISC recommendations as a rule of thumb when deciding how long to keep personal data and other information relating to research projects. However, there are a number of factors which may require the retention of material for longer than 10 years, or indefinitely:

- Any retention or archiving requirements imposed by research funders must be met. For example, funders may require that research data (in anonymised or non-anonymised form) and other information should be deposited in a data archive, and that records of the project should be kept for a specified period. These requirements should be explained to research subjects as part of the process of gaining informed consent.

- It may be justifiable to keep non-anonymised research data indefinitely as a permanent archive if it relates to a project of major national or international significance. Non-anonymised data may also need to be kept for longer than 10 years if it is required as part of a longitudinal study.

- The information supplied to research subjects, consent forms and other records which document the obtaining of consent must be kept for at least as long as the data is kept in non-anonymised form.
Ownership of research data after leaving the Institution

Primary legal responsibility under the Data Protection Act for the personal data which staff gather and use as part of the formal records of a research project rests with the Institution as the employer as the “data controller”.

Staff have no right to remove such data without the Institution’s permission. Doing so could also compromise the rights of research subjects, e.g. by causing data to be moved to an environment with inadequate security. Staff wishing to take non-anonymised research data with them at the end of their employment must seek permission from the Head of College. Staff granted permission will be required to sign a confidentiality agreement requiring them to comply with the Data Protection Act, Swansea University Research Integrity Policy and any undertakings made to research subjects. A copy of the data will be retained by the University unless the appropriate retention period has passed.

Students are individually responsible under the Data Protection Act for personal data which they gather and use in their studies, although students are required in their research to abide by Swansea University Research Integrity Policy Framework on Research Ethics & Governance. Students may take personal data gathered by them in their research with them when they leave the Institution, unless the research was conducted as part of an Institutional research project in which the student participated, or the agreement with the funder or sponsor of the research specifies otherwise.

Students are reminded that they must continue to meet the requirements of the Data Protection Act and other legal and ethical requirements when holding and using the data.

Can research subjects gain access to the data about them?

One of the most fundamental rights granted to individuals by the Data Protection Act is the right to gain access to the information which organisations hold about them. However, this right is limited in regard to research data. Organisations are not required to grant individuals access to research data about them if all of the following conditions are met:

- The data must not be used to “support measures or decisions with respect to particular individuals”. In other words, the information must be used solely for research purposes, and not in ways which directly affect individuals;

- Statistics and research results must not be published in a way which identifies any research subject; and

- Use of the data must not cause or be likely to cause substantial damage or substantial distress to any individual who is a research subject. This is likely to be met by ensuring that the data is only published and disseminated in anonymised form; by following strict data security procedures and by preventing public access to the original data during research subjects’ lifetimes. However, as a matter of ethical research practice, Swansea University will normally provide research subjects on request with the information held about them which was gathered in research conducted by University staff, subject to the need to
protect personal data on other individuals and to meet confidentiality requirements.

Requests by individuals for access to research data about them will be dealt with as Data Protection requests, and should be submitted to the University Data Protection Officer.

Research data gathered and held by University students in the course of their studies cannot be requested under the Data Protection Act.
Section J

POLICY ON RESEARCH DATA MANAGEMENT

The University promotes the highest standards in the management of research data and records as fundamental to both high quality research and academic integrity.

It acknowledges its obligations that sound systems should be in place to promote best practice, including through clear policy, guidance, supervision, training and support.

The University recognises that accurate and retrievable research data are an essential component of any research project and necessary to verify and defend, when required, the process and outcomes of research. Research data are valuable to researchers for the duration of their research, and may well have long-term value for research, teaching and for wider exploitation for the public good, by individuals, government, business and other organisations, as a project develops and after research results have been published.

Researchers should keep clear and accurate records of their research. This includes procedures, protocols, approvals, sources used and results obtained, giving due consideration to the requirements of anonymity and confidentiality. Researchers must determine the retention requirements for their research data and records on a project by project basis or at least for clearly defined categories of projects, taking account of:

- the legal and regulatory framework for particular types of research;
- the terms and conditions imposed by external research sponsors/funders;
- the commercial, political or ethical sensitivity of particular types of research, or any research for particular external sponsors.

Colleges, departments, and Professional units and service providers and, where appropriate, research sponsors and external collaborators, need to work in partnership to implement good practice and meet relevant legislative, research funder and regulatory requirements.

Research data and records should be:

- accurate, complete, authentic and reliable;
- identifiable, retrievable, and available when needed;
- secure and safe;
- kept in a manner that is compliant with legal obligations and, where applicable, the requirements of funding bodies and project-specific protocols; and
- able to be made available to others in line with appropriate ethical, data sharing and open access principles.

How long should research records be kept?

It is important to protect the integrity and auditability of the research. Each research project is unique and judgement is required to determine how long records should be kept. Research data and records should only be retained for as long as they are of continuing value to the
researcher and the wider research community, and as long as specified by research funder, patent law, legislative and other regulatory requirements. A Data Management Plan (DMP) should be established before the project starts, covering all project records and this is often required as part of a research funding application.

Data should normally be preserved and accessible for a minimum of 10 years after completion of the research. Records from studies with major health, clinical, social, environmental or heritage importance, novel intervention, or studies which are on-going or controversial should be retained for at least 20 years after completion of the study. It may be appropriate to keep such study data permanently within the university, a national collection, or as required by the funder’s data policy.

Where research is supported by a contract with or a grant to the University that includes specific provisions regarding ownership, retention of and access to data, the provisions of that agreement will take precedence.

If research data and records are to be deleted or destroyed, either because the agreed period of retention has expired or for legal or ethical reasons, this should be done so in accordance with all legal, ethical, research funder and collaborator requirements and with particular concern for confidentiality and security.

Research carried out for the NHS or under contract for a commercial organisation is subject to that body’s own archiving, data protection and retention policies. For Clinical Trials of Investigational Medicinal Products (CTIMP) archiving needs should be undertaken according to the European Union Regulations and detailed requirements are given in the clinical trials toolkit which can be found at http://www.ct-toolkit.ac.uk

A data manager and/or data monitoring committee should be appointed for CTIMP studies and should take into account the regulations. A Trial Master File should be set up at the beginning of a trial and maintained throughout the trial in accordance with Good Clinical Practice. There is more specific and detailed guidance at http://www.ct-toolkit.ac.uk/routemap/archiving.

Researchers should be aware of the archiving policies of other organisations involved in the research and are responsible for:

- managing research data and records in accordance with the relevant principles and requirements;

- developing and documenting clear procedures for the collection, storage, use, re-use, access and retention or destruction of the research data and records associated with their research. This will include, where appropriate, defining protocols and responsibilities in a joint or multi-institution collaborative research project. This information should be incorporated, where appropriate, in a research data management plan;

- planning for the on-going curation (at the University or using third-party services) of their data after the completion of the research or, in the event of their departure or retirement.
from the University, reaching agreement with the head of department/College (or his/her nominee) as to where such data will be located and how this will be stored; and

- ensuring that any requirements in relation to research data and records management placed on their research by funding bodies or regulatory agencies or under the terms of a research contract with the University are also met.

The following should be noted:
- a custodian should be designated for any archived information.
- data should be stored in line with other policies.
- data should be stored in a way that permits a complete retrospective audit if necessary.
- data should be safely stored, with appropriate preservation and backup procedures in place.
- data, particularly personal data, should be treated in confidence, i.e. kept securely with no unauthorised access.
- should a research team cease to exist or the lead moves to another Institution, the expectation is that the responsibility for the information belongs to the University that hosted the original research.
- research hosted within the NHS should comply with the data retention policy of the host Trust, provided that the minimum requirements of this policy document are adhered to.

The University will be responsible for:

- providing access to services and facilities for the storage, backup, deposit and retention of research data and records that allow researchers to meet their requirements under this policy and those of the funders of their research;
- providing researchers with access to training, support and advice in research data and records management;
- providing the necessary resources to those operational units charged with the provision of these services, facilities and training.

The University’s Research Ethics & Governance Sub-Committee, a sub-committee of the University Research Committee, would be responsible for guiding the development and updating of the policy.

Concordat on Open research data:

Published in July 2016, the ‘Concordat on Open research data’ has been developed by a UK multi-stakeholder group. The development of the Concordat is to help ensure that research data gathered and generated by members of the UK research community is made openly available for use by others wherever possible in a manner consistent with relevant legal, ethical, disciplinary and regulatory frameworks and norms, and with due regard to the costs involved. The Concordat, proposes a series of clear and practical principles for working with research data that cover the many roles needed to support the research process. The Concordat sets out ten principles with which all engaged in research can demonstrate that they:
• are acting in an appropriate manner concerning research data;
• conform to all ethical, legal and professional obligations relevant to their work;
• nurture a research environment that makes data open wherever practical and affordable;
• use transparent, robust and fair processes to make decisions concerning data openness;
• have appropriate mechanisms in place to provide assurances as to the integrity of their research data; and
• recognise the importance of data citation and credit acknowledgement.

The 10 principles of the concordat on Open access is as follows:

Principle 1:
Open access to research data is an enabler of high quality research, a facilitator of innovation and safeguards good research practice.

Principle 2:
There are sound reasons why the openness of research data may need to be restricted but any restrictions must be justified and justifiable.

Principle 3:
Open access to research data carries a significant cost, which should be respected by all parties.

Principle 4:
The right of the creators of research data to reasonable first use is recognised

Principle 5
Use of others’ data should always conform to legal, ethical and regulatory frameworks including appropriate acknowledgement.

Principle 6
Good data management is fundamental to all stages of the research process and should be established at the outset.

Principle 7
Data curation is vital to make data useful for others and for long-term preservation of data.

Principle 8
Data supporting publications should be accessible by the publication date and should be in a citeable form.

Principle 9
Support for the development of appropriate data skills is recognised as a responsibility for all stakeholders.
Principle 10
Regular reviews of progress towards open research data should be undertaken.

Further information on the concordat on open research data can be accessed via the URL http://www.rcuk.ac.uk/documents/documents/concordatonopenresearchdata-pdf/
RESEARCH GRANT APPLICATIONS – GOVERNANCE PROCEDURES

The University has arrangements in place for managing key requirements relating to the development of research proposals and external funding applications.

RESEARCH DEVELOPMENT

The Research Development function of the Research Engagement & Innovation Services (REIS) advises potential applicants of opportunities available for external funding. The team is located across the four Research Hubs and in the REIS section in the Talbot Building. As part of the process, Principal Investigators and their teams are made aware of the key legislative requirements affecting external funding. PIs are requested to take note of sponsor terms and conditions, which often make reference to legal requirements. Further information on researcher support can be obtained from the URL below

http://www.swansea.ac.uk/research/researcher-development/researchstaff/

Legislative requirements affecting external funding are listed below:

Research Governance Framework (RGF)

The Research Governance Framework outlines the principles of good governance that apply to all research undertaken within the remit of the Minister for Health and Social Services for Wales. Any research undertaken in the area of health and social care for which the University is the ‘sponsor’ requires to meet high ethical and financial standards of governance that reflect transparent and robust decision making and monitoring process. The University’s adherence to the research governance framework is tested by external audits and inspections.

The Department of Research Engagement & Innovation Services (REIS), is responsible for monitoring sponsorship of research projects for the University. The Research Governance Framework Officer, based in REIS is responsible for receiving and reviewing applications for the University to act as Sponsor.

Data protection:

- In the UK, the use of identifiable data in research is governed by the Data Protection Act (1998) and the common law duty of confidence.

- The Data Protection Act is based on the European Data Protection Directive (95/46/EC). In January 2012, the European Commission published a draft Data Protection Regulation with a view to replacing the existing Data Protection Directive and associated Member State legislation. Unlike a Directive, a Regulation takes direct effect in all EU Member States and does not have to be transposed.

http://www.swansea.ac.uk/the-university/world-class/vicechancellorsoffice/compliance/dataprotection/dataprotectionatswanseauniversity/
Export control:

- The University requires a policy on Export Control. (Example of a University [policy](http://www.imperial.ac.uk/media/imperial-college/research-and-innovation/research-office/public/Export-Controls-[pdf].pdf))

- The Government’s Export Control legislation seeks to ensure that UK science and technology is not exported into wrong hands. The Department for Business, Innovation & Skills (BIS) has issued specific guidance for academics. ([Guidance](https://www.gov.uk/guidance/export-control-legislation-for-uk-academics-and-researchers))

**PROJECT SERVICES – GOVERNANCE OF AWARDS**

The Project Services team is charged with ensuring the establishment and monitoring of systems of control and accountability, including financial and operational controls and risk assessment. They work with Colleges and in particular with the Principal Investigators to assist them to discharge their obligations and financial responsibilities. The Projects are owned by the respective Colleges and form part of the overall business plan.

Projects are managed within a defined Legislative and Regulatory framework which includes:

- Sponsor terms and conditions established by contract and subject to UK contract Law.
- Sub-contracts, Collaborations, Partnerships and other third party agreements.
- Audit frameworks e.g. Welsh European Funding Office (WEFO), European Funds Audit Team (EFAT), Research Council UK, Swansea University internal audit.
- HMRC VAT – Finance department provide guidance on these issues and REIS communicates to PIs and Administrators
- HESA statistical return – REIS maintains systems which provide datasets in compliance with these returns. Any changes to guidance should be communicated via Finance department as they have overall responsibility for the whole return.

REIS Project Services manages these responsibilities within the context of a mature and robust financial control environment. REIS conduct periodic reviews of project expenditure and highlight overspends to relevant Colleges. REIS produce an annual report to Finance Committee highlighting risks. REIS approves staff expenditures and major non-staff expenditures >£25k per item. REIS advise on eligibility and highlights any doubtful items. Where REIS identifies non-compliance or issues of high risk there are clear escalation paths via the Risk Manager to SMT.

Aside from the University internal auditors and external auditors each Funder has its own audit regime and REIS plays a key supportive role in allowing open access to financial systems and management information. Documentation is archived in an accessible manner and REIS staff will be available to provide explanations where necessary.

Links to the key governance procedures are given below:

- Applying for funding: [http://www.swansea.ac.uk/reis/supportforacademics/](http://www.swansea.ac.uk/reis/supportforacademics/)
- **Quality Enhancement**: arrangements in place for Internal Peer Review under the University’s Quality Enhancement Policy which can be accessed via the REIS website at [http://www.swansea.ac.uk/media/RD_Process_Quality_Enhancement.pdf](http://www.swansea.ac.uk/media/RD_Process_Quality_Enhancement.pdf)

- **Signing Authority on Research Grant Applications** - and the requirements in place for approval of research grant applications prior to submission to relevant funder form part of the University’s Financial Policies and Procedures [http://www.swansea.ac.uk/finance/staffinformation/financialpoliciesandprocedures/section E12 http://www.swansea.ac.uk/media/E%2012%20RI%20June%2015%20changes_JW%20(3).pdf](http://www.swansea.ac.uk/finance/staffinformation/financialpoliciesandprocedures/section E12 http://www.swansea.ac.uk/media/E%2012%20RI%20June%2015%20changes_JW%20(3).pdf)

- **Registration of Research Projects** - provides details on the requirements in place for registration of research projects. *(information on this to be added)*

- **Facilities, Equipment and Risk Assessment** *(information on this to be added)*

The University has arrangements in place for managing key requirements relating to the development of research proposals and funding applications. Information on these can be found at:

- **Applying for funding**: [http://www.swansea.ac.uk/business-and-industry/r-and-i/funding-bids/applying%20for%20funding/](http://www.swansea.ac.uk/business-and-industry/r-and-i/funding-bids/applying%20for%20funding/)

- **Peer Review**: arrangements in place for Peer Review under the University’s Peer Review Policy Framework which can be accessed via the word document ‘Guidance notes for Peer Reviewing research enabling funding proposals’ and can be accessed via URL [www.swansea.ac.uk](http://www.swansea.ac.uk/)

- **Signing Authority on Research Grant Applications** - and the requirements in place for approval of research grant applications prior to submission to relevant funder *(information on this to be added)*

- **Registration of Research Projects** - provides details on the requirements in place for registration of research projects. *(information on this to be added)*

- **Facilities, Equipment and Risk Assessment** *(information on this to be added)*
Section L

POLICY ON RESEARCH RELATED HEATH AND SAFETY

Health, Safety and well-being of participants:

All researchers (including PhD students) in a research establishment must:

- take responsibility for their own health and safety and ensure that they don’t compromise the health and safety of others by the things they do or fail to do;
- work safely and efficiently;
- follow the organisation’s policy, guidance and safe systems of work;
- attend training and put it into practice in the workplace;
- risk-assess, or assist with the risk assessment of their work;
- use protective equipment as recommended;
- not change research or other work protocols without first discussing the change with their manager and specialist safety advisers as appropriate;
- report incidents that have resulted in, or could have resulted in, injury or damage;
- assist in the investigation of accidents with the aim of introducing preventative measures;
- report unsafe conditions or actions;
- work co-operatively to improve health and safety standards and performance;

As a general rule, people participating in research should not be exposed to risks that are greater than, or additional to, those that they encounter as part of their normal lifestyles. Researchers have a responsibility to protect participants from any harm arising from research. If it is expected that participants may suffer harm, unusual discomfort or other negative consequences, whether during the research or in the future, as a result of their participation in research, the lead researcher must, prior to any person’s participation, obtain:

- approval of independent, accredited ethics reviewers (e.g. University ethics reviewers, an NHS Research Ethics Committee or the national Social Care Research Ethics Committee);
- obtain informed consent of the prospective participant.

Depending on the nature of the research, researchers have a responsibility to ask participants about any factors, such as pre-existing medical conditions, that might create risks to them if they participate in a given research project, and participants must be advised of any special action they should take to avoid risk.

Before participating, people should be informed of how to contact the lead researcher, the Head of Department, or, ultimately, the Registrar within a reasonable time period, if, following participation they experience stress, harm or have any other concerns about their research.

In the case of clinical trials, research should only take place where the foreseeable potential risks and inconveniences to the prospective participants (i.e. trial subjects and/or patients) are deemed likely to be outweighed by the potential benefits for them and for future patients. In certain cases a patient may explicitly support a research project and support invasive treatment that may be very harmful if, due to the particular circumstances (for example, if s/he is terminally ill), s/he feels that it is worth taking a significant, potentially life threatening
risk. This example represents the point at which participants may feel they have a right to participate as well as a right to withdraw, a right to be harmed, in exceptional circumstances, as well a right to be protected from harm.

In the case of non-invasive research methods such as interviews and questionnaires, the content and line of questioning may be highly sensitive, may raise confidential personal issues, and may intrude, or be perceived to intrude, upon a participant’s comfort and privacy. The initial judgment about whether or not questions are sensitive and likely to cause harm or discomfort rests with the lead researcher. For advice in such cases, the lead researcher should initially consult the College Research Governance Support Officer or Chair of College Research Ethics Committee.

The Management of Health and Safety at Work Regulations 1999 requires employers to have suitable arrangements in place for “the effective planning, organisation, control, monitoring and review” of their risk identification and control systems. This approach is recommended by the HSE document *Successful health and safety management* (HSG65). In a system intended to manage the health and safety aspects of a research project, this means putting in place organisational health and safety policy and guidance and:

- planning the health and safety arrangements for the activity *(PLAN)*
- implementing the planned health and safety controls and carrying out the activity *(DO)*
- checking that the arrangements and controls put in place to stop injury, damage and ill health are working as planned *(CHECK)*
- reviewing the activity to ensure that the health and safety arrangements were adequate and proportionate and then feeding any changes into the next research activity *(REVIEW)*

The University, Principal Investigator or researcher should:

- identify potential health and safety implications of all research projects.
- undertake reasonable steps to ensure the health and safety of all research participants and researchers.
- where appropriate, obtain Occupational Health clearance for researchers entering health and social care environments.
- ensure that staff and students whose research involves the participation of vulnerable groups such as the old, the young and the sick have Criminal Records Bureau disclosure before their research commences.
- ensure that appropriate risk review methods are in place for any potential and on-going risks are appropriately addressed, including containment, shielding and monitoring.

For further information on how to conduct research safely please consult the document ‘responsible research – Managing health & safety in research: guidance for the not-for-profit sector’ [http://www.iosh.co.uk/ushaguide](http://www.iosh.co.uk/ushaguide)

While writing up a project funding proposal and prior to embarking on any research project, please consult the University’s Health and Safety policies via the following link: [http://www.swansea.ac.uk/estates-and-facilities-management/safetyoffice/policiesandprocedures/](http://www.swansea.ac.uk/estates-and-facilities-management/safetyoffice/policiesandprocedures/)
Section M

POLICY ON IP AND PROCEDURES FOR IMPLEMENTATION OF IP

M1. INTELLECTUAL PROPERTY

Introduction

M1.1 The policy and rules of Swansea University in respect of:

- the ownership of Intellectual Property created by staff of the University ("University Personnel")
- the use and commercialisation of Intellectual Property; and
- the implementation and administration of the Intellectual Property Policy.

This policy may be supplemented from time to time by guidance, made in accordance with the Procedures.

M1.2 to Commercialise means to realise commercial or financial benefit through the exploitation of Intellectual Property, and Commercialisation shall be interpreted accordingly.

M1.3 to Create means to create, devise, design, invent, discover, be the author of or otherwise originate any Intellectual Property and Creator shall be interpreted accordingly.

M1.4 Intellectual Property ("IP") means (1) patents, copyright, database rights, design rights, trade marks, topography rights, plant breeders’ rights and all other intellectual or industrial property rights whether registered or unregistered such as exist now or in future under the law of England and Wales, the law of the European Union or the law of any other jurisdiction throughout the world (2) the right to apply for, and applications for, such rights and (3) all extensions and renewals of such rights. Intellectual Property shall also include other intellectual assets such as inventions and discoveries and any other product or attribute of intellectual or academic activity (whether or not formal property rights subsist or are capable of subsisting therein) such as (but without limitation) know-how, knowledge and expertise, skills, techniques, and the results of experiments, tests, or calculations.

M1.5 University Personnel means any members of staff or employees of the University.

M1.6 Procedures means Swansea University’s Procedures for Implementation of its Policy on Intellectual Property as amended from time to time in relation to the implementation and administration of this Policy.
M2. General Principles

The general principles underlying this policy are:

M2.1 The University owns the Intellectual Property created by University Personnel, except to the extent this policy provides otherwise.

M2.2 University Personnel who have created Intellectual Property which is Commercialised should receive a fair share of the commercial benefit, as should the University and the relevant University College(s).

M2.3 Whenever University funds, facilities, personnel or other resources are involved in (1) creating Intellectual Property which is exploited commercially or (2) undertaking other commercial activities, the University must obtain good value for its investment.

This is because:

- As a charity the University has a duty to ensure that the use of its resources is properly accounted for, and

- Most of the University’s activity and resources is funded by public money. In general, public money or resources cannot be used to confer a direct or indirect benefit on a business undertaking, because of the danger of unlawful state aid. Where there is unlawful state aid, it must be paid back.

Nevertheless, where the use of University resources is insignificant in the creation of the Intellectual Property, the University may waive its ownership of the Intellectual Property having regard to guidelines established under the Procedures.

M2.4 In respect of Intellectual Property which the University determines not to commercialise or otherwise exploit, the University should have the right to use that Intellectual Property for its own purposes and to receive a share of any benefits of commercialisation, but should not unreasonably refuse to license or assign the Intellectual Property to the Creator.

M3 Ownership of Intellectual Property - University Staff

M3.1 By law, rights in any Intellectual Property created by an employee of the University during the course of his or her employment belong to the University.

M3.2 Intellectual Property created by a member of staff within his or her employed area of academic or research expertise during his or her period of employment with the University are presumed to have been created during the course of his or her employment, and so belong to the University.

M3.3 In any event, if University funds, facilities, personnel or other resources are used, the
University makes it a condition of use that any resulting Intellectual Property belongs to the University.

M3.4 University Personnel have a duty to disclose to the University any Intellectual Property that they have created during their period of employment, which may reasonably be considered suitable for commercial exploitation. Subject to that duty, University Personnel must keep confidential at all times and must not publish or disclose any such Intellectual Property, except as expressly permitted by the University under this Policy or otherwise in writing.

M4 Teaching Materials and other Academic Materials

M4.1 The principle which the University applies to Teaching Materials and other Academic Materials is that the University should be entitled to use the IP for its own purposes and receive a share of any proceeds from commercialisation, but does not insist on ownership.

M4.2 The Creator shall own the copyright in teaching materials, academic and other publications (books, articles etc.), theses and dissertations, lesson plans and learning modules except where they are comprised of original computer software, details of an invention or other commercially exploitable information or know-how not in the public domain, or when the materials have been specifically commissioned by the University or in circumstances where Clause 6 is applicable and the University is contractually required to own the copyright.

M4.3 The University shall be granted an unconditional, perpetual and irrevocable non-exclusive right to copy, use and modify these materials for all purposes connected with the University and any affiliated or subsidiary institution. The license related to Academic materials shall be non-exclusive. The license for Teaching Materials, lesson plans and learning modules shall be exclusive during the term of employment and non-exclusive thereafter. In its discretion, the University will provide reasonable and appropriate acknowledgement of the Creator.

M4.4 The Creator shall not publish without the express written consent of the University commercially sensitive information of the University, details of any potentially patentable invention, or any information in violation of a Confidentiality Agreement between the University and a third party.

M4.5 In the event the Teaching Materials or other Academic Materials or any other material are commercialised, the University shall be entitled to receive 15% of any proceeds over £2000.

M4.6 It is the obligation of the Creator to ensure that any license or assignment of the intellectual property rights in Teaching or other Academic Materials or any other matter to a third party, such as an academic publisher, is made subject to the rights of the University to use and modify such materials.
The Creator(s) shall indemnify and keep the University indemnified against all costs, claims, damages or expenses incurred by the University or for which the University may become liable arising out of or relating to any use or commercialisation of the Teaching Materials or other Academic Materials or any other matter by the author, including any tax, national insurance, and related interest and penalties.

**M5  Commercialising Intellectual Property**

**M5.1** No University Personnel may, without express authority from the University, enter into any discussions, negotiations, arrangements or agreements with any person or organisation in relation to any Intellectual Property which belongs to the University.

**M5.2** University Personnel must inform the University of any potential Commercialisation of Intellectual Property. Unless the University expressly authorises otherwise, Commercialisation shall only take place via the University. The University shall determine if and how the University shall Commercialise Intellectual Property that it owns in accordance with the Procedures, including any provisions for consultation which are contained in the Procedures.

**M5.3** Generally, if the University decides that it does not wish to Commercialise Intellectual Property, the University will license or assign the Intellectual Property to the Creators where it can be shown to its reasonable satisfaction that assigning ownership or licensing will be on terms which are consistent with the University’s obligations as a charity and the use of public funds. If the IP is commercialised by the Creator, the University will be entitled to a share of revenue in accordance with guidelines set out in the Procedures.

**M5.4.** The University may, in accordance with the Procedures, issue disclaimers of ownership of Intellectual Property in appropriate cases or provide for a license or assignment of the Intellectual Property to the Creators.

**M6  Contract Research and Consultancy**

**M6.1** Where the University enters into a contract for the supply of research or consultancy services, it is likely that there will be special provisions relating to IP generated in the course of supplying those services.

**M6.2** Any Intellectual Property generated by University Personnel in supplying those services will belong to the University, and will be dealt with in accordance with the relevant contract.
M7  Revenue Sharing

M7.1 The University will distribute the net revenue or other tangible benefit received by the University (after recovery by the University of its reasonable costs and expenses in connection with the identification, protection, Creation or Commercialisation of such Intellectual Property) deriving from Intellectual Property created by University Personnel in accordance with the following formula. Where there is more than one Creator, they will share their entitlement between them equally, unless they otherwise agree among themselves.

<table>
<thead>
<tr>
<th>AMOUNT</th>
<th>CREATORS</th>
<th>UNIVERSITY SCHOOL</th>
<th>UNIVERSITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>First £ 2000</td>
<td>100%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Next £2000-£20000</td>
<td>60%</td>
<td>30%</td>
<td>10%</td>
</tr>
<tr>
<td>Next £20,000-£100,000</td>
<td>50%</td>
<td>35%</td>
<td>15%</td>
</tr>
<tr>
<td>Next £100,000-£250,000</td>
<td>40%</td>
<td>40%</td>
<td>20%</td>
</tr>
<tr>
<td>Additional Amounts</td>
<td>35%</td>
<td>35%</td>
<td>30%</td>
</tr>
</tbody>
</table>

M7.2 The University’s commitment is subject to and shall be modified to reflect:

24.2.1 any major overarching initiative(s) entered into by the University, following relevant consultations, which may have different reward models;

24.2.2 the Creator’s right to receive other benefits through the Commercialisation process (primarily, equity ownership in a spin-out company, in which case if a creator accepts shares or options over shares in the Spin-Out, the Inventor will not be entitled to receive additional revenue from the University).

M8  Breach of Policy or Guidance

M8.1 Any breach by University Personnel of this policy or of any guidance made in accordance with the Procedures may amount to a disciplinary matter and / or an infringement of the University’s rights, and consequently may lead to disciplinary or legal action being taken by the University.

M9  Implementation and Dispute resolution

M9.1 Responsibility for the implementation and administration of this Policy shall lie with the Vice Chancellor, who may delegate that responsibility to another person.

M9.2 If the Vice Chancellor or Chair of Council is personally interested in any matter related
to the University’s IP or has some other conflict of interest with the University related
to any commercial matter, then the functions of the Vice Chancellor and/or the Chair
of Council (as the case may be) under this policy and the Procedures shall be exercised
by such independent person or persons as the Council may determine.

M9.3 The Procedures shall include an internal dispute resolution procedure.

M9.4 In the event University Personnel allege that the University has not complied with this
Policy and its Procedures, he or she may request that the matter be resolved by an
arbitrator to be agreed upon between the University and the University Personnel, of
if they are unable to agree on the identity of the person within one calendar month of
the request to arbitrate, by an arbitrator appointed by the President of the Law Society
of England and Wales. The arbitration will take place in Swansea and be conducted
according to laws of England and Wales. The decision of the arbitrator shall be binding
on the University and the staff member and the costs shall be borne as decided by the
expert. Either Party would be free to bring proceedings in the courts in order to seek
mandatory, declaratory or other relief which is not available from an arbitrator.
PROCEDURES FOR IMPLEMENTATION OF THE POLICY ON INTELLECTUAL PROPERTY

M10. Introduction

On 17 March 2008, Council approved the creation of the Swansea Intellectual Property Group to manage and commercialise the University’s Intellectual Property. The group is part of the Department of Research and Innovation.

M11. Definitions

Except where they are defined differently in this document, words and phrases defined in the IP Policy shall have the same meaning in this document.

M11.1. Authoriser

means the individual set out in the table below:

<table>
<thead>
<tr>
<th>Authoriser</th>
<th>Staff Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair of Council</td>
<td>Vice Chancellor</td>
</tr>
<tr>
<td>Vice Chancellor</td>
<td>Registrar and Pro Vice Chancellors</td>
</tr>
<tr>
<td>the appropriate Pro Vice Chancellor</td>
<td>Heads of College or Heads of Institutes</td>
</tr>
<tr>
<td>Registrar</td>
<td>Senior Administrators and Heads of Non-School based Departments</td>
</tr>
<tr>
<td>Head of College</td>
<td>Academic, academic-related, research or technical staff or others line-managed by the relevant Head of College.</td>
</tr>
<tr>
<td>Head of Institute</td>
<td>Those who are line-managed by the Head of Institute</td>
</tr>
<tr>
<td>Senior Administrator</td>
<td>Those who are line-managed within the relevant administrative division</td>
</tr>
</tbody>
</table>

M11.2 Department means the Department of Research and Innovation.

M11.3 Director means the Director of the Department of Research Engagement and Innovation Services who also serves as the Head of the Swansea IP Group.

M11.4 IP Group means the Swansea IP Group, a group within the Department that has primary responsibility for the administration and implementation of the IP Policy.

M11.5 Outside Body means a company in which the University has less than a 50% shareholding, directly or indirectly, a government body, another entity not controlled by the University, or an individual who is not a University employee.
M11.6 **University Resources** means any:

- M11.6.1 funds, facilities, employee time or other resources (including, without limit, equipment and consumables, use/supply of heat, light or power) of the University or a University subsidiary; or

- M11.6.2 use of the University’s name or crest or other mark or distinguishing feature in the promotion of the work, if the costs of the resources have not been fully reimbursed to the University.

M12 **Ownership of Intellectual Property**

M12.1 The ownership of Intellectual Property is determined by the IP Policy. Under the IP Policy, the University can disclaim ownership of resulting Intellectual Property created only with insignificant use of University Resources.

M12.2 Insignificant use means that:

- 29.2.1 only a small amount of unrestricted University funds has been used;

- 29.2.2 only insignificant University Resources have been used, such as use of office space, library and other general use information sources, personal computers and personal office equipment; and

- 29.2.3 the Intellectual Property has been created exclusively during the personal unpaid time of the creator.

M12.3 The IP Group in consultation with the relevant Authoriser will determine whether the use of University Resources has been insignificant.

M12.4 In accordance with the IP Policy, Intellectual Property created pursuant to an agreement with an Outside Body will, in all cases, belong initially to the University so that ownership may vest pursuant to the agreement.

M12.5 University Personnel must ensure that agreements (such as individual consultancy agreements or other employment arrangements) do not conflict with the IP Policy. It is the responsibility of each member of staff and his/her relevant Authoriser to ensure that this rule is kept and copies of all such agreements are deposited with the IP Group.

M12.6 University Personnel must provide reasonable assistance and cooperation to ensure that Intellectual Property is fully vested in the University.

M12.7 Non University Personnel (such as some Senior Research Fellows, visiting academics, individuals with honorary appointments, and emeritus staff) who may have an association with the University or access to University Resources, unless agreed otherwise, are required to transfer to the University any Intellectual Property they
create in the course of their association with or activities for the University or through use of University Resources. They will be treated as University Personnel for the purposes of revenue-sharing. An agreement must be in place between the University and the individual or his/her employer before the individual’s appointment begins. Such individual must keep any confidential information to which he or she has access and only use it for the purpose for which it was supplied, in each case as if he or she were an employee of the University. It is the responsibility of the Head of College or Head of Institute to ensure that this rule is kept and that copies of all such agreements are deposited with the IP Group.

M13 Protection and Commercialisation of Intellectual Property

M13.1 The IP Group has primary responsibility for protection and Commercialisation of Intellectual Property.

M13.2 The IP Group will decide, after consultation with the Creator and the Authoriser, an appropriate strategy for any protection and Commercialisation of Intellectual Property.

M13.3 The University will not promote, support or commercialise any Intellectual Property-related project which contravenes University policies or which in its judgement might adversely affect its reputation. It is the responsibility of the IP Group to ensure that this rule is kept.

M13.4 The University recognises that it may in its discretion (after consultation with the Creator and the Authoriser) place Intellectual Property in the public domain.

M13.5 University Personnel must disclose to the IP Group all Intellectual Property (and associated materials) which they have created that may be owned by the University and which may be commercialised.

M13.6 A Creator who has created any Intellectual Property (whether he/she believes that the ownership of such Intellectual Property may be claimed by the University or not) owes a duty of good faith to the University, under which he or she must disclose the Intellectual Property to the IP Group. The disclosure will be in the form of the Intellectual Property Disclosure Form, which shall be in such form as the IP Group may from time to time specify.

M13.7 The IP Group shall enforce the IP Policy and has the right and duty to apply these Procedures for all Intellectual Property owned by the University regardless of whether it has been disclosed to the University by the Creator.

M13.8 A Creator of Intellectual Property may submit an application to the IP Group requesting that such Intellectual Property be licensed or assigned to the Creator and setting out the Creator’s proposals for Commercialisation of the Intellectual Property and the advantages and benefits to the University of those proposals. Such application must be signed by all of the Creators of the Intellectual Property, if there
is more than one.

M13.9 In all cases, the IP Group will review the information contained within the Intellectual Property Disclosure Form and other information necessary to make an informed decision as to whether and if so how to Commercialise the IP Property. The Creator may be required to complete an Invention Record in such form as the IP Group may specify.

M13.10 The IP Group will notify the Creator(s) of whether it will Commercialise the Intellectual Property and of other steps that it will take.

M13.11 The IP Group, in its discretion, will determine if and how it will protect any Intellectual Property and how to best Commercialise it. If the IP Group subsequently decides not to Commercialise all or part of the Intellectual Property, it will notify the relevant Creator.

M13.12 The IP Group will be exclusively responsible (with the assistance of the Creator) for the discussions with potential assignees, licensees, collaborators or other commercial recipients or users of the Intellectual Property and with investors and financiers, for the development of a business plan and for the negotiation of appropriate licences or other agreements.

M13.13 The time frame for Commercialisation of any Intellectual Property will be determined by the IP Group depending on factors such as market conditions and the state of development of the Intellectual Property.

M13.14 Each Creator shall provide reasonable assistance to the IP Group such as providing additional information, attending meetings with potential licensees/investors and advising on further developments and improvements of the Intellectual Property.

M13.15 If the IP Group decides not to Commercialise any Intellectual Property, on request from all of the Creators, the Director will consider to the extent possible a license or assignment to the Creator. A license or assignment will (1) be conditioned on a reservation for use by the University for administrative, promotional, teaching and research purposes, (2) be subject to tax and liability indemnities, (3) provide for compensation to the University in accordance with and otherwise comply with the conditions set out in Clause 4.17, and (4) be on such other terms and conditions as are necessary to protect the interests of the University, its staff or students. It shall be the Director’s responsibility to ensure that this is done.

M13.16 If the Creator believes that the IP Group is not acting diligently, then he or she (acting collectively if there is more than one) may request that the commercialisation be reviewed by the Registrar. The Registrar, if he/she decides that the IP Group is not acting in a timely manner, will set up requirements for the IP Group. If the IP Group fails to meet them, the Registrar may deem that the University will not Commercialise the Intellectual Property and require that the Intellectual Property be licensed or assigned to the Creator.
M13.17 Where the University licenses or assigns any Intellectual Property to the Creator, then the Creator:

M13.17.1 unless the University otherwise consents, may not use, and will procure that anyone to whom they transfer the Intellectual Property does not use, the University’s name in any way, except for the following statement:

“The idea was originally conceived and developed at Swansea University.”

M13.17.2 pursuant to the IP Policy, will pay to the University

(a) any expenses already incurred by the University in connection with the development, registration or exploitation of any such Intellectual Property (including patent agents’ fees). The amount and timing of such payment will be established in the license or assignment.

(b) an amount equal to 15% of the total of any income (for example royalties, license fees, dividends, consultancy fees, or the equivalent) or capital (for example, lump sums, shares in companies or equivalent) realised by or on behalf of the creator or any Associate of the Creator from the Commercialisation of such Intellectual Property.

M13.17.3 An Associate of the Creator may be either a personal associate or a business associate.

M13.17.4 A personal associate is a person that is (1) a spouse, civil partner or other person in a close personal intimate relationship with the Creator (and includes former spouses and civil partners); or (2) is a relative of the Creator (brother, sister, uncle, aunt, nephew, niece, lineal ancestor or lineal descendant, treating a relationship of the half-blood as a relationship of the whole blood, and including adoptive or step children and adoptive or step parents).

M13.17.5 A business associate of the Creator can be a person or an entity. A person is a business associate of the Creator if he or she is or has ever (1) been a business partner of the Creator or of a personal associate of the Creator, (2) employed the Creator or a personal associate of the Creator, (3) been employed by the Creator or by a personal associate of the Creator or by an entity which is an Associate of the Creator, (4) been a shareholder or director of the same company (other than a stock-exchange listed company) as the Creator or of a personal associate of the Creator, or (5) been a person with whom the Creator has had business dealings other than on an arm’s length basis. An entity is considered an Associate of the Creator if the Creator or a personal associate of the Creator or any person who is a business associate of the Creator (singularly or jointly) has control of it, directly or indirectly. A person is to be taken as having control of an entity if the entity is accustomed to act in accordance with instructions from that person, or if that person has voting power of one third
or more at any general meeting of the entity or any of its parents, or if that person has the power to appoint the majority of the board of directors or other governing body of that entity.

M13.18 Before leaving the employment of the University, each member of Staff must deposit with their Authoriser any physical and electronic representation including, but not limited to, original drawings, diagrams, recorded know-how, laboratory note books, computer code, and databases related to Intellectual Property which he/she has created. It is the responsibility of each member of staff and the relevant Authoriser for that person to ensure that this rule is kept and that details of all such representations are deposited with the IP Group.

M13.19 In negotiating agreements with an outside body relating to Intellectual Property, the IP Group and Department will adhere to any relevant University Policies.

M13.20 The Vice-Chancellor may establish an advisory group to advise on Commercialisation strategy and Commercialisation arrangements.

M14 Revenue Sharing

M14.1 For the purposes of revenue sharing under Clause 7 of the IP Policy, the value of any Intellectual Property, in the case of a license or assignment or other income generation arrangement (but not a spin-out) normally will be the net income and capital received by the University (but not any income received for research in connection with the Commercialisation after the deduction of all expenses incurred by the University (or its nominated subsidiary company)) in connection with the development, protection, marketing and Commercialisation of the relevant Intellectual Property.

M14.2 In the case of a Spin-Out:

M14.2.1 if the Creator accepts shares or options over shares in the Spin-Out, the Creator will not be entitled to receive additional compensation or revenue of any kind from the University;

M14.2.2 if the Creator does not accept shares or options for shares in the Spin-Out, the value of the Intellectual Property will be the value of the proceeds (dividends or otherwise) received by the University from the Spin Out after the deduction of all expenses incurred by the University (or its nominated subsidiary company) in connection with the development, protection, marketing and Commercialisation of the relevant Intellectual Property.

M14.3 No individual payment of any Creator’s share will be paid until it reaches £500.
M15. MISSING CREATORS

A Creator, no longer an employee, who is entitled to payments under the University’s revenue sharing arrangements must inform the IP Group in writing of his/her current address or current banking details where any revenue payments may be mailed or deposited. If the IP Group is not given such information, the funds may be invested in a deposit account for three years, unless claimed earlier. Amounts unclaimed for 3 years from the date the revenue is received by the University will be forfeited.

M16. TAX AND NATIONAL INSURANCE

All benefits (such as payments or equity shares) received or receivable by Creators who are current employees of the University will be subject to deduction of income tax and national insurance at source, unless the University otherwise determines with the agreement of HMRC.

M16.1 The University before making payments to or conferring other benefits on former employees must protect itself from potential liabilities for tax, national insurance, interest and penalties and may, as a condition precedent to making such payment or conferring such benefit require:

M16.1.1 a written confirmation from the Creator (1) that he/she will declare such payment on all relevant tax returns (2) that the University may disclose such payment or benefit to HMRC and, pending its decision may withhold any payment or benefit and (3) that he/she will indemnify the University against any tax, national insurance, interest and penalties payable in respect of such payment or benefits; and / or

M16.1.2 actual payment of any known or reasonably anticipated tax, national insurance, interest and penalties which may arise in respect of revenue sharing benefit, and the University will deduct such payment from any amount the University owes the former employee.

M16.2 Creators must in any event indemnify the University against any tax, national insurance, interest and penalties that become due in the future with respect to revenue sharing benefits previously paid.

M16.3 It is the responsibility of the individual Creator and of the Director to ensure that the relevant paperwork is in place to ensure compliance with this Clause 5.

M17 Confidentiality

M17.1 Confidentiality agreements in the name of the University which are related to research, Intellectual Property, or Commercialisation activities must be signed by the Director or an authorized delegate. An individual requested to sign a confidentiality agreement may only sign as an individual.
M17.2 Confidential information covered by a confidentiality agreement must not be disclosed unless disclosure is authorised. In addition, University Personnel must not disclose University confidential information unless authorised.

M17.3 All University Personnel must be familiar with the confidentiality requirements contained in confidentiality agreements or research agreements, including any restrictions on disclosure of research results or their publication. Some agreements may give the Outside Body the final decision over whether papers are approved for publishing, which could impact on an individual researcher’s career. Sometimes confidentiality agreements restrict publication until a patent application can be filed. All individuals must know the restrictions related to disclosure of research results, and if in doubt, contact the Department or the Outside Body for advice.

M17.4 University Personnel must

- M17.4.1 take appropriate advice if he/she is unsure if there may be an invention or design disclosure required by an agreement;

- M17.4.2 adhere to the terms of any agreement regarding confidentiality and take steps in the use, storage and maintaining of such information, as are appropriate to preserve its confidentiality.

- M17.4.3 maintain comprehensive records of information received or disclosed and minutes of meetings where oral disclosures are made; and

- M17.4.4 notify the IP Group if he/she is concerned that confidential information belonging to either an Outside Body or the University is not being appropriately treated.

M18 Conflicts of Interest

The University, a public institution, has a fiduciary duty to protect the financial interests of the taxpayer and when there is the possibility that an actual or perceived conflict of interest may result from undertaking an action, University Personnel shall be obliged to follow the University’s policies and procedures on conflicts of interests. The Director shall establish procedures for the disclosure and management of conflicts of interest (actual, potential or perceived) that arise within the context of research or consultancy, the protection, exploitation, use or Commercialisation of the University’s intellectual property.

M19 Advice and Interpretation

University Personnel may request an interpretation of the IP Policy and these Procedures from the IP Group.

M20 Implementation

The IP Group shall have wide authority and discretion, within the confines of (1) the
University’s Charter and any Regulations, Ordnances or other provisions made by Council (2) the IP Policy and (3) any directions given by or on behalf of the Vice-Chancellor to adopt administrative processes, guidance, forms and interpretations necessary to effectively implement the IP Policy and these Procedures.

M21 Dispute Procedure

M21.1 A dispute in a matter arising out of the IP Policy or these Guidelines and Procedures will be referred to the Authoriser and the Director.

M21.2 If they are unable to agree or if their decision remains disputed by the Creator the matter shall be resolved by a panel comprised of the Registrar (acting as chair person), the relevant Head of School or Institute, the Pro Vice Chancellor of Science and Engineering (or if such individual is one of the parties in dispute, such party’s Authoriser) and two members of the Council whose decision on the matter shall be final.

M22. Amendment

These Procedures have been endorsed by the Council; amendments to these Procedures, which are not inconsistent with the IP Policy, may be made by the Finance Committee.
Section N

N1. Publication and Dissemination of Research Findings:

Swansea University Green Open Access Policy

UK policy on access to publicly funded scholarly research has changed the UK research publication landscape significantly. While much remains for discussion, it is already known that the post-2014 REF mandates the deposit of Journal Article and Conference Proceedings in a publicly accessible repository. This policy encompasses those requirements while seeking to collect, disseminate and promote the scholarly output of the university’s staff as widely as possible.

This Green Open Access Policy becomes a formal requirement from 1st March 2015 and requires researchers to deposit the full text of their research publications in the University’s Research Information System (RIS) for onward publication to the University’s publicly accessible research repository (Cronfa). (Note 1)

Wherever possible researchers will be expected to make all published research outputs available as Green Open Access, however, recognizing the still changing landscape, it is initially mandatory for journal articles and conference proceedings. (Note 2)

The University’s Research Information System is an internal system to allow the university to collate and evaluate its research output, and will be used for the submission of research outputs and supporting documents to the REF exercise. Cronfa makes our researchers’ work visible to the world, and is indexed by Google Scholar and other search engines. Publishing work in a research repository is a requirement for REF eligibility, can increase the academic and wider visibility of research, and promotes collaboration and citations.

The University Research Deposit Policy requires that:

1. The peer-reviewed final accepted version of a research output must be deposited in RIS immediately on acceptance for publication, together with any relevant embargo information, and

2. Authors must use “Swansea University” within the research output when stating their address.

Help in using RIS and in meeting these criteria is available from the Library, including a RIS user guide. Assistance and support can be provided by your subject team.

Links: Research Information System, Cronfa, HEFCW/HEFCE OA Policy.

Note 1: RCUK funded projects can still apply for funding to pay gold open access, Article Processing Charges – see this page for further details.
**Note 2:** Full-text deposit is required by the REF eligibility criteria. Public availability is normally immediate, but reasonable embargo periods can be honoured. (Max 12 months STEM, 24 months arts and humanities) Under REF eligibility criteria, mandated output types will be ineligible for REF submission if the deposit and accessibility requirements are not met.

**N2. Research Publication Integrity for Authors, Reviewers, and Editors**

Researchers should be mindful of the ethics of publication, and seek to ensure that their authorship, publication, peer-review, editing, and related practices are undertaken with integrity. This is particularly important for collaborative authorship and publication where there is a significant difference between the status of the individuals involved (e.g. well established researchers and early career researchers; academic supervisors and postgraduate researchers).

**Publication and Authorship**

- Organisations and researchers should accept their duty to publish and disseminate research in a manner that reports the research and all the findings of the research accurately and without selection that could be misleading.

- Organisations should ensure that sponsors and funders of research: respect the duty of researchers to publish their research and the findings of their research; do not discourage or suppress appropriate publication or dissemination; and do not attempt to influence the presentation or interpretation of findings inappropriately.

- Organisations should provide training and support to guide researchers in the publication and dissemination of research and the findings of research that involves: confidential or proprietary information; issues relating to patents or intellectual property; findings with serious implications for public health; contractual or other legal obligations; and/or interest from the media or the general public.

- Researchers should address issues relating to publication and authorship, especially the roles of all collaborators and contributors, at an early stage of the design of a project, recognising that, subject to legal and ethical requirements, roles and contributions may change during the time span of the research. Decisions on publication and authorship should be agreed jointly and communicated to all members of the research team.

- Authorship should be restricted to those contributors and collaborators who have made a significant intellectual or practical contribution to the work. No person who fulfils the criteria for authorship should be excluded from the submitted work. Authorship should not be allocated to honorary or “guest” authors (i.e. those that do not fulfil criteria of authorship). Researchers should be aware that anyone listed as an author of any work should be prepared to take public responsibility for that work and ensure its accuracy, and be able to identify their contribution to it.
• Researchers should list the work of all contributors who do not meet the criteria for authorship in an acknowledgements section. All funders and sponsors of research should be clearly acknowledged and any competing interests listed.

• Researchers must clearly acknowledge all sources used in their research and seek permission from any individuals if a significant amount of their work has been used in the publication.

• Researchers must adhere to any conditions set by funding or other bodies regarding the publication of their research and its findings in open access repositories within a set period.

• Researchers should declare any potential or actual conflicts of interest in relation to their research when reporting their findings at meetings or in publications.

• Researchers should be aware that submitting research reports to more than one potential publisher at any given time (i.e. duplicate submission) or publishing findings in more than one publication without disclosure and appropriate acknowledgement of any previous publications (i.e. duplicate publication) is unacceptable.

• Researchers who are discouraged from publishing and disseminating their research or its findings, or subjected to attempts to influence the presentation or interpretation of findings inappropriately, should discuss this with the appropriate person(s) in their organisation so that the matter can be resolved.

The **Committee on Publications Ethics** (COPE) exists to promote integrity in research publication, and aims to define best practice in the ethics of scholarly publishing to assist researchers, authors, editors, editorial board members, owners of journals, and publishers. The COPE website contains many resources, including:

• Principles of Transparency and Best Practice in Scholarly Publishing;
• How to Handle Authorship Disputes: A Guide for New Researchers;
• Ethical Guidelines for Peer Reviewers;
• Text Recycling (i.e. Publication Overlap) Guidelines;
• A Guide to Ethical Editing for New Editors;
• A Code of Conduct and Best Practice Guidelines for Journal Editors;
• A Code of Conduct for Journal Publishers;
• A series of Discussion Documents on publication ethics;
• Flowcharts for Dealing with Suspected Misconduct (e.g. fabricated data, plagiarism, and duplicate publication); and
• Guidelines for retracting Articles.

COPE website [http://publicationethics.org/about](http://publicationethics.org/about)

The **Council of Science Editors** (CSE) also provides a wealth of advice on integrity in research publication. For example, the CSE *White Paper on Promoting Integrity in Scientific Journal
Publications includes detailed advice on:

- Authorship and author responsibilities
- Reviewer roles and responsibilities
- Editor roles and responsibilities

CSE website: http://www.councilscienceeditors.org
INTRODUCTION AND PURPOSES

O1. Swansea University encourages its Staff Members to engage in activities that go beyond the traditional academic role and to establish links with charitable institutions, government, commerce and industry locally, nationally, and internationally. These external activities promote staff development and the reputation of the University and further advance regional economic development and public interest as a whole.

O1.1 By performing external activities, a Staff Member may be placed in a position in which an outside interest may conflict, or appear to conflict, with University duties. Such conflicts arise because of the situation, and even though the Staff Member is acting objectively, neutrally and with professional integrity, it may still appear that his or her decisions are influenced by personal or economic interests.

O1.2 This Policy does not cast aspersions on Staff Members but provides a mechanism to protect their reputation by establishing an objective set of principles regarding the management of conflicts.

The purposes of this Policy are to:

(a) assist Staff Members in identifying Conflicts of Interest that arise in the areas of research consultancy and commercialisation of intellectual property;
(b) provide guidance to those who review and manage Conflicts of Interest; and
(c) incorporate transparency and probity in the management and resolution of Conflicts of Interest.

To accompany this Policy, Procedures have been established for reporting, assessing and managing Conflicts of Interest and providing for oversight of the process.

The University has policies relevant to other types of Conflicts of Interest that may arise. The University’s Policy on Personal Consultancy Services addresses conflicts of commitment that occur when the private interest of a Staff Member may interfere with his or her responsibilities to the University, particularly in respect of the time and energy devoted to University activities. The University’s “Code of Conduct on Personal Relationships” addresses conflicts that may arise because of personal relationships. Swansea University’s “Research Committee Guidelines on Good Research Practice” provides a broad policy on research integrity. In its Fraud Policy, the University commits itself to openness, probity and accountability. Staff Members must comply with those policies in addition to this Policy.
This Policy applies to all Staff Members and relates to Conflicts of Interest arising in connection with research, consultancy or the commercialisation of intellectual property of the University.

DEFINITIONS

“Authoriser” means the person identified in the table below:

<table>
<thead>
<tr>
<th>Authoriser</th>
<th>Staff Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair of Council</td>
<td>Vice Chancellor</td>
</tr>
<tr>
<td>Vice Chancellor</td>
<td>Registrar and Pro Vice Chancellors</td>
</tr>
<tr>
<td>Pro Vice Chancellor, as appropriate</td>
<td>Heads of Colleges or Heads of Institutes</td>
</tr>
<tr>
<td>Registrar</td>
<td>Senior Administrators and Heads of Non-College-based Departments</td>
</tr>
<tr>
<td>Heads of College</td>
<td>Academic, academic-related, research or technical staff, or others line-managed by the relevant Head of College</td>
</tr>
<tr>
<td>Heads of Institute</td>
<td>Those who are line-managed by the relevant Head of Institute</td>
</tr>
<tr>
<td>Senior Administrators</td>
<td>Those who are line-managed within the relevant administrative division</td>
</tr>
</tbody>
</table>

“Commercialise” means to realise commercial or financial benefit through the exploitation of intellectual property, and “Commercialisation” shall be interpreted accordingly.

“Conflict of Interest” means an interest that has the potential to compromise or bias the professional judgement or objectivity of the holder of the interest, or has the appearance of having the potential to compromise or bias the professional judgement or the objectivity of the holder of the interest.

“Director” means the Director of the Department of Research and Innovation (or such other person as may be specified by the Vice-Chancellor from time to time).

“External Appointment” means any appointment which results in a Staff Member or any Related Party of that Staff Member holding office (whether pursuant to a contract of employment or otherwise) as a director, officer or trustee, or such similar position which gives rise to a fiduciary duty to act in the best interests of the external entity in which such an appointment is held.

“Financial Interest” means a financial interest of a Staff Member in the form of Payments, Investments, or IP Revenue, or the expectation or possibility of future Payments, Investments or IP Revenue; or a similar financial interest of a Related Party of the Staff Member which is known by the Staff Member.
“Insignificant Financial Interest” means:

i. In respect of an Investment. Where a Financial Interest consists of an investment, the University will consider it as insignificant if all of the following conditions are met:

(a) the Investment is in a company that is listed on a recognised stock exchange;
(b) the value of the shares does not exceed £5000 of the Staff Member’s salary at any time; and
(c) there is no relationship or connection, explicit or implicit, between the acquisition of the shares and any research to be conducted for that company.

ii. In respect of a Payment. Where the Financial Interest is in the nature of a payment, it will be treated as insignificant if the Payments are less than £5000 in any twelve month period in the aggregate from all sources, and that the payment of the consultancy fee is not related or connected in any way on a proposed relationship between the University and the relevant undertaking. Gifts and hospitality expenses paid by a company may contribute to a Conflict of Interest.

“Investments” means any interest in shares, share options, warrants and other securities and interests in an external undertaking, and the term ‘investment’ shall be construed accordingly.

“IP Revenue” means revenue related to the commercialisation and exploitation of intellectual property such as licensing fees, royalties, and other types of revenue sharing arrangements (excluding those made pursuant to the University’s Intellectual Property Policy).

“Payments” means payments for services including consulting fees, director’s fees, stipends and honoraria, or payments in kind, forgiveness of debt, property, intellectual property, revenues derived from intellectual property such as licensing fees or royalties, or other items of value.

“Procedures” means the “Procedures for Managing Conflicts of Interest in Research Consultancy and Commercialisation Activities.”

“Related Party” means a Staff Member’s immediate family (i.e. spouse, parents, siblings or children); partner; close personal friends; and any other person with whom a Staff Member has a relationship which is likely to appear to a reasonable person to influence the Staff Member’s objectivity.

“Staff Member” means a member of University staff, including students when acting as a Staff Member.

“University Spin-Out” means a company to which the University has assigned or licensed intellectual property and in which the University had an equity interest.

PRINCIPLES
The University expects Staff Members to act, and believes that they do so, with probity.

It is recognised that the existence of an actual or perceived Conflict of Interest arises from a situation and is rarely the product of, or indicative of, any wrongdoing. However, it is important that Conflicts of Interests are disclosed and managed.

The University must deal with Conflicts of Interests in a prompt, fair, reasonable and objective manner, with due consideration of the impact on a Staff Member’s work, career and reputation.

A student’s education must not be negatively impacted because of the interest of a research sponsor.

A Staff Member has an obligation to act in the best interests of the University in performance of his or her University duties and activities, including research and consultancy.

A Staff Member should only be compensated for research in his/her core area of research through the University, and should not conduct research under circumstances in which a reasonable person could believe that the research is affected by an expectation of direct or indirect financial gain other than in accordance with the University’s policies.

Staff Members must publish their research results in a comprehensive, non-biased and timely manner.

University resources, including staff time, should only be used for University purposes and activities and not for personal businesses, commercial or consulting activities, save where otherwise agreed by the University in writing.

**CONFLICTS OF INTEREST**

A Conflict of Interest exists if a reasonable person (e.g. a manager, a student, a collaborator, a colleague, a member of the public, a research sponsor or a regulator) believes that the actions and judgements of the Staff Member are likely to be influenced by a Financial Interest or an External Appointment.

Areas impacted by Conflicts of Interest in research consultancy and commercialisation activities are:

**The University’s Educational Mission**
The principal mission of Swansea University is the education of its students. Staff Members involved in the education, training, or supervision of a student, or the direction, evaluation or grading of a student’s work (“educational activities”) must ensure that these educational activities are performed to the best of their ability without any Financial Interest or External Appointment detracting from these educational activities.

**Research Integrity**
Staff Members must adhere to the highest ethical standards of scientific integrity. If a researcher has a Conflict of Interest relating to research activities, integrity alone may be insufficient to protect the researcher and the University from suspicion and damage to reputation. Various aspects of the research may be impacted by a Conflict of Interest such as the choice of research, its design and protocols, the conduct of the research, the interpretation of results, or the publication and reporting of such results.

Public Accountability/ Use of Public Funding

The University as a public body receives public funding, and it is inappropriate to use its resources for the purposes of performing research, consultancy or commercialisation activities that will result in private gain to the Staff Member except in accordance with University policy.

EXAMPLES OF CONFLICTS OF INTEREST

This Policy cannot address all conceivable Conflicts of Interest, however some examples of actions that may typically give rise to a conflict are set out below:

i. Acting as an academic supervisor, either for students or post-doctoral candidates, in a research project where the research is sponsored by an external entity in which the supervisor has a Financial Interest or External Appointment.

ii. Performing educational activities for a student when the Staff Member has a Financial Interest or External Appointment in an external entity which is owned or controlled by the student.

iii. Participating in research sponsored by an external entity in which the Staff Member has a Financial Interest or External Appointment.

iv. Performing research which may affect the value of intellectual property owned by or licensed to the Staff Member.

v. Conducting research externally that would normally be conducted by the University.

vi. Conducting research or consultancy on a private basis when that research or consultancy should be conducted by the University, unless the University has indicated that it does not wish to engage in such research or consultancy.

vii. Performing research on intellectual property owned or licensed to an external entity, if the researcher has a Financial Interest or External Appointment in the external entity.

viii. Agreeing to perform consultancy under terms and conditions that might preclude the Staff Member or the University from working on related research or consultancy being conducted by the University.

ix. Engaging in consultancy work that might cause substantial absences from the University and increase the work load on other Staff Members.
x. Using or disclosing confidential information of the University or a third party to other organisations that sponsor research or consultancy work for the Staff Member.

xi. Performing research on behalf of an external entity in which a Related Party has an Investment or from which a Related Party receives Payments.

42. DISCLOSURES OF A FINANCIAL INTEREST AND EXTERNAL APPOINTMENT

42.1 A Staff Member must make the following disclosures:

Annual Disclosures

All Staff Members must complete the “Declaration of Outside Interests by Staff” (as it may be varied from time to time) annually and at such other times during the course of the year when necessary to reflect a significant change in a Staff Member’s circumstances.

Specific Disclosures

To ensure that any possible Conflicts of Interest are identified and managed at an early stage, each Staff Member must make a Specific Disclosure of any Financial Interest and/or External Appointment that is relevant to proposed or on-going research, consultancy or commercialisation activity. A Financial Interest must be disclosed, regardless of whether it is deemed insignificant, under the provisions of this Policy. The Procedures will establish specific requirements related to specific disclosures.

Public Disclosures

A Staff Member formally discussing or commenting on research results must disclose any Financial Interests or External Appointments in an external entity affected by the research. This requirement extends to any discussion or comments that may be publicly distributed in any media such as television or radio programmes, newspapers, or electronic media, or in discussions or comments made before the public.

A Staff Member must comply with any specific requirements regarding Conflicts of Interest that may be imposed by a relevant third party (e.g. academic or professional publications, or conference organisers).

COMMERCIALISATION ACTIVITIES

Principles of Staff Member Involvement in Commercialisation Activities

Commercialisation activities are particularly susceptible to Conflicts of Interest because of the possibility of direct financial benefits accruing to Staff Members coupled with the potential use of public funding being used for improper personal gain. The following rules apply in commercialisation activities:
• Staff Members may hold an Investment in a University Spin-Out and may receive Payments from the Spin-Out but must disclose them.

• Staff Members may serve as a Director, hold other External Appointments of a non-executive nature, or serve as a consultant in a University Spin-Out with the consent of the Director, subject to any special conditions imposed by the Director, and in compliance with other relevant University policies.

• Full-time Staff Members may not serve as senior managers of a University Spin-Out without the prior written consent of the Director.

An External Entity’s Use Of University Resources

An external entity may not use University space, unless the space has generally been reserved for such use (for example, a business incubation centre).

In all cases in which University resources are used or research is performed on behalf of an external entity in which the Staff Member has an Investment or External Appointment, the University shall be fully compensated for providing the resources.

42.2 ADMINISTRATIVE STAFF

42.3 Staff Members involved in the negotiation and administration of research grants and contracts, consultancy contracts and commercialisation activities are subject to special, more stringent requirements. These Staff Members (for example, members of the Department of Research and Innovation, or technology transfer or commercial officers of the Schools) must be able to negotiate and administer research, consultancy or commercialisation activities in the best interest of the University without Conflicts of Interest.

42.4 An administrative Staff Member nominated by the University to an External Appointment shall be deemed to accept the nomination in the discharge of his or her duties as a Staff Member of the University, and shall not accept any Payments from the external entity unless authorised in writing by the Director.

42.5 An administrative Staff Member shall not hold an Investment in, or receive Payments from, an external entity (1) which was established as a result of the administrative Staff Member’s work in the University, or (2) which has a contractual relationship with the University related to research, consultancy, or IP commercialisation. This prohibition does not apply to shares which are purchased subsequent to the listing of the external entity on a recognised stock exchange.

43 MANAGEMENT OF CONFLICTS IN RESEARCH, CONSULTANCY AND COMMERCIALISATION ACTIVITIES AND DISPUTE RESOLUTION
43.1 The Director has primary responsibility for the management of conflicts in research activity. The Director’s responsibilities are established in the Procedures.

43.2 A Staff Member shall have the right to appeal the Director’s decisions to a panel composed of a lay member of Council, a representative appointed by the President of the University and College Union, and a Pro-Vice Chancellor. The dispute and its resolution and justification shall be recorded. A generalised record shall be made available upon request of a University employee, however, the report shall be generalised so it will not disclose confidential information.

43.3 In the event a Staff Member alleges that the University has not complied with this Policy and its Procedures, he or she may request that the matter be resolved by an arbitrator to be agreed upon between the University and the Staff Member, or if they are unable to agree on the identity of the person within one calendar month of the request to arbitrate, by an arbitrator appointed by the President of the Law Society of England and Wales. The arbitration will take place in Swansea and be conducted according to laws of England and Wales. The decision of the arbitrator shall be binding on the University and the Staff Member and the costs shall be borne as decided by the expert. Either party would be free to bring proceedings in the Courts in order to seek mandatory, declaratory or other relief which is not available from an arbitrator.

44 **DEVIATIONS FROM THIS POLICY**

The Vice-Chancellor may, upon request of the Monitoring Panel, approve a deviation from this Policy when justified by the University’s interests as long as the principles of probity and transparency are maintained.

45 **IMPLEMENTATION**

The Registrar shall have wide authority and discretion within the confines of (1) the University’s Charter and any Regulations, Ordnances or other provisions made by Council, (2) this Policy, and (3) any directions given by or on behalf of the Vice-Chancellor to adopt administrative processes, guidance, forms and interpretations necessary to effectively implement this Policy and the Procedures.
SECTION P

POLICY ON RESEARCH RISK ASSESSMENT
&
SUITABILITY OF FUNDERS/COLLABORATORS

Indemnity

Undertaking a liability risk assessment of research projects is an obligation of the University, and the lead Researcher must ensure that there is the necessary insurance cover in place prior to the start of their project. Authorisation may be required in certain instances and will need to be checked by the University’s Insurance Officer. Examples include Clinical Trials and the use of drones in research.

The University’s Insurance Officer is responsible for providing advice on all matters relating to the University’s insurance policies, insurance claims, maintenance and administration of all records relating to the University’s insurance policies.

Further information on the University’s covers can be found within the University’s Financial Policies and Procedures, and through the following link:-

http://www.swansea.ac.uk/finance/staffinformation/insurance/

Suitability of funders/Collaborators

In line with its Research Integrity policy, the University does not knowingly collaborate with, or accept funding from:

- Tobacco industry;
- Organizations considered illegal under UK law;
- Organizations whose aims and objectives are contrary to objectives and principles of the University.

Any researcher concerned with the nature of potential funding or collaborator should raise it with the University Research Governance & Compliance Manager or the Director of Research & Innovation Office.
POLICY ON STUDENT RESEARCH

The same principles of research integrity, research ethics, and research governance should be applied to student research as they are to all other research. The same high ethical standards should also be expected of student research. It is important that student research is recognized as such, that it is screened to determine whether it requires ethical approval, that no such research proceeds without adequate ethical consideration and appropriate ethical approval, and students are sufficiently well equipped and effectively supported to ensure that all aspects of the research are undertaken with integrity and ethical probity. College Research Ethics & Governance Committees are responsible for ensuring that student research is undertaken in accordance with this Framework.

Student research may present particular challenges with respect to ethical review because of the large numbers, short timescales, limited scope, and diversity of the projects involved. The knowledge, experience, and capability of students will also vary enormously. College Research Ethics & Governance Committees should therefore establish procedures specifically for reviewing research projects undertaken by undergraduate students and students on taught postgraduate courses. The ESRC’s Framework for Research Ethics (updated January 2015) notes that in many cases student research may be managed at subject/department level and overseen by a light-touch subject/departmental ethics committee using an initial checklist, referring applications to full ethical review when it is appropriate so to do. Established protocols for commonly occurring research can expedite the review process. In some instances, student research may be considerably constrained (e.g. restricted to pre-approved protocols or fully determined by the supervisor or module co-ordinator) or even proscribed (e.g. research with personal data that would fall within the scope of the Data Protection Act, research with children or vulnerable groups or research without informed consent). Research on sensitive topics (e.g. child abuse, domestic violence, bereavement, terrorist organisations), research involving vulnerable participants, and research which exposes the researcher or others to avoidable risks (e.g. involving data collection late at night, researching on security sensitive websites) should always be subject to careful ethical scrutiny by a committee or panel.

Students are individually responsible under the Data Protection Act for personal data which they gather and use in their studies. Students may take personal data gathered by them in their research with them when they leave the Institution, unless the research was conducted as part of an Institutional research project in which the student participated, or the agreement with the funder or sponsor of the research specifies otherwise. Students are reminded that they must continue to meet the requirements of the Data Protection Act and other legal and ethical requirements when using the data. (See Section I for fuller details.)

When a student (undergraduate or postgraduate) is undertaking research they should have a designated research supervisor, which may be the module co-ordinator in appropriate circumstances. Supervisors should work closely with their students in considering ethical aspects of proposed research in keeping with this Framework. This is especially important for undergraduate and taught postgraduate research projects (e.g. Dissertations), as well as for postgraduate research students.
Ethical issues will be addressed in accordance with Swansea’s Research Ethics and Governance Framework, which is compliant with ESRC’s Framework for Ethics. It is the responsibility of the principal supervisor to seek approval from relevant College Research Ethics and Governance Committee before any research involving human subjects or datasets commences. The Centre’s Reference Group will provide independent scrutiny of how ethical issues are managed.

It is the research supervisor’s responsibility to inform students about the circumstances in which ethical review of their research is needed, and also the process to be gone through. The ethical review process should be clearly explained to the student and support should be provided to the student throughout the process of obtaining ethical approval to conduct the research. As this process may take some time, the supervisor and student should agree on a timetable to complete the work necessary to obtain ethical approval. This process should also be planned with awareness of submission deadlines for the student.

Any application for ethical review should be completed with the help and advice of the supervisor, who should also sign the application for ethical approval prior to submission to the relevant College Research Ethics & Governance Committees.

After submission of the application for ethical approval, the student and supervisor should receive a prompt, clear response from the Committee. Where further work on the application is needed before approval can be granted, clear details should be provided to the student and supervisor regarding the shortcomings in the application, and how they might be addressed before approval is possible.

When the research is required to undergo external ethical review (e.g. via IRAS https://www.myresearchproject.org.uk/) internal ethical review should be conducted prior to this process.

Where students are conducting research outside the UK, ethical approval should be sought first internally through the Research Ethics Committee of the relevant College. Approval may also need to be sought in the country in which the research is to take place (e.g. data collection). In the event of a conflict between Swansea University requirements, and local requirements, Swansea University requirements should prevail.

Colleges should ensure that the training programmes they provide incorporate the range of issues addressed in this Framework document so that students embrace an ethics culture from the start of their research careers. Research integrity and research ethics should be an integral part of a student’s programme.

All students undertaking research should be made familiar with the appropriate principles and practices of research integrity, ethics and governance as part of their research training. For postgraduate research students, this is likely to be through a combination of subject-specific training, supervision, and the University’s Research Skills Development Programme. For other students, this is likely to be embedded within their modules, and instilled during supervision.
Students will complete modules on the ethics of social research. Each student will meet regularly with their supervisors, who will monitor whether the students have identified and addressed ethical issues satisfactorily.

Where the research undertaken by students leads to its publication – in academic journals for example – principles of publication ethics should not be contravened (e.g. regarding criteria for authorship). For further guidance, see for example: http://exchanges.wiley.com/ethicsguidelines

Students should declare any conflicts of interest that are relevant to their research (e.g. a student researching an organisation within which they are also employed), as should their supervisors.

Any alleged or suspected misconduct by a student when conducting or reporting their research will be subject to the appropriate investigatory and disciplinary processes.

**Duty of care towards a student undertaking research**

Some types of research may put the researcher themselves in a position of vulnerability, or involve the risk of potential harm or verbal abuse from participants. Research involving sensitive topics, or where participants have revealed distressing information, could also cause distress to the researcher. Consideration therefore also needs to be given to issues of researcher safety.

As there is a relationship between the University and the Student, it is likely that this relationship is sufficiently close enough for a duty of care to exist; and the University should work under this assumption.

As part of the duty of care relationship to the Student, the University needs to ensure that the Student’s health and well-being are paramount. Some of the data may be distressing. To protect students’ welfare, the Centre team will hold regular private meetings with each student to monitor wellbeing. Students showing signs of trauma will be encouraged to make use of professional services at the University. If an individual finds primary source materials too distressing to continue viewing and analysing them, allocation of responsibilities within the supervisory team will be adapted to ensure the student can continue without being exposed to these materials.

The University advises academic tutors to “offer a level of supervision appropriate to the work and student/s, based on a risk assessment approach. For student projects the academic tutor should organise a risk assessment approach and agree and write down relevant standards, guidance and local instructions”. Students must also take responsibility for their own health and safety.
1. INTRODUCTION AND DEFINED TERMS

1.1. This document sets out the policy and rules of Swansea University in respect of the ownership of Intellectual Property (“IP”) created by Students of the University.

1.2. Except where they are defined differently in this document, words and phrases defined in Swansea University’s “Policy on Intellectual Property” and Swansea University’s “Procedures for Implementation of its Policy on Intellectual Property” shall have the same meaning in this Policy.


1.4. “Staff IP Policy” means Swansea University’s Policy on Intellectual Property, as it may be amended from time to time.

1.5. “Student” means any person registered as an Undergraduate or Postgraduate Student of the University or following any course as if a Student.

1.6. “Student IP Policy” means this Policy.

2. GENERAL PRINCIPLES

The general principles underlying this Policy are:

2.1. Intellectual Property created by a Student will be owned by the Student, except when there are other exceptional circumstances as provided in this Policy.

2.2. In cases where the University owns IP created by a Student, the Student and the University are entitled to a fair share of the commercial benefit accrued.

2.3. In all cases, ownership of IP created by a Student will be subject to the rights of a third party sponsoring the activity in the course of which the Intellectual Property is created.

3. OWNERSHIP OF INTELLECTUAL PROPERTY OTHER THAN COPYRIGHT CREATED BY STUDENTS

When a Student acting as an employee creates IP, the Staff IP Policy applies. Subject to
that, the following rules apply.

4. **Undergraduate Students**

4.1. IP created by an Undergraduate Student (UG Student) will be owned by the UG Student except when the Intellectual Property has been created in a project specifically funded or commissioned by the University or a third party, or where the UG Student makes significant use of University resources to create the IP. “Significant use of University resources” in this context means that the Student used resources to a greater degree than generally used or expected to be used by Undergraduate Students, and “University Resources” include intellectual supervision, human resources, laboratory or computer facilities, University background IP, or other resources.

4.2. The decision of whether there has been a significant use of University Resources shall be made by the Director of the Department of Research and Innovation (or such other person as delegated by the Vice-Chancellor) in consultation with the Head of College and the research or supervisor of the Student, and the Student. If there is no agreement, Clause 10 applies.

5. **Postgraduate Students**

5.1. A Postgraduate Student (PG Student) absent other factors is not considered as an employee of the University.

5.2. Frequently a PG Student is required to perform research or consultancy activities as a component of their studies (“Research Activities”). As a condition of participating in such activities:

5.2.1. The PG Student must enter into a written agreement which establishes the ownership and the use of IP created in the Research Activities. The agreement will be fair and reasonable giving consideration to all relevant factors, including, but not limited to, whether the PG Student is bringing significant background IP to the project, or is self-funded. In the absence of such an agreement, IP will be owned by the University so it can comply with any research funding obligations.

5.2.2. In all cases in which the Research Activities are funded by a third party, the PG Student must accept the IP and confidentiality provisions of the research agreement between the University and the third party. The Principal Investigator of a project shall notify the Student working on that project of any requirements imposed by the sponsor regarding ownership of IP.
5.2.3. The PG Student must not disclose any confidential information or commercially sensitive information of the University or a third party and is deemed to have consented to any confidentiality obligation imposed by a relevant third party.

5.2.4. The PG Student must act in a manner which is fully consistent with the University’s obligations in respect of the Research Activities, must comply with all relevant contractual obligations, and is deemed to have consented to all obligations placed upon him or her by the research agreement, including those relating to confidentiality and ownership of IP.

5.2.5. A PG Student will sign all documents and take other reasonable actions at the University’s or a third party’s expense that are required to confirm the University’s or a third Party’s ownership of the IP.

5.3. The University shall appropriately reference the Student IP Policy in recruitment documents and publish the Student Policy in the Student Handbook.

5.4. A Postgraduate Student enrolling in a postgraduate degree program will be required to complete and sign a form in which he or she:

5.4.1. Acknowledges and accepts the provisions of this Student IP Policy.

5.4.2. Agrees to disclose any invention work in progress or other Intellectual Property relevant to the Research Activities that he or she will be doing, including a disclosure of any third party that may have a claim to that IP.

5.4.3. Accepts and agrees to abide by the confidentiality terms imposed by a third party sponsor of the Research Activities in which the Student will be involved, and commits not to disclose the University’s confidential or commercially sensitive information.

5.4.4. Agrees to disclose IP which he or she creates in the Research Activities.

5.4.5. Agrees to make relevant enquiries into the requirements of the sponsor of the research project or of the University in which he or she will be participating.

5.4.6. Agrees to enter into a written agreement with the University regarding the ownership and use of IP that he or she creates in the Research Activities.

5.5. It is the responsibility of each Principal Investigator to ensure that an IP agreement is entered into between the PG Student and the University. The Department of Research and Innovation shall provide a template to the Colleges and approve any specific agreement reached with the Student.

6. **WORK BASED LEARNING.**

   Intellectual Property created by a Student as part of a work-based learning experience
will be owned by the company, unless otherwise agreed between the Student and the company.

7. OWNERSHIP OF COPYRIGHT

7.1. The general rule is that a Student shall own the copyright in materials, such as a thesis or other materials for course work that he or she has authored. The University shall have the absolute right (1) to use the materials for its own internal purposes of detecting plagiarism or cheating, and (2) to control the material on electronic media hosted on the University websites.

7.2. The University may use the materials, other than as specified in Clause 4.1, with the agreement of the Student.

7.3. If a Student produces written material (including a thesis) in a project sponsored by a third party or if the material was specifically commissioned by the University, the copyright shall be owned by the University or the third party unless there is an agreement to the contrary. This means that:

7.4. Confidentiality requirements, restrictions on the right to publish, and restrictions on access to the thesis or other documents will be determined in accordance with any contractual obligations between the University and a third party.

7.5. Copyright in software that is or will be used by the University, and copyright integral to other Intellectual Property that is owned by the University or a third party, will be owned by the University or the third party.

7.6. When the University or a third party owns the copyright in materials produced by a Student pursuant to the terms of this Policy, the Student waives any moral rights in the work.

7.7. A Student, at the University’s expense, will sign all documents and take other reasonable actions that are required to confirm the University’s or a third Party’s ownership of IP when such ownership is required under the terms of this Policy.

7.8. Although a Student may own the copyright in materials that he or she has produced, the Student must comply with University regulations regarding plagiarism and will not knowingly and wilfully assist others in plagiarising the work by allowing others to use their materials.

8. REVENUE SHARING

8.1. In all cases where a Student has created Intellectual Property that is commercialised by the University, the Student will be entitled to share in the benefits as though he or she were a Staff Member.
8.2. In such cases, rules and procedures relating to revenue sharing, which are set out in the Staff IP Policy and Procedures, shall apply to the Student.

9. DISCLAIMERS

The University may, in accordance with the Procedures, issue disclaimers of ownership of Intellectual Property in appropriate cases or provide for a license or assignment of the Intellectual Property to the Student or Students who created it.

10. INTERNAL DISPUTE RESOLUTION.

If a Student disagrees with the decision of the Director, the Student may appeal the decision to a committee comprised of the Registrar (or such other person as delegated by the Vice Chancellor) who shall serve as Chairperson, the Head of the College which administered the project in which the IP was created, and a Staff Member or a Student nominated by the Student. Their decision shall be final.

11. ARBITRATION.

If after the decision of the committee identified in Clause 10, the Student alleges that the University has not complied with the Student IP Policy, he or she may request that the matter be resolved by an arbitrator to be agreed upon between the University and the Student, or if they are unable to agree upon the identity of the person within one calendar month of the request to negotiate, by an arbitrator appointed by the President of the Law Society of England and Wales. The Arbitration will take place in Swansea and be conducted according to the laws of England and Wales. The decision of the arbitrator shall be binding on the University and the Student and the costs shall be borne as decided by the arbitrator. Notwithstanding the provisions of this clause, both the University and the Student are free to bring proceedings in the courts in order to seek mandatory, declaratory or other relief which is not available from an arbitrator.

IMPLEMENTATION

11.1. The Registrar shall have wide authority and discretion, within the confines of (1) the University’s Charter and any Regulations, Ordnances or other provisions made by Council, (2) the IP Policy, and (3) any directions given by or on behalf of the Vice-Chancellor to adopt administrative processes necessary to effectively implement this Policy.

11.2. The Swansea IP Group within the Department of Research and Innovation shall issue guidance and interpretations, and establish procedures and documents necessary to implement this Policy.
TRAINING ON RESEARCH INTEGRITY

In conformity with its obligations as described in the **Concordat to Support Research Integrity** (2012, p.14), the University is committed to providing staff and students engaged in research with training, in order to maintain excellence in research integrity.

An online training on research integrity (Epigeum) is provided for all research active staff and research managers. A separate training programme for specialist areas of research integrity is offered through the APECS development and training services and REIS. The University expects all research active staff and supervisors of research students to undertake training. The University also expects all staff and students to have a working knowledge of this Framework.

The lead Researcher or Principal Investigator of a research project is expected to be responsible for, and encouraging to, all members of the research team in developing their skills, and to lead and foster an open exchange of research ideas. A PI must ensure that appropriate direction of research and supervision is provided at all stages of the research process, including the preparation of funding applications in accordance with the University’s financial regulation, data collection, data storage, and data analysis and publication and dissemination.

All researchers should ensure that they have the necessary skills, training and resources to carry out research to the required standards and that any gaps are filled by appropriate training. Researchers should be sufficiently well informed of the appropriate sponsor, funder, Institutional, legal, ethical and moral obligations and requirements to enable compliance.

All students undertaking research should be made familiar with the appropriate principles and practices of research integrity, ethics and governance as part of their research training. For postgraduate research students, this is likely to be through a combination of subject-specific training, supervision, and the University’s Research Skills Development Programme. For other students, this is likely to be embedded within their module, and instilled during supervision.

It is essential that members of College Research Ethics & Governance Committees attend training sessions, and that Committee Chairs have regular training and professional development opportunities. If Colleges are providing ‘Discipline specific’ training events then they should cover the various aspects of this Framework, including:

- principles of research ethics (e.g. publication ethics and informed consent);
- relevant aspects of law (e.g. concerning data protection);
- guidance on data management (e.g. secure storage of data);
- guidance on procedures for applying for ethical approval both within the University and externally (e.g. through IRAS);
- guidance regarding insurance and sponsorship;
• guidance regarding handling of conflicts of interest; and
• procedures for dealing with misconduct in research.

The University is committed to providing regular ‘update’ sessions on research integrity, ethics, and governance as new guidelines and relevant documentation emerge.
UK Research & Integrity Office Recommended Checklist for Researchers

The Checklist lists the key points of good practice in research for a research project and is applicable to all subject areas. A PDF version is available from www.ukrio.org

(Before conducting your research, and bearing in mind that, subject to legal and ethical Requirements roles and contributions may change during the time span of the research):

1. Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it?

2. Is your research design appropriate for the question(s) being asked?

3. Will you have access to all necessary skills and resources to conduct the research?

4. Have you conducted a risk assessment to determine:
   • Whether there are any ethical issues and whether ethics review is required;
   • The potential for risks to the organisation, the research, or the health, safety and well-being of researchers and research participants; and
   • What legal requirements govern the research?

5. Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant?

6. Will your research comply with all requirements of legislation and good practice relating to health and safety?

7. Has your research undergone any necessary ethics review (see 4 above), especially if it involves animals, human participants, human material or personal data?

8. Will your research comply with any monitoring and audit requirements?

9. Are you in compliance with any contracts and financial guidelines relating to the project?

10. Have you reached an agreement relating to intellectual property, publication and authorship?

11. Have you reached an agreement relating to collaborative working, if applicable?

12. Have you agreed the roles of researchers and responsibilities for management and supervision?
13. Have all conflicts of interest relating to your research been identified, declared and addressed?

14. Are you aware of the guidance from all applicable organisations on misconduct in research?

**When conducting your research:**

- Are you following the agreed research design for the project?
- Have any changes to the agreed research design been reviewed and approved if applicable?
- Are you following best practice for the collection, storage and management of data?
- Are agreed roles and responsibilities for management and supervision being fulfilled?
- Is your research complying with any monitoring and audit requirements?

**When finishing your research:**

- Will your research and its findings be reported accurately, honestly and within a reasonable timeframe?
- Will all contributions to the research be acknowledged?
- Are agreements relating to intellectual property, publication and authorship being complied with?
- Will research data be retained in a secure and accessible form and for the required duration?
- Will your research comply with all legal, ethical and contractual requirements?
Section T

POLICY ON UNDERTAKING RESEARCH WITH CHILDREN AND YOUNG PEOPLE

Introduction

This policy is for Swansea University staff and students who undertake research with children under the age of 18 years, and young people who are vulnerable (within this context to mean young people who are more exposed to risks than their peers. For example, in terms of deprivation (food, education, and parental care), exploitation, abuse, neglect, violence, and disability)

The policy has been developed in line with the following:

- The National Society for the Prevention of Cruelty to Children (NSPCC) guideline on research with Children: ethics, safety and avoiding harm
- Children Act 1989 and 2004
- Social Services and Wellbeing (Wales) 2014 Act
- The Medicines for Human Use (Clinical Trials) Regulations 2004, and the subsequent amendments

The policy identifies particular issues which must be taken into consideration when undertaking any research with children and it must be read in conjunction with the following:

- ESRC Research Ethics Framework
- Swansea University’s Safeguarding Vulnerable Groups Policy
- Any discipline specific requirements to the area of work

In the context of this policy, the term ‘researcher’ includes students at both undergraduate and postgraduate level, salaried teaching, research and project staff, including casual members of staff, who will have direct (or indirect) contact with children and young people throughout the course or period of their research, ‘Researchers’ (as defined above) who have significant subject access to children should have an enhanced DBS disclosure performed prior to undertaking any research. The researcher should also undertake a minimum Level 2 or equivalent, ‘Regional Safeguarding Children Board training’ which deals with recognition and referral of abuse. The training will allow staff to understand and report any abuse identified during the process of a research interaction.

The guidance applies to all children who are contacted either through an organisation or body such as a school or club or contacted independently through their home and is designed to be used in conjunction with the All Wales Child Protection Procedures and Her Majesty’s Government (2015) Working Together Guidance.

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2 All Wales Child Protection Procedures 2008 can be accessed as follows:
The Children Act 1989\(^1\) defines a ‘child’ as a person under the age of 18 years. The Management of Health and Safety Regulations 1999 regard a ‘child’ as a person who is not over the minimum school leaving age and a ‘young person’ as a person who has not attained the age of 18 years. In this Guidance, any reference to a child or children includes young persons’ up to the age of 18 years.

Please note that specific regulatory requirements exist in UK legislation which should be followed while conducting clinical trials involving children. Further information is available from the Medicines and Healthcare products Regulatory Agency (MHRA).

**Key Principles**

Research involving children and young people should only be conducted to investigate issues that will likely benefit children in particular and society in general. The aims of research should contribute to present or future benefits for children (e.g. health, well-being, development). Research involving children is important for the benefit of all children, and a research procedure which cannot directly benefit the child, is not necessarily unethical, if the findings might benefit future generations of children. Research where there is no benefit to the individual child participant should be of minimal risk. Any research with children must be conducted in line within the Welsh legal and policy context. Outcome of the research should contribute to the evidence to promote rights of children and young people. Any research with children must be subjected to risk assessment. In the past, the concern to protect children from the potential harms of research may have denied them potential benefits. To ensure that this group are not exploited, it is important to assess carefully the potential benefits and harm to children at all stages of any research. As the benefits of research are not predictable, the researcher must be satisfied that the research is not contrary to the child participant's interests. The foreseeable risks should be kept as low as possible: the potential benefits from the development of furthering of knowledge must outweigh any foreseeable risks. Research needs should be based on clear ethical guidelines and measures must be in place to protect any children who are involved. Child protection concerns can be exposed when undertaking research with children and young people; ethically robust solutions and pathways must be identified to handle any such concerns. Researchers must ensure that children must be respected by providing the right support and by knowing who to contact with concerns.

This policy is aimed at ensuring that any researcher undertaking work with this vulnerable group think through the ethical issues and find ethically justifiable solutions.

**Ethical guidance for researchers:**

All proposals involving research on children must be submitted to the relevant College research ethics committee (CREC) for approval. Researchers and the Research Ethics Committees must assess whether the research or the inclusion of child participants is justified. Any research project must balance the need of the research with the rights, well-being and safety of the children as participants. Having a clear ethics statement at the

\[\text{http://www.childreninwales.org.uk/our-work/safeguarding/wales-child-protection-procedures-review-group/}\]

\(^1\) Children Act 1989, Section 105 - \[\text{http://www.legislation.gov.uk/ukpga/1989/41/section/105}\]
beginning of a project can help researchers assess potential risks to a child or procedures to follow if abuse is disclosed, identified or if the researcher has concerns. Prior to embarking on a research project involving children and young people, a researcher needs to consider the following:

- How to obtain informed consent and assent
- How to manage the risk of potential harm to participants and themselves.
- What to do with the information gathered during the research.
- What to do if concerns are raised or abuse is identified or disclosed.

Further guidance and useful information on the ethical issues of conducting clinical trials involving children is also available from the World Health Organisation webpages

- and from the Nuffield Council on Bioethics

*(The following guidelines has been drafted from the NSPCC guidance for applicants to the Research Ethics Committees, HM Government (2015) Working Together Guidance)*

1. **Voluntary participation based on valid informed consent and assent:** The key principle of ethical research is that the participants involved in research should agree to participation voluntarily, on the basis of full, detailed and robust information. Consent is possibly the most important but most complicated issue for researchers hoping to involve children as part of their study. Consent should not be thought typically as a one off event but an ongoing process for the duration of the research, which means that a participant who has agreed to be part of the study can withdraw consent at any time. This is especially important in research that extends over time. A researcher should ensure that all research participants have a reasonable understanding of the research, so that they can give their permission to be part of it. An option of ‘Proxy consent’ (*the process by which people with the legal right to consent to for a minor or a ward delegate that right to another person*), who can act properly on behalf of children and young people should be considered. Even if formal consent for the whole process has been sought and given at the beginning, it would be appropriate to check that the participant is happy to take part if some time has passed between the interviews/contacts especially in instances where the research has extended over some time. Similarly, it should be made clear to participants that even if they have given consent at the beginning of the process, they are entitled to decline to answer any particular question (s) or to not participate in any particular part of the research, without giving a reason, and are entitled to decide not to take part at any point, again without giving a reason. Participants should have the right to withdraw from a study without fear of punitive measures, penalty or threats etc. Participants can also ask for their data to be removed from the study where practical. The process of assent engages children and provides them with the opportunity to make their own decisions as well as ensuring their willingness to participate even where this has no legal force. Researchers are encouraged to refer to the ‘Fraser guidelines’, which, even though relates to sexual health, in practice are used to assess an individual’s understanding in other contexts.
Consideration must also be given to the capacity of a participant to consent; this will depend on their cognitive level of understanding of the potential risks and benefits of taking part in research. The following guidelines may be helpful but in all cases the researcher should justify the approach taken to obtaining consent:

- Whilst it is recognised that young people aged 16 years and over are able to consent, further good practice consideration should be given to also obtaining consent from the young person’s parents. Each situation will have to be carefully considered and justified by the researcher in terms of both the complexity of the research goals and processes and the competence of the young research participant.
- For young people aged between 12 and 15 years, assent should be sought from the young person and consent from the parent, guardian, carer or other appropriate adult with the duty of care and considerations as per the ‘Fraser guidelines’.
- For children younger than 12 years, consent should be sought from the parent, guardian, carer or any other appropriate adult with a duty of care. Assent must also be sought from the child. In research, the child’s wishes should be paramount and therefore if a child does not assent to participate then this overrides the consent from parents, guardian or carer. Researchers should be aware of the signs that a child does not want to participate. For example, a child may say ‘no’ or be non-responsive by ‘pulling away’ or ignoring. Provision of information should also be made available in differing formats i.e. pictorial, braille etc. depending on the group that is involved in the research.

**Disclosure:**

Whilst maintaining confidentiality is a priority in research more generally, one of the key issues for researcher with children and young people is a proper consideration of disclosure, especially if issues of child protection or other safeguarding concerns arise in the course of the research. It is vital that the process of disclosure is made clear to the participants -and those who may legitimately consent for them - know what the boundaries of confidentiality are. Guidance in line with the All Wales Child Protection Procedures (2008) needs to be followed, alongside the mandatory reporting guidance as part of Social Services & Wellbeing (Wales) 2014 Act.

Researchers should also have a good grasp of when and how protocols concerning confidentiality may be overridden, including guidance about what constitutes information that should be discussed with a third party; what the researcher should do within a data collection setting if they become aware of information that should be passed on; whom they should be reported to; and what the processes are for deciding whether the information should be disclosed. Consideration regarding reporting issues to designated safeguarding lead (in case of concerns) should be considered.

**Consent process:**

Researchers should assess the most appropriate method of obtaining consent for their research project. It is normal practice to provide information leaflets about the research to participants. However, the material should be tailored so that they are appropriate to
needs and capacities of the participants. The information should be in an easily understandable form that uses lay language rather than technical terms. Depending on the age and cognitive ability of the participants, it may sometimes be necessary to provide several versions including translated version of the information leaflets and forms to participants. Other forms and types should also be made available according to the child’s cognitive ability and understanding. Details of any incentives for participation must appear in the participant information sheet and should be made known to potential participants before they consent to take part. Ideally incentives should be in the form of high street vouchers and not money unless this can be specifically justified. If incentives are provided, participants must receive the incentives even if they withdraw early from the study. The consent process should always take into consideration local cultural values and privacy of individuals. Mechanisms should be put in place to remove participants data if they retrospectively withdraw their consent.

Gatekeepers:

In order to access research participants, the researchers may have to make contact with ‘gatekeepers’ to participants (e.g. teachers, doctors etc.), who may have a role in arbitrating access and / or the protection of participants. Parents should also be considered to offer a gatekeeping role for potential research participants, and should be consulted with regards to planned research being undertaken with their children. Through parents being consulted and versed with the proposed study would enable them to consider the study and give due regard to providing consent for their child to participate.

Excessive reliance should not be placed on gatekeepers to recruit participants to research studies. The position of ‘gatekeepers’ may vary enormously and where the gatekeeper is in a position of power with respect to the potential research participants, a situation may arise where the potential participant may feel coerced or pressurised to take part in research. Another problem could be that the ‘gatekeepers’ do not explain the research to the participant appropriately. It is the responsibility of the researcher therefore to ensure that potential participants do understand what taking part in the research involves, and that they do so freely by going through a thorough process of voluntary and informed consent.

2. Identifying potential risks of harm to participants and researchers:

The research design and protocols must take into account processes for reducing/minimising risks and harm to both participants and researchers. The research design and questions must have measures in place to address the impact of any harm or upset through provision of support services, advice and guidance. For social research, the main risk to participants is causing emotional or psychological distress which can be linked to a number of issues including:

- Vulnerable individuals can find participating in research stressful.
- Research may ‘reawaken’ old feelings or memories or hidden or suppressed feelings or memories.
- Additional concerns may come up; and
- Participants may worry about what they have shared.
All those undertaking research with children must demonstrate that they have given due consideration to the above in the selection of their aims and research questions, in the methods they intend to use and the mechanisms for analysis, and reporting practices.

For research that requires physical exercise, the main risk to the participants will be, causing physiological harm or discomfort through the research methods or recovery from participating. All those undertaking such research with children must be able to demonstrate that they have chosen the most appropriate methodology which is as non-invasive as possible, and that they are fully trained to undertake such methodologies. First aider(s) must be available for all physical testing in case of adverse event.

All studies involving children should seek to be inclusive and accessible, and pay due regard to the child’s best interests, especially with respect to safeguarding the health and wellbeing of the child participant now and in their future. Children who have been abused can be particularly vulnerable and researchers must give careful consideration to the psychological impact of sensitive research on the participant. Researchers need to be clear with participants from the outset that confidentiality may have to be breached if there is a disclosure relating to serious harm, abuse and/or other child protection concerns. If a participant divulges any information that gives rise to child protection concerns, or where the researcher observes or receives evidence of incidents likely to cause serious harm, the researcher has a duty to take steps to protect the child or other children to protect both the children and themselves. Researchers must consider how participants are likely to cope with being asked to talk about their past experiences. Debriefing participants at the end of the study or a stressful situation in order to identify any participant needs and referring them to appropriate help should be built into the research design. Any participant information sheet or ‘thank you leaflet’ must take into consideration information and contacts for immediate help and support if participants are distressed post an interview, or interaction with the researcher. Any correspondence with participants should also consider the literacy levels, language and cultural issues.

Undertaking qualitative research brings additional risks because of the nature of the data collection. The research design should take into consideration ways in which additional risks can be minimised. Interview schedules should be structured so that more sensitive material is in the middle of the interview and participants are given a chance to return to more ‘normal’ level of conversation at the end of the interview. The interview should remain focussed on the research topic and difficult topics are given enough time so that they are not ‘crowded’ towards the end. Researchers conducting qualitative interviews also need to make sure that the boundary between a research interview and counselling is rigorously maintained, even when the researcher is also a trained counsellor.

Risks to researchers:

Researchers should also consider their own physical safety, especially when working outside of the workplace, with human tissue, or at unsocial times. Furthermore, researchers should be mindful of the psychological burden that can be placed on researchers involved with clinical populations or with regards to certain, sensitive social research questions. The main ways in which this risk is mitigated is through having a robust risk assessment process that involves on-going risk assessment by the researcher, and by ensuring that an appropriate and
adequate level of internal and external support is available for the researcher before, during and after the data collection.

3. **Disclosure of identity and personal information:**

While interviewing friends and family, researchers must take care not to disclose or discuss contents from interviews with other family members so that the research is not ethically compromised. A participant’s personal information and their identity should remain confidential unless a child is at risk of harm. A researcher must include a confidentiality policy that clearly sets out the circumstances when a researcher can and should break confidentiality. The procedures should also include reference to sources or places where a researcher or child can access further support if harm or distress arises in or after the research.


**Complaints procedure:**

Procedures should be in place to facilitate participants making complaints about the research in general and the researcher in particular. Ideally arrangements should include the ability to talk to someone not connected with the research, for example, the Chair of the College Research Ethics Committee or a substitute in case the Chair is involved in the research. Consideration should also be given to facilitating children to make complaints by identifying an appropriate adult (e.g. teacher, carer or social worker) with a good relationship to the child and discussing the issue with them so that children can talk to them if they are concerned.


Child Abuse and Neglect occurs when somebody inflicts harm to a child or fails to act to prevent harm. Children may be abused in a family setting or in an institutional or community setting, by those who are known to them or, more rarely, by a stranger. A child or young person up to the age of 18 years can suffer abuse or neglect and require protection via an inter-agency Child Protection Plan.

**Physical Abuse.**

Physical abuse may involve hitting, shaking, throwing, poisoning, burning or scalding, drowning, suffocating, or otherwise causing physical harm to a child. Physical harm may also be caused when a parent or carer feigns the symptoms of, or deliberately causes, ill health to a child whom they are looking after. This situation may be described as fabricated or induced illness by carer.

**Possible signs of physical abuse:**

- Unexplained injuries or burns, particularly if they are recurrent
- Refusal to discuss injuries
- Improbable/inconsistent explanations for injuries
- Untreated injuries or lingering illness not attended to
• Admission of punishment which appears excessive
• Shrinking from physical contact
• Fear of returning home or of parents being contacted
• Fear of undressing
• Fear of medical help
• Aggression/bullying
• Over compliant behaviour or a ‘watchful attitude’
• Running away
• Significant changes in behaviour without explanation
• Deterioration in work
• Unexplained pattern of absences which may serve to hide bruises or other physical injuries

**Emotional Abuse**

Emotional abuse is the persistent emotional ill treatment of a child such as to cause severe and persistent adverse effects on the child’s emotional development. It may involve conveying to a child that they are worthless or unloved, inadequate or valued only in so far as they meet the needs of another person. It may feature age or developmentally inappropriate expectations being imposed on children. It may involve causing children frequently to feel frightened or in danger, for example by witnessing domestic abuse within the home or being bullied, or, the exploitation or corruption of children. Some level of emotional abuse is involved in all types of ill treatment of a child, though it may occur alone.

**Possible signs of emotional abuse:**

• Continual self-deprecation
• Fear of new situations
• Inappropriate emotional responses to painful situations
• Self-harm or mutilation
• Compulsive stealing/scrounging
• Drug/solvent abuse
• ‘Neurotic’ behaviour – obsessive rocking, thumb-sucking and so on
• Air of detachment – ‘don’t care’ attitude
• Social isolation – does not join in and has few friends
• Desperate attention-seeking behaviour
• Eating problems, including overeating and lack of appetite
• Depression, withdrawal

**Sexual Abuse**

Sexual abuse involves forcing or enticing a child or young person to take part in any sexual activity, whether or not the child is aware of what is happening. The activities may involve physical contact, including penetrative or non-penetrative acts. It may include non-contact activities, such as involving children in looking at, or in the production of, pornographic material or watching sexual activities, or encouraging children to behave in sexually inappropriate ways.
Sexual abuse is not solely perpetrated by adult males. Women can also commit acts of sexual abuse as can other children.

**Possible signs of sexual abuse:**

- Bruises, scratches, burns or bite marks on the body
- Scratches, abrasions or persistent infections in the anal or genital regions
- Pregnancy (particularly in the case of young adolescents who are evasive concerning the identity of the father)
- Sexual awareness inappropriate to the child’s age – shown for example in drawings, vocabulary, games and so on
  - Attempts to teach other children about sexual activity
  - Refusing to stay with certain people or go to certain places
  - Aggressiveness, anger, anxiety, tearfulness
  - Withdrawal from friends

**Possible signs of sexual abuse in older children**

- Promiscuity, prostitution, provocative sexual behaviour
- Self-injury, self-destructive behaviour, suicide attempts
- Eating disorders
- Tiredness, lethargy, listlessness
- Over-compliant behaviour
- Sleep disturbances
- Unexplained gifts of money
- Depression
- Changes in behaviour

**Neglect**

Neglect is the persistent failure to meet a child’s basic physical and/or psychological needs, likely to result in the serious impairment of the child’s health or development. It may involve a parent or carer failing to provide adequate food, shelter and clothing, failing to protect a child from physical harm or danger, or the failure to ensure access to appropriate medical care or treatment. It may also include neglect of, or unresponsiveness to, a child’s basic emotional needs. Neglect may occur during pregnancy as a result of parental substance misuse.

**Possible signs of neglect:**

- Constant hunger
- Inappropriate clothing
- Untreated medical conditions
- Compulsive stealing or scrounging
- Frequent lateness or non-attendance at school
- Poor personal hygiene
- Low self-esteem
- Poor social relationships
- Constant tiredness

**Safeguarding**
The welfare of children is everyone’s responsibility (Laming; 2009). The researcher may have limited, yet regular, contact with children allowing them to become aware of possible areas of concern. Additionally, the subject matter being discussed may lead to disclosure of matters of concern. As such, the researcher has a duty to safeguard children and to protect them from harm.

The Government requires that any organisation, whether statutory, voluntary or other, that has contact with children must have a Child Protection Policy. In addition, all representatives are required, by law, to report any suspicions or concerns about a child’s welfare to the social services department at the local authority.

The Children Act 2004, HM Government (2015), Working Together & All Wales Child Protection Procedures (2008), places a clear responsibility of safeguarding children on all agencies who have contact with children and families in their routine work. There are several ways in which the researcher may become aware that a child has been or is being abused and/or neglected including:

a. An allegation made by the child directly (a disclosure);
b. Through reports or allegations made by another person;
c. Through observing signs or indicators of abuse;
d. Through an admission from an abuser.

The suspected abuse of a child must be reported to social services or to the police. They are the agencies with statutory powers to investigate suspected abuse. Other agencies/organisations must not undertake their own internal child protection enquiries as there are mandatory reporting procedures under Social Services & Wellbeing (Wales) Act 2014.

It would be useful to draw up a pathway or protocol of what to do if concerns are raised.

**General Responsibilities of the Researcher**
All researchers working with children and young persons’ should:

- Be fully trained in the methodologies and techniques intended to be used.
- Treat the children and young person’s rights and well-being with the utmost importance
- Be alert to potential indicators of abuse and neglect
- Be alert to the risks which individual abusers, or potential abusers, may pose to children
- Be aware of the effects of abuse and neglect on children
- Contribute as necessary to all stages of the safeguarding process
- Respond positively in every case understand his/her role and responsibilities to safeguard and promote the rights and well-being of children;
- Be familiar with and follow the University’s Child Protection Policy and Safeguarding protocol and /or that of the host organisation (e.g. school, youth club/group) and should seek training.
- Any researcher with access to children must undergo level 2 recognition and referral training, so that they know what to do, should a disclosure be made to them. (Rationale: significant subject access).
- Additionally Enhance DBS disclosure should be undertaken prior to commencing data collection/research with the child.
- Have access to and be familiar with HM Government (2015) Working Together Guidance
  - Have access to and comply with the All Wales Child Protection Procedures (2008);
  - Have received child protection training commensurate with his/her role;
- Ensure that he/she has been subject to, and cleared by, an up-to-date Disclosure and Barring Service (DBS) check. This should be done through........ You will need to contact Swansea University's .......................to arrange this.
- Know the protocols around raising concerns
- Know the named safeguarding lead officer
- The researcher is legally obliged to report any issues of concern to his or her line manager and/or safeguarding officer in the first instance. Where these concerns are not appropriately addressed, safeguarding concerns should be reported to the authorities.
- with regards to the physical and emotional health and well-being of the children with whom he/she works. It is the responsibility of the researcher to ensure that he/she is aware of the appropriate avenues to follow in reporting any concerns.
- The researcher must ensure that he/she responds appropriately to a disclosure or suspicion of child abuse.
- In the case of immediate danger to the child, the researcher should contact the police or social services directly.
- **Under Duty of Care good practice, the researcher must recognise his/her individual responsibility to his/her own safety and that of others with whom he/she works.**

Note: the researcher should not be:
- Responsible for assessing the accuracy of an allegation.
- Held personally responsible for the physical and/or emotional welfare of any child with whom he/she work.

**Dealing with Disclosures and /or Recognising a Concern**

When dealing with a disclosure from a child or recognising a concern the researcher should:
a. Listen to the child. If you are shocked by what they tell you, try not to show it. Take what they say seriously. Children rarely lie about abuse and to be disbelieved adds to the traumatic nature of disclosing. Children may retract what they have said if met with revulsion or disbelief.
b. Accept what the child says. Be careful not to burden them with guilt by asking “why didn’t you tell me before?” Show the child that you have heard what they are saying, and that you take their allegations seriously.
c. Encourage the child to talk, but do not prompt or ask leading questions. Do not interrupt when the child is recalling significant events.
   d. Do not make the child repeat his/her account.
e. Stay calm and reassure the child that they have done the right thing in talking to you. It is essential to be honest with the child, so do not make promises you may not be able to keep, like “I’ll stay with you” or “everything will be alright now”.
f. Do not promise confidentiality as you are under a duty to refer a child who is at risk. Reporting concern is not a betrayal of trust.
g. Try to alleviate any feelings of guilt that a child displays. For example, you could say: “you’re not to blame” or “you’re not alone, you’re not the only one this sort of thing has happened to.”
   h. Acknowledge how hard it must have been for the child to tell you what happened.
   i. Empathise with the child – do not tell them what they should be feeling.
j. Explain what actions you must take in a way that is appropriate to the age and understanding of the child.
k. Make a record of what you have been told, using the exact words if possible, as soon as possible and no later than 24 hours after the event.
   l. Do not destroy your original notes in case they are required by a court.
m. Record the date, time, place, any noticeable non-verbal behaviour and words used by the child. If the child uses their family’s own private sexual words, record the actual words used, rather than translating them into proper words.
   n. Draw a diagram to indicate the position of any bruising.
o. Be objective in your recording: include statements and observable things rather than your interpretations or assumptions.
p. **Make sure that you continue to support the child, providing time and a safe space through the process of investigation and afterwards.**
q. **Get some support for yourself, without disclosing confidential information about the child to colleagues.**
r. If you require advice or support, contact …………………or NSPCC helpline (see annex for contact details). The need to seek advice however, should not delay any emergency action needed to protect a child.
s. If you are unable to contact your …………..for advice, you should report your concerns to ………………….
t. Report any concerns to the ………………………. or team member with responsibility for child protection within the research team or, if appropriate, to the member of staff of the host organisation with designated responsibility for child protection.
u. Do not confront the alleged abuser. All concerns reported to social services are taken seriously. It is better to have discussed it with an expert who has experience and responsibility to make an assessment.

v. Make a note of the date, time, place and individuals who were present at any discussion you have.

**Specific Circumstances**

**A child or young person discloses a child protection concern in a formal setting (school/youth club etc.).**

If you have any reason for concern you must inform the ... and the lead individual for child protection within the setting (frequently the manager/ head teacher etc.). It will be the responsibility of this lead individual to contact social services and you should confirm that this has been done. If you are not satisfied with the lead contact’s response, you should inform the person with responsibility for child protection within the academic College who should inform social services.

**A Child or young person discloses a child protection concern outside of a formal setting (within the home or in community context)**

If you have any reason for concern, these should be raised with the .../ person responsible for child protection within the project, who should pass on these concerns to the local authority duty team.

**A child or young person raises a concern during a focus group/group discussion**

A child or young person may choose to disclose concerns during a focus group or group discussion. In such circumstances, the limits of confidentiality should be restated and the child should be asked to speak to the researcher after the session. If the child becomes distressed, it is best to terminate the group session and seek support from other staff. Follow-up will be as set out above.

**The child or young person is at immediate risk of harm**

In the event that the researcher suspects that the child or young person is in immediate danger, the situation should be treated as an emergency. In such circumstances the researcher should:-

a. Should contact the NSPCC and/or duty team to seek advice on the action to take in an emergency situation. If you are unable to make contact, do not delay reporting your concerns;
   b. Should contact the Police (999) and inform the ...;

c. Should not under any circumstances, confront or contact the accused, or talk to friends and/or family of the abused.

**Responsibilities of the Principal Investigator**

**General Responsibilities of the Principal Investigator**

a. The Principal Investigator is responsible for ensuring that the researcher working with children and young people is familiar with appropriate child protection procedures and is equipped with appropriate knowledge and skills.
b. The Principal Investigator is responsible for ensuring that the researcher working directly with children and young people has an up-to-date DBS check.

c. The Principal Investigator should follow local child protection procedures for communicating child protection issues to the appropriate authorities, whilst keeping the best interests of the child and the researcher as the primary focus.

**Responsibilities of the Principal Investigator in the event of a child protection concern**

A phone call/written referral to social services should be made as soon as a problem, suspicion or concern becomes apparent, and certainly within 24 hours.

During office hours, referrals may be made by telephone to the local social services office. Outside of office hours, a referral should be made to the Emergency duty team.

Social services should acknowledge the referral within one working day of receiving it. Social services should be contacted again if a response has not been received within 3 working days.

Any discussion about a child’s welfare should be recorded in writing by the Principal investigator, including a note of the date and time, and details of the individuals participated in the discussion.

At the end of any discussion there should be clear agreement about what actions will be taken and by whom, with details disseminated to the relevant parties.

If the decision by social services is that no further action is taken, this should be recorded in writing, including the reasons for that decision.

It is mandatory under the Social Services & Wellbeing (Wales) Act 2014 that any concerns are referred to social services, even if one may think it to be unimportant or that the cultural context is not fully understood. The information provided could be crucial in a broader context.

There is no restriction stated in the Data Protection Act or other legislation that prevents concerns being shared for the purpose of protecting children. Therefore, the facilitation of information-sharing during the enquiry is to be encouraged (Ref: Laming 2009)

Wherever possible, consent should be obtained, but the public interest in child protection always overrides the public interest in maintaining confidentiality or obtaining consent. A child’s safety is always of paramount consideration.

- **Other Responsibilities**

  **Responsibilities of the ………………………….**

  The ………………………….is responsible for ensuring that all research involving children and young adults is undertaken in compliance with these procedures. The……………………….should ensure that all staff and students undertaking research with children and young people receive appropriate child protection training and DBS checks, via the …………………………….

  - **Abuse by a Professional Person**

    It is best practice to avoid misunderstandings and to be clear about the correct procedure when working with or having contact with children. Staff should be advised to avoid any
physical contact with a child or young person that could be construed as over-familiar and to be aware of the implications of lone-working. It is important that any disclosure made by a child is passed to social services or the police and at no time should an adult agree with a child to keep secrets.

If the behaviour of a member of staff causes concern with regard to his/her relationship with children:

- do not dismiss these concerns or suspicions
- discuss the concerns with the named person who has responsibility for safeguarding children.
- if the above is inappropriate, or it is the felt that the concern has not been taken seriously, social services should be contacted.
- social services has a protocol for responding where there are allegations regarding a professional, and the University should expect to be involved in a subsequent strategy discussion.
Conducting Clinical Trials Involving Medicinal Products with children

(It is expected that any such studies would obtain approval from NHS REC and local Research & Development offices)

If you are undertaking a Clinical Trial of an Investigational Medicinal Product (CTIMP) involving with a new medicines or a current medicine without a waiver you may need to carry out a paediatric investigation plan (PIP). The Paediatric Regulations 2006 provide additional protection for a minor who is being considered for a clinical trial i.e. a person under the age of 18 years. They regulations require, among other provisions, that:

- the MHRA will require advice from an Expert Advisory Group under the auspices of the Commission on Human Medicine before an application for a Clinical Trial Authorisation can be considered;
- an ethics committee considering the trial must receive advice on the relevant field of paediatric care; and
- a person with parental responsibility or a legal representative must give informed consent and may withdraw the young person at any time; and

In relation to the young person:

- Staff with knowledge of the trial and experience with young persons must inform him/her of the risks and benefits of the trial according to his/her capacity to understand;
- The researcher must consider the young person’s explicit wish to refuse to participate or to be withdrawn from the trial at any time;
- The clinical trial must relate directly to an illness from which the young person suffers or that can only be carried out on minors; and
- The trial must aim to provide some direct benefit for this group of patients.

Researchers and trial sponsors have a responsibility to follow the regulations regarding these types of research projects and to ensure that all required authorisations are in place prior to recruitment beginning.

Further information on CTIMPs can be found on the MHRA webpages:

https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

and also in relation to the requirements for a paediatric investigation plan (PIP):

POLICY FOR CLINICAL RESEARCH

1. The University’s Aims:

The University seeks to promote a culture of honesty and integrity in clinical research and to protect the dignity, rights and welfare of all those involved in clinical research (whether as participants, staff, students or external third parties) and to promote high ethical standards of research and governance. The University achieves this by:

- developing a culture within the University that embraces the principles set down in this policy and in applicable legislation to protect the rights, dignity and welfare of those involved in clinical research;
- providing ethical and governance guidance that communicates best practice and legislative requirements, and offering ongoing support and training to staff and students to maintain high ethical and governance standards;
- maintaining a research review process with a level of scrutiny in proportion to the risk of harm or adverse effect.

This policy should be read in conjunction with the University’s Research Integrity Ethics and Governance Framework which reflects the commitments outlined in the funder-endorsed Concordat to Support Research Integrity which Swansea University completely supports.

Currently under development is a University handbook for Clinical Research Governance which will provide information and guidance on research conduct for clinical research.

2. Scope and Sanctions

This policy applies to all staff irrespective of grade and position, and all students in all Colleges and Schools of Swansea University who are engaged in University led research involving human participants, their organs, tissue or data, regardless of whether or not the research is conducted on University premises or uses University facilities.

The University regards any breach of this policy as a very serious matter, which may result in disciplinary action, the ultimate sanction being dismissal for staff and expulsion for students. In appropriate circumstances, the Research Ethics and Governance subcommittee has the power to withhold, suspend or withdraw approval of research, whether as part of disciplinary proceedings or otherwise.

3. Professional Bodies and Legislation

The University expects researchers:
• to observe standards of research practice set out in guidelines (including ethical guidelines) published by scientific and learned societies and other relevant professional bodies;

• when undertaking research within health and social care to be aware of, and adhere to the requirements of the Research Governance Framework for Health and Social Care in Wales (RGF), and where relevant, the applicable RGFs for other UK nations and to be aware of NHS ethics requirements;


4. Clinical Research Projects

The University is committed to ensuring that any clinical research project complies with all legal, ethical and other applicable guidelines.

Appropriate care should be taken when research projects:

• prospectively assign human participants (singly or in groups) to a health related intervention(s) and evaluates the effects on health outcomes;

• involve vulnerable groups of human participants, for example, those who lack substantive medical capacity as defined by the Mental Capacity Act 2005, those who lack agency due to circumstantial disempowerment and those with significant dependencies or any form of covert research which does not involve full disclosure to participants.

• involve an intervention such as drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventative care or any other areas.

There are different categorisations of research project involving human participants as defined below.
4.1 Research Project Classification

Early in the planning process, you need to first decide if your project is research. Clinical research is any health-related research that involves humans, their organs, tissue and/or data.

If your project is clinical research, then it is important to consider whether it will be classified as a Clinical Trial of an Investigational Medicinal Product (CTIMP) or a Medical Device Trial. This is important because, if so, it will have to be carried out under either the Clinical Trial Regulations or the Medical Devices Regulations, and different processes will need to be followed. Such research projects will require the costed services of a Clinical Trials Unit.
For further information on research projects:

4.2 Interventional Clinical Research Projects

These are projects which involve humans as participants and involve an invasive experimental element. These include surgical trials, trials involving old or new medicinal products (whether licensed or not), or device trials (whether CE marked or not) used in usual or non-usual clinical practice.

If your research is in this category please contact Swansea Trials Unit: STU@swansea.ac.uk or Tel: 606225 for further advice or information prior to submitting a funding application.

4.3 Non-Interventional Clinical Research Projects

These are research projects which involve humans as participants but do not involve any invasive experimental element. Such research projects include questionnaire or qualitative studies, observations or cohort studies and retrospective data analysis.

If you think your research is in this category please contact your College Research Ethics and Governance committee in the first instance.


The Human Tissue Act (2004) came into effect in 2006. It was introduced as a legislative framework for the removal, storage and use of human organs and tissue. The Human Tissue Authority (HTA) was set up to regulate the use and storage of human samples in research and other activities such as post mortem, transplantation and public display.

The Medical School holds a joint HTA research licence with ABM University Health Board. For further information please access the Swansea University HTA page or contact abm.HTA@wales.nhs.uk.

6. Ethical Review Process

The University is committed to providing an ethical review process which is competent, rigorous and proportionate to the potential risks identified. Where a high risk is identified, this is assessed against the benefits to patient or public good.

The University meets this commitment by:

- using a procedure that distinguishes research that requires review under external procedures, such as that requiring review by the Health Research Authority and separates out low-risk research for ‘light-touch’ expedited review from those research projects requiring further scrutiny by College Committee’s;

- appointing to internal ethical review committees a combination of members who are independent of the University or who are no longer involved in research, and also
those who are still active in the research areas submitted to the committee for review, that reflect the interests of researchers, participants and third parties;

- keeping under regular review the effectiveness of the ethical review process, including the composition of its review committees.

For further information on internal ethical review please access Swansea University Research Ethics page.

7. Sponsorship of Research Projects involving Human Participants

All research within the remit of the National Health Service or Social Services is governed by the Research Governance Framework for Health and Social Care in Wales (RGF). This Framework requires that all research projects involving human participants, their organs, tissue or data has an identified Sponsor to take responsibility for the initiation, management, financing and monitoring of a clinical research project.

The Sponsor maintains responsibility for additional legal requirements in CTIMPS or device projects. Some research projects can be co-sponsored between two or more organisations, where responsibilities are delegated in a formal co-sponsorship agreement.

Under no circumstances can a University employee act as the Sponsor for their own research project. For further information on internal ethical review please access Swansea University Sponsorship page (currently under development).

Prior to a proposal being submitted to a funding body, Research, Engagement and Innovation Services (REIS) will conduct a governance review. In particular, they will want to ensure that adequate funding is being sought to ensure adequate monitoring of the research project, Trial and Data Manager as appropriate for the trial, non-University costs such as pharmacy, manufacture, laboratory, license and application fees and any other third party/vendor costs as appropriate.

The University is currently reviewing all procedures and will keep researchers advised as processes are updated.

8. Definitions

The definitions given against the following terms are for the purpose of this policy, and not necessarily applied across the entire University; variations of these definitions might exist with Colleges and Schools across different disciplines. However, the principles of this document apply to all.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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Version 2 (Senate approved July 2015; Updated March 2017)
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Investigator (CI)</td>
<td>person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study whether or not that person is an investigator at any particular site</td>
</tr>
<tr>
<td>Co-Sponsor</td>
<td>A legal body in a position to take on some responsibilities outlined in the Research Governance Framework and Medicines for Human Use (Clinical Trials) Act 2004. Co-Sponsorship is to be negotiated and agreed between the Parties, according to an agreed protocol.</td>
</tr>
<tr>
<td>Clinical Research</td>
<td>any health-related research project that involves humans as participants, their tissue and/or data.</td>
</tr>
<tr>
<td>*Clinical Trial</td>
<td>any research project that prospectively assigns human participants (singly or in groups) to a health related intervention(s) and evaluates the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventative care etc.</td>
</tr>
<tr>
<td>Clinical Trial of an Investigational Medicinal Product (CTIMP)</td>
<td>A clinical trial that tests, or uses as a reference a pharmaceutical form of an active ingredient or placebo. This can include products with an existing marketing authorisation when used or assembled in a way different from the approved form, or for an unapproved indication, or to gain further information about an approved use. All CTIMPs are legally required to comply with the Medicines for Human Use (Clinical Trials) Regulations 2004 and associated amendments.</td>
</tr>
<tr>
<td>Clinical Study (Observational study)</td>
<td>any research project where human participants identified as belonging to groups for study are assessed for health outcomes but are not assigned to a specific intervention. Observational study models include Cohort, Case-control, Case-only, Case-cross-over, Ecologic or community studies, Family-based etc.</td>
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<tr>
<td>Good Clinical Practice (GCP)</td>
<td>an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials. It also serves to protect the rights, integrity and confidentiality of trial participants.</td>
</tr>
</tbody>
</table>
| Intervventional Clinical Research | invasive diagnostic, therapeutic, mechanistic or other research procedures or process involving access to:  
- Health Board patients;  
- Health Board staff recruited as participants;  
- Health Board facilities or staff;  
- Healthy volunteers (recruited outside of the NHS). |
| Non-Interventional Clinical Research | means non-invasive research procedures or process involving:  
- “Direct Access” where the researcher has direct contact with the participant;  
- or  
- “Indirect Access” where such contact is indirect (i.e. involves the use of participant data and or Material only). |
| Principal Investigator | the leader responsible for a team of individuals conducting a study at a site |
| Research Governance Framework for Health and Social Care in Wales (RGF) | outlines the principles of good governance that apply to all research undertaken within the remit of the Minister for Health and Social Services for Wales, and the responsibilities of all parties involved to ensure these principles and applicable standards are met. There are associated Frameworks for the other UK nations with plans to produce a new UK policy framework. |
| Sponsor | for Non-CTIMPs, the sponsor is defined by the RGF as the individual, organisation or group taking responsibility for securing the arrangements to initiate, manage and finance the clinical trial or study. For CTIMPs, the sponsor is defined by the Medicines for Human Use (Clinical Trials) Regulations 2004 as the individual or organisation(s) taking responsibility for the initiation, management, and financing (or arranging financing) of the research project, encompassing responsibility in four main areas:  
- Authorisations  
- Conduct/Management  
- Safety/Pharmacovigilance  
- Manufacture/labelling of investigational medicinal products.  

Sole sponsorship – one organisation assumes the full responsibility for sponsorship of the research project.  

Co-sponsorship – arrangement whereby sponsor responsibilities are distributed between two organisations clearly outlined in a co-sponsorship agreement. For the University this is generally with a NHS organisation. |


Acknowledgements:

Swansea University would like to gratefully acknowledge consulting and adopting policies and guidelines in the development of this Framework on work undertaken by other Institutions, including:

1. Aberdeen University

2. University of Bristol – Research Governance & Integrity Policy.
   http://www.bristol.ac.uk/media-library/sites/red/migrated/documents/rgi.pdf

3. Cardiff University
   http://www.cardiff.ac.uk/racdv/resgov/Research%20Governance%20at%20CU/research-governance-at-cu.html

4. City University London
   http://www.city.ac.uk/health/research/research-governance

5. University of Oxford
   http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/

6. University of London
   http://www.london.ac.uk/fileadmin/documents/foi/RM_guidance_-Research_data.pdf

7. University of Manchester
   https://www.manchester.ac.uk/research/environment/governance/

8. University of Nottingham
   http://www.nottingham.ac.uk/research/ethics-and-integrity/index.aspx

9. Northumbria University
   https://www.northumbria.ac.uk/research/ethics-and-governance/

    http://www.sheffield.ac.uk/polopoly_fs/1.112642!/file/Full-Ethics-Policy.pdf


12. Canterbury Christ Church University- University Research Governance Framework

    https://www.soas.ac.uk/infocomp/dpa/dparesearch/file49912.pdf

14. UK Research Integrity Office (www.ukrio.org)
15. Procedure for the Investigation of Misconduct in Research

16. Singapore Statement on Research Integrity
Singapore Statement on Research Integrity
http://www.singaporestatement.org/

17. European Science Foundation (www.esf.org)
   European Code of Conduct for Research Integrity
   http://www.esf.org/activities/mo-fora/research-integrity.html

18. Government Office for Science (www.bis.gov.uk/go-science)
   Rigour, Respect, Responsibility: a Universal Ethical Code for Scientists
   http://www.bis.gov.uk/assets/goscience/docs/u/universal-ethical-code-scientists.pdf

19. Research Councils UK (www.rcuk.ac.uk)
RCUK Policy and Guidelines on Governance of Good Research

20. The Universities UK (UUK) Concordat to Support Research Integrity
(http://www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx)
Useful resources:

For more detailed guidance the following links provide useful information.

- The National Research Ethics Service (NRES) [http://nres.nhs.uk/](http://nres.nhs.uk/)
- NHS Health Research Authority (HRA) [http://www.hra.nhs.uk](http://www.hra.nhs.uk)
- RCUK Policy and Guidelines on Governance of Good Research [http://www.rcuk.ac.uk/Publications/researchers/grc/](http://www.rcuk.ac.uk/Publications/researchers/grc/)
- Universities UK Concordat to Support Research Integrity [http://www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx#VPYka4teKfQ](http://www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx#VPYka4teKfQ)
- Framework for Research Ethics (FRE) [http://www.esrc.ac.uk/about-esrc/information/framework-for-research-ethics/](http://www.esrc.ac.uk/about-esrc/information/framework-for-research-ethics/)
- Economic and Social Research Council [http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx](http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx)
- The British Psychological Society [www.bps.org.uk](http://www.bps.org.uk)
- The British Sociological Association [http://www.britsoc.co.uk](http://www.britsoc.co.uk)
- The General Medical Council (Research Guidance) [http://www.gmc-uk.org/guidance/ethical_guidance/research.asp](http://www.gmc-uk.org/guidance/ethical_guidance/research.asp)
- Nursing & Midwifery Council [www.nmc-uk.org](http://www.nmc-uk.org) search under ‘Research and audit’
- An overview of the Freedom of information Act can be found here: [http://www.shef.ac.uk/polopoly_fs/1.1198261/file/FOIOverview.pdf](http://www.shef.ac.uk/polopoly_fs/1.1198261/file/FOIOverview.pdf)
- UK Research Integrity Office [http://www.ukrio.org/](http://www.ukrio.org/)
- Integrated research application system IRAS - single system for applying for the permissions and approvals for health and social care / community care research in the UK [https://www.myresearchproject.org.uk/](https://www.myresearchproject.org.uk/)


- Committee on Publication Ethics (COPE) [http://publicationethics.org/resources/code-conduct](http://publicationethics.org/resources/code-conduct)


- Duty of care in further and higher education sectors, JISC Legal Information [http://www.jisclegal.ac.uk/Portals/12/Documents/PDFs/dutyofcare.pdf](http://www.jisclegal.ac.uk/Portals/12/Documents/PDFs/dutyofcare.pdf)


Staff & Students accessing security sensitive material online

Universities play a vital role in carrying out research on issues where on occasion security sensitive material is relevant. If circulated carelessly, such material is sometimes open to misinterpretation to the authorities and can put the author(s) in danger of arrest and prosecution under, for example, counter-terrorism legislation. Therefore certain procedures for independently registering and storing material, through the research ethics process, are recommended.

There is a vast amount of security sensitive material which could be highly relevant to many kinds of perfectly legitimate academic research. However, prosecutions under counter-terrorism legislation in the UK have sometimes been brought on the basis of an accumulation on personal computers of downloaded material and other data. This happens due to police being unable to distinguish between the accumulation of such material for legitimate research purposes and the accumulation of material for terrorist purposes.

The issue is that researchers may not download material that is security sensitive but also visit security sensitive web-sites as such visits may be interpreted by police as evidence of sympathy for, and perhaps even willingness to collude with, terrorism. Students who visit extremist sites out of curiosity, aside from research, could be interpreted as contravening counter terrorism legislation.

University researchers trying to carry out security sensitive projects which are highly attuned to the demands of counter terrorism need protection from intrusive and excessive oversight where possible. This could be achieved by a legitimate oversight process within the College/University which reveals people as researchers. An example of a legitimate research project would be where a postgraduate research project involving terrorism related material is agreed by a College Research Ethics Committee and the Head of College/Director of Research and the University Research Ethics & Governance Sub Committee has been made aware of the project.

The general ethical justification for doing this is straightforward: unauthorised acquisition and use of security sensitive information can carry risks to the public, and the researchers can be suspected of obtaining and using it in ways that can be harmful, with costs to themselves and the Institution. For a student or member of academic staff to declare that they are using security sensitive information is in keeping with openness in research and helps reduce misidentification of information gathering as a suspect or criminal.

Besides requiring the declaration itself, the University may provide secure storage of security sensitive material on a University server overseen by the University IT department, a College Ethics officer or suitable counterpart. Central and secure storage, and a convention among researchers of not exchanging files for this store with others, would keep security sensitive material off personal computers and would shield the material from unjustified external scrutiny and misinterpretation.

Central and secure storage could involve researchers registering to use security sensitive
material which would result in the student being issued with a link to a password protected documents file on a central university server to which the student could upload security sensitive documents. These documents would be accessed by the researcher only and would subject to a norm of non-circulation. College Ethics officers or their counterparts overseeing the store would only know the document titles on the server and names of researchers. The method would enable research material to be kept secure and perhaps away from legal jurisdiction.

PhD projects will encounter significant ethical issues, including paedophilia and terrorism. Relevant UK legislation (e.g. Terrorism Act 2000 and 2006) contains safeguards to ensure research of the nature proposed is not criminalized. Before the commencement of the projects the Centre will notify the Special Casework branch of the Crown Prosecution Service and the Home Office’s Office for Security and Counter-Terrorism (which monitors traffic on extremist websites) of the research project. At the start of the project the students will also receive information on their duty to report any terrorism-related activity they encounter online.

Each student will have a designated PC within the University for data collection. They will not use other devices to collect data, to protect them from risk of suspicion and to protect their identity online. IP addresses of these computers will be anonymized through an anonymizing proxy. Secure facilities will be available to store hard and electronic copies of data. Centre members will treat all primary source data as confidential and not disseminate it or share it with others (subject to any legal duty to disclose the data to law enforcement agencies). As part of the appointment process, PhD students will be asked to complete a Disclosure and Barring Service security check.

Where translation is necessary, a reputable company will be employed which has policies in place to protect the anonymity and welfare of its employees.

A range of materials including computer-mediated communications and training materials will be collected from extremist websites, discussion boards and social media. Researchers will not attempt to obtain consent to use these materials: many will have been posted anonymously and it will be impossible to obtain explicit consent; and because revealing full details of researchers and the project may threaten their welfare. Data from closed online sources will be obtained from a reputable and established cyber security company, which complies with all relevant legislation. No individuals will be identified in any of the project’s publications.

The centre is mindful that the ethical issues outlined must be weighed against the benefits of the proposed research. The Centre will deepen existing understanding of contemporary threats to human security in all its forms. These insights will be used to produce recommendations for the development of policies and strategies. Not only will this benefit national and international communities in the widest sense, the evaluation of these strategies in terms of their legal, political and social impacts will benefit those communities that are most directly affected by counterterrorism laws and policies.
**Home Office ‘Prevent Duty guidance’ for England and Wales:**

Universities are expected to carry out a risk assessment for their institution which assesses where and how their students might be at risk of being drawn into terrorism. This includes not just violent extremism but also non-violent extremism, which can create an atmosphere conducive to terrorism and can popularise views which terrorists exploit. Any institution that identifies a risk should develop a *Prevent* action plan to set out the actions they will take to mitigate this risk. Compliance with the duty will also require the institution to demonstrate that it is willing to undertake *Prevent* awareness training and other training that could help the relevant staff prevent people from being drawn into terrorism and challenge extremist ideas which risk drawing people into terrorism.

Home Office expect appropriate members of staff to have an understanding of the factors that make people support terrorist ideologies or engage in terrorist-related activity. Such staff should have sufficient training to be able to recognise vulnerability to being drawn into terrorism, and be aware of what action to take in response.

In terms of accessing security sensitive material, students and staff must comply with the:

- Terrorism Act 2006 – sections 2 and 3 of chapter 11 outlaws the dissemination of terrorism publications (which has a wide definition)
- University regulations - [http://www.swansea.ac.uk/iss/mits/computer%20regs/](http://www.swansea.ac.uk/iss/mits/computer%20regs/)

**Discussing with Police and/or Security Services**

South Wales Police are the Constabulary responsible for the Swansea area. They have dedicated Counter Terrorism Security Advisors (CTSAs) who are coordinated, trained and tasked by National Counter Terrorism Security Office, a specialist police organisation co-located with the Security Service within the Centre for Protection of National Infrastructure. However, for non-urgent crime prevention advice, organisations can contact their local Crime Prevention Tactical Advisor as a starting point.

Anyone planning to undertake security sensitive research must contact the University’s Research Ethics Compliance Officer to seek advice on:

- how best to safely protect the student if terrorists were able to contact him/her
- how to access information safely without contravening any laws.
APPENDIX 4

Glossary of Key Terms

The following is largely drawn from the ESRC’s Framework for Research Ethics.

**Assent:** Agreement from an individual not able to provide free and informed consent to take part in research.

**Authorship:** According to the Committee on Publication Ethics (COPE), Authorship refers to the creator or originator of an idea or the individual or individuals who develop and bring to fruition the product that disseminates intellectual or creative work. Authorship conveys significant privileges, responsibilities and legal rights; in the scholarly arena, it also forms the basis for rewards and career advancement. At a minimum, authors should guarantee that they have done the work as presented and that they have not violated any other author’s legal rights (e.g. copyright) in the process.

**Biobank:** (research tissue bank) ([http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/](http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/)): A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project.

**Broad consent:** has been seen as essential to facilitating biobank research. Participants are asked to consent to the use of samples and data within a biobank, at the time of collection rather than to a specific project or types of research. Broad consent means consenting to a framework for future research of certain types. Included in this framework is ethics review of each specific research project by an independent ethics committee as well as strategies to update regularly the biobank donor and ongoing withdrawal opportunities. If anything in the framework changes, the participant should re-consent.

**Coercion:** For consent to participate in research to be ethically sound any possibility that the consent is the result of coercion must be excluded. The presence of coercion invalidates the consent of the participant.

**Confidentiality:** Normally, information gathered about a research participant should be protected, for example by anonymisation or other strategies that obstruct the identification of participants. Information about participants that is kept either electronically or in hard copy should be stored securely and protected prior to its disposal. Participants should be made aware of the limits of these protective strategies in keeping with the terms of the Data Protection Act (1998) and the Freedom of Information Act (2000).

**Conflict of Interest:** A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgement and objectivity. Conflict of interest may involve individuals as well as institutions and is broadly divided into two categories: **intangible** – those involving academic activities and scholarships; and **tangible** – those involving financial relationships.

**Controlled data:** are data which may be identifiable and thus potentially disclosive but to which access may be granted to users who have been accredited and their data usage has
been approved by a relevant Data Access Committee. Data service providers may provide details of their policies regarding access to controlled data, for example the UK Data Service (http://ukdataservice.ac.uk/get-data/data-access-policy/controlled-data.aspx).

**Cultural sensitivity:** Diversity enriches and strengthens the research culture and performance of any organisation. Diversity means that research may differ widely from one context to another. Thus the ethical issues relating to human participation in research may also differ considerably from one academic discipline to another. This therefore suggests that formal ethical review of research proposals involving human participants, personal data or human tissue is probably most effectively carried out within subject areas, according to the parameters provided by the Institutional Framework.

**Data Custodian (Data Controller):** is a person who determines the purposes for which and manner in which any personal data are to be processed in line with the Data Protection Act (https://ico.org.uk//for-organisations/guide-to-data-protection/).

**Data Depositor/Data Producer:** A data depositor/data producer is an individual or organisation who is named on a license as having sufficient responsibility to grant particular rights on behalf of a data collection. The depositor/producer may be the principal investigator, creator or the copyright owner of a data collection, but does not have to be.

**Deception:** Deception runs counter to informed consent, and deprives the participant of information that would allow them to make decisions affecting their participation under conditions of reasonable understanding of the research context, aims, and scope. It is normally unacceptable in research conduct. The use of placebo, however, in randomised controlled trials is not typically thought of as deceptive, even though the participant may not know whether they are being subjected to interventions or not. There may on occasion be good reasons to withhold reasonably full information to the participant but these must be specified prior to approval, making clear why the knowledge gained is valuable and why it may only be generated under conditions of partial (e.g. misleading information, incomplete information, partially true information) or full deception. Where deceptive methods are approved, debrief is thought to be important to retain trust in the research community.

**Dignity & Respect:** Researchers should not design research that threatens the dignity of the research participant and should avoid methods that may embarrass or compromise the dignity of the participant. One way of failing to respect the dignity of a participant is by using them simply as a means to one’s own ends (goals) as a researcher. Typically, the researcher has more to gain from the research than the research participant. Debrief and feedback to participants is thought to be a clear token of respect. Research involving animals, the environment, and cultural objects should be undertaken with due care and respect.

**Enduring consent:** This is where there is no time limit on consent given unless consent is withdrawn. Human participants do not need to be re-contacted should any of their personal data be reused for further research. Securing enduring consent may be essential in longitudinal studies. It may also be important for data for which access is provided by the UK Data Service. Principles of preserving confidentiality apply.
**Ethics protocols:** The use of approved protocols for commonly occurring situations such as research with normally developing children in schools. These can expedite ethics review as principal investigators can confirm in a light-touch review to their REC that there is an approved protocol that appropriately covers the ethics issues raise by their research. It will be the responsibility of the College REC to approve the suggested protocol for the work.

**Excellence:** Excellence in research is work that demonstrates originality and has an observable impact on the subject. Researchers must strive for excellence when conducting research, and seek to produce and disseminate work of international (or, where appropriate, national) quality.

**Expedited review:** In exceptional circumstances, it may be necessary for a proposal involving possible risk of harm to receive a full review at short notice. An expedited review is carried out by one or more members of a Research Ethics Committee (REC), commonly its chair, and not by a member of the department due to carry out the research.

**Freely given informed consent:** Informed consent entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision on their possible involvement. Typically, the information should be provided in written form, time should be allowed for the participants to consider their choices and the forms should be signed off by the research participants to indicate consent. Where participants are not literate, verbal consent may be obtained but this should wherever possible be witnessed and recorded. In other circumstances, for example telephone interviews, written or witnessed consent may not be possible, but verbal consent should be secured. Where consent is not to be secured, a full statement justifying this should be submitted to the REC for review. In longitudinal research it may be necessary to explain the need for (and limitations of) enduring consent. The primary objective is to conduct research openly and without deception. Deception (i.e. when participants are intentionally not fully informed or are misinformed about the purpose of the research for methodological reasons) should only be used as a last resort when no other approach is possible. Any research involving deception should be submitted to the REC for review. This principle also requires that research staff need to be made fully aware of the proposed research and its potential risks to them.

**Human participants:** Human participants are defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and fetuses, human tissue and bodily fluids, and human data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements).

**Informed consent:** Normally, the informed consent of the research participant is a requirement of ethically sound research. The participant should be informed of the nature and duration of the research in clear terms and given sufficient time to decide whether or not to take part. Also, the participant should be made aware that they can opt not to continue to participate in the research at any time (or at least up to the point of anonymisation of data) without fear of duress or penalty. Some inducements may be thought to compromise informed consent, undermining the voluntariness of the consent. A failure to express the
aims, methods and scope of the research to the participant may also undermine the possibility of informed consent.

**Integrity:** Research integrity refers to the active adherence by researchers and research organisations of the ethical principles and professional and legislative standards essential for the responsible practice of research. Researchers should present their work accurately, respect the principles described in the Framework, make known any conflicts of interest, and respect recognised criteria for authorship.

**Lay member (of a REC):** This person should have no affiliation to the research organisation apart from membership of the REC and may provide the perspective of the research participant to the REC.

**Light-touch review:** Light-touch reviews identify those projects where the potential for risk of harm to participants and others affected by the proposed research is minimal. In many cases this is the only ethics review necessary. An ethics checklist should be completed. RECs need to confirm that only a light-touch review is justified.

**Nonmaleficence:** Participation in research should not normally harm the participant or compromise their interests.

**Personal data:** Under the Data Protection Act 1998 ‘personal data’ is defined as data which relates to a living individual who can be identified a) from those data or, b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual. Under this act, personal data consists of information as to (a) the racial or ethnic origin of the data subject, (b) his/her political opinions, (c) his/her religious beliefs or other beliefs of a similar nature, (d) whether he/she is a member of a trade union (within the meaning of the [1992 c. 52.] Trade Union and Labour Relations (Consolidation) Act 1992), (e) his/her physical or mental health or condition, (f) his/her sexual life, (g) the commission or alleged commission by him/her of any offence, or (h) any proceedings for any offence committed or alleged to have been committed by him/her, the disposal of such proceedings or the sentence of any court in such proceedings.

**Privacy:** Research methods should not normally violate the privacy of participants. Researchers should be sensitive to contexts where people might reasonably expect to have their behaviour observed, or not, and recorded for research purposes.

**Research Ethics Committee:** A Research Ethics Committee (REC) is charged with reviewing research for ethical approval. The independence of a REC is founded on its membership, on strict rules regarding conflict of interests, and on regular monitoring of and accountability for its decisions.

**Research ethics:** Research ethics refers to the moral principles guiding research, from its inception through to completion and publication of results and beyond – for example, the
curation of data and physical samples, knowledge exchange and impact activities after the research has been published.

**Research project lifecycle**: includes the planning stage, the period of funding for the project and all activities that relate to the project once funding has ended. The research lifecycle also includes knowledge exchange and impact realisation activities, the dissemination process and the archiving, future use, sharing and linking of data.

**Research**: Research is defined as any form of disciplined inquiry that aims to contribute to a body of knowledge or theory.

**Responsibility** for the ethical conduct of research, including its presentation and publication, lies with the researcher. The researcher should consider their project design against standard ethical guidelines for the conduct of research (see below for links to relevant documents), as well as the regulations in this Framework document.

**Results & methods**: Research is ethically justified to the extent that the aims and the methods employed are ethically sound. So even if a research project could generate results which might benefit thousands of people, if the methods proposed to generate those results were not ethically sound, the research would only be approved under exceptional circumstances.

**Student research**: Normally, the aim of research is the generation of new knowledge. But in student-level research part of the value of the research process lies in its educative value, in training new generations of researchers. Thus the generation of new knowledge is not a strict requirement for ethical approval of student research. It should be stressed, however, that the same ethical principles that constrain research generally also apply to student research.

**Transparency in research ethics**: The full, accurate, and open disclosure of relevant information is always important. Where the research involves new and innovative methodologies which raise distinctive considerations (e.g. online research), this is especially important.

**Valid consent**: Consent is valid if it meets three conditions: participant has capacity to make a decision; the process is free from coercion; and the consent is informed. For consent to be ‘valid’ the participant must be capable of understanding all the potential risks involved. Where this may be in doubt, the Mental Capacity Act 2005 and Adults with Incapacity (Scotland) Act 2000 may apply.
Swansea University Policy for Research Data Management (RDM)

Swansea University recognises that effective data management practices are required to support the full research lifecycle. The UK research environment, including policies from funding councils, increasingly require comprehensive research data curation: including planning, ingest, preservation and access.

Data is fundamental to the conduct of high quality research and will be treated as a resource for the future.

This policy outlines the key principles of RDM at Swansea University, seeking to balance responsibilities within research projects and centrally. This policy should be read in conjunction with the Research Governance Framework.

Scope

This policy applies to all members of the University and all data created during research or similar activities that support research outputs. Datasets may range from large databases in the medical and computational domains to a survey data gathered by graduate students.

Certain research areas may have specific requirements, e.g. clinical trials. See the Swansea University Research Governance Framework for more information.

This policy does not extend to a project’s administrative data and records: bid documents, contracts, funding notifications, project records and so forth, which will be managed through the Research, Enterprise and Innovation Service. (Read more...)

Responsibilities

The Principal Investigator is responsible for ensuring that bids, contracts and project work meets the requirements laid down by funders and/or the university. The university will support this activity through training and providing advice and guidance.

Technical responsibility for providing the infrastructure necessary to ensure the long-term retention of data will lie with Swansea University IT Services. Other aspects of data cataloguing, curation and access will lie with Swansea University Libraries.

Research data is owned by Swansea University and/or project funders in line with the Policy on Intellectual Property. (Read more...)

Data Management Planning

Increasingly it is good practice to define a data management plan for all research projects, and these are increasingly being expected by funders at the bid stage. Data management
plans should be living documents that present initial plans but also reflect any changes in a project’s data creation and curation practice during the lifetime of the project.

Costs of research data curation and storage should for large datasets be considered during the bid writing stage and, where permitted, be included within bids.

**Data Ingest**

1) Metadata and data management plans should be reviewed to ensure accuracy of the descriptions
2) Data should be checked for accuracy and completeness
3) Data Access (availability and licensing) requirements

Contact [iss-research@swansea.ac.uk](mailto:iss-research@swansea.ac.uk) for further information and to arrange metadata and data ingest. Metadata will normally always be registered centrally and may also be registered and held in other relevant external repositories. Where the research data will be held other than in ISS central systems, responsibility for ensuring curation, security, data protection, backups and format migration vests solely with the PI.

**Data Access**

A principle of the new research environment is that publicly funded research should be publicly available - this includes to other research groups and to the public and commercial users. The rights of the university and researchers to exploit this data academically and commercially can be preserved, along with data protection matters, while meeting these demands, but every case may require individual evaluation. As a minimum, metadata should be available and the conditions of access clearly laid down in the data management plan for each new research project.

Each research output published should include a brief statement on research data access.