

## **Research Integrity & Governance Code of Practice**

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## **Foreword**

To be among the very best in the world is the most challenging goal we can set ourselves. We have done so because it is only through working to achieve the very highest international standards in research, teaching and other activities that we can realise the full potential of the academic community that is Cardiff University. Our vision reflects our service to society and we pursue our vision in the belief that all those with an interest in the University should expect no lesser ambition.

Our Mission is to pursue research, learning and teaching of international distinction and impact.

Features of our vision are a striving for excellence, integrity and innovation in every aspect of activity; a strongly collaborative approach; open and effective communications and an inclusive culture based on dignity, courtesy and respect.

The staff and students of Cardiff University are expected to adhere to the standards of the 'Research Integrity & Governance Code of Practice (Code of Practice).

Cardiff University's guiding principles for its actions include: outstanding academic and professional performance; respect for people and diversity; academic freedom; financial resilience; integrity; and environmental and social sustainability. The University is committed to and supports the Universities UK 'Concordat to Support Research Integrity' as well as the Research Councils UK 'Policy and Code of Conduct on the Governance of Good Research Conduct'.

The University continually strives for the highest quality research conducted with the highest levels of research integrity. We have policies, procedures and training resources to allow staff and students to achieve this. This Code of Practice aims to promote and to summarise these and to set out expected Research Integrity standards. Please read this RI Code of Practice and visit the websites it references and help Cardiff University to continue to be associated with the highest standards of Research Integrity and academic achievement.

**Professor Hywel Thomas**

**Pro-Vice-Chancellor for Research, Innovation and Enterprise**

## **1. Statement of Principle**

### **1.1 Introduction**

This document applies to all subject areas and to all members of staff and students involved in research at the University, including its staff and students conducting research outside the University but as part of their University role, as well as any persons not employed by the University but with permission to carry out research at the University (all referred to hereafter as Researchers). It is the responsibility of Researchers to be fully aware of and to be trained in current good practice and statutory requirements relevant to their research area. It is the responsibility of all Researchers to make themselves familiar with and abide by this Code of Practice. This Code of Practice has been designed to promote good conduct in research in all stages of a research project, assist Researchers to meet legal and ethical requirements and help prevent misconduct, in order to assist Researchers to conduct research of the highest quality. Any breach of this Code of Practice may be grounds for disciplinary action.

All Researchers have a responsibility and a duty of accountability to society, to their profession, to the University and to the funders of the research, to accept full responsibility for the professionalism and integrity of all aspects of the conduct and publication of their research, and for the activities of any staff or students under their direction. This extends to reporting conflicts of interest, actual or potential, or suspected misconduct, in the appropriate manner. Researchers must also accept responsibility for taking steps to ensure the safety of those associated with the research, the probity of the financial management of the research project, and for seeking to provide optimum value for the public or private funds invested in the project. All legal and ethical requirements laid down by the University or any other properly authorised bodies must be adhered to.

### **1.2 The Objectives of Research**

The primary objective of research is the deepening and broadening of knowledge and understanding by expert, responsible and professional means, including the dissemination of results through publication, teaching, applied research and consultancy.

Research should also seek to meet the following additional objectives:

- i. The training of new Researchers in appropriate methods and professional standards of research;
- ii. The promotion of the interests and benefits of research;
- iii. The securing of the exploitation of results for the public good and the benefit of the University and its members of staff and students.

### **1.3 Collegiality**

The University is a diverse, interdisciplinary community of scholars and Researchers who are in many ways dependent upon each other. As an institution and as individuals it is important to support the notion of effective, active collegiality. In developing and carrying out research projects, groups and individuals need to be fully aware, at all stages of the research process, of the possible immediate and long term implications of their proposed actions. Undertaking certain types of research or taking certain courses of action may impact on the trust and respect required to nurture creative academic collegiality within research groups, Schools, Research Institutes, Colleges or the University as a whole. Researchers need to be aware of this dimension to their activity and act in a collegiate manner at all times.

## **2. Principles in Research**

### **2.1 Excellence**

Researchers should strive for excellence when conducting research and aim to produce and disseminate work of the highest quality. This Code of Practice is intended to support this goal.

### **2.2 Honesty and Integrity**

Maintaining professional standards is fundamental to research. A culture of honesty and integrity should be fostered in all areas of research activity.

Researchers must be honest in respect of their own actions and in their responses to the actions of other Researchers. This includes honesty in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of others; in conveying valid interpretations and making justifiable claims based on research findings. Researchers must not engage in nor conceal misconduct and have a responsibility to report potential incidences of misconduct in an appropriate manner. The repercussions of failing to behave honestly in any of these, or other, actions can be widespread and may be regarded as a disciplinary offence. The University's procedures for dealing with allegations of misconduct in academic research can be found at [Annex 1](#).

### **2.3 Openness**

Research methods and results should be open to scrutiny, discussion and debate. Subject to considerations of confidentiality and protection of intellectual property rights, Researchers should be open with other Researchers and the public regarding their work and promote the open exchange of ideas and information. There should be transparent and open communication in declaring conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting work to other researchers and the public.

The University supports the Research Councils UK position on open research outputs and data. Subject to legal, ethical and commercial constraints, all publicly funded research outputs and data should be made openly available in a responsible manner and appropriate format. To comply with the requirements for the Research Excellence Framework, metadata should be deposited in an institutional open access repository once the output has been accepted for publication, with the full text of the final author's refereed version deposited within 3 months.

### **2.4 Accountability and Responsibility**

The primary responsibility for safeguarding the integrity of any research undertaken lies with the individual Researcher. It is his/her responsibility to ensure that the work meets all professional standards and the principles outlined in this document.

Researchers should recognise that in and through their work they are ultimately accountable to the general public and must act accordingly. All Researchers should be aware of and must comply with the University's policies and guidelines and the legal and policy requirements that regulate their field

of study, especially the basic principles relating to ethics, information, finance and health and safety. Please refer to [Annex 1](#) for links to further information in these areas.

All Researchers must ensure the work undertaken is consistent with any agreements and terms and conditions related to the project. This includes ensuring the programme is carried out as defined in the original proposal, the finance is used solely for the purpose it was intended, reports are accurate and produced on schedule, and that there is adherence to the conditions regarding publication, data management and intellectual property ownership. Any failures in any of these respects or instances of misconduct (refer to section 5) should be reported in line with the requirements of the project and of the University.

Researchers should follow the requirements and guidance of any professional bodies in their field of research. Researchers who are members of a regulated profession should follow the requirements and guidance of their profession.

## **2.5 Rigour**

As a research-led institution the University promotes good research practice, emphasising integrity and rigour. A rigorous approach to research is part of the professional integrity to which all Researchers must adhere.

Researchers should conduct research according to the highest standards of rigour in line with prevailing disciplinary norms and standards. Rigour should be applied when performing research and using appropriate methods; in adhering to agreed protocols when appropriate; in drawing interpretations and conclusions from the research; in the verification of the results before publication; and in communicating the results.

## **2.6 Care and Respect**

Care and respect must be extended to all participants in and subjects of research, including humans, animals, the environment and cultural objects. Researchers should address any concerns relating to the dignity, rights, safety and well being of all involved in research. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations.

Due care and attention must also be paid to issues of equality and diversity throughout the research process (for further details of this and the requirements of the Equality Act 2010, see section 3.6).

## **3. Commitments for Research**

### **3.1 Leadership and Supervision**

The Group Leader/Lead Investigator of a research project or, in the case of student researchers, the student's main supervisor, is responsible for ensuring that all researchers under their supervision/management have been suitably apprised of their responsibilities under this Code of Practice and that they undertake all aspects of research in line with its provisions. This includes ensuring:

- i. the dignity, rights, welfare and safety of any research participants;
- ii. research is conducted in accordance with guidelines (including best practice and health and safety procedures), and approval obtained from all necessary bodies before research commences (with any proposed amendments to the agreed protocol also being approved);

- iii. that a risk assessment of the planned study is undertaken to determine the potential risks to the organisation, the research, the safety and wellbeing of the participants and researchers, and identify the legal and ethical requirements governing the research [refer to [Annex 1](#) for recommended checklist for researchers];
- iv. the study complies with all relevant legal and ethical requirements;
- v. a thorough awareness of Equality and Diversity requirements and share that knowledge with those under their leadership.
- vi. each research team member is qualified and experienced to fulfil their role including ensuring students and Researchers have adequate supervision, support and training and have undertaken appropriate checks, e.g. Disclosure and Barring Service checks and/or Baseline Personnel Security Standard checks;
- vii. procedures are in place to collect, store, manage and keep secure high quality data and, subject to legal, ethical and commercial constraints, to make such data available upon completion of the research project. That these procedures are documented in a data management plan where required;
- viii. reports on research progress and outcomes are produced on time and to an acceptable standard;
- ix. research results are disseminated promptly and fed back as appropriate to participants;
- x. findings are open to review through accepted scientific and professional channels and research data is appropriately registered to facilitate access;
- xi. arrangements are in place to manage financial and other resources provided for the study, and any intellectual property arising;
- xii. he/she accepts the key role of detecting and preventing misconduct by taking responsibility for all aspects of research integrity which relate to a particular publication;
- xiii. that provision is made for the continued management of research data if a Researcher in the project team or the student being supervised leaves the University;
- xiv. that where collaborations with external organisations are entered into, there is formal agreement regarding data ownership prior to project commencement.

A research Group Leader/Lead Investigator is expected to establish an atmosphere of organisation and co-operation in his/her team, fostering the open exchange of ideas and ensuring that robust management practices exist to safeguard the honesty and integrity of the research conducted. New Researchers (including research students) must be given access to this Code of Practice, and any other appropriate guidelines on best practice.

Research Group Leaders/Lead Investigators must ensure that Researchers are not placed under commercial or other pressures that prevent the normal pursuit of thorough and honest investigation.

### **3.2 Research Data and Records**

#### **Research Data and Records Management**

A primary principle of good research practice is the effective management of research data and records. The University will provide guidance, training, technical support and infrastructure to assist Researchers to manage their research data and records effectively and in line with this Code of Practice. Researchers must ensure that they are fully cognisant of, and comply with, any funder policies, relevant legislation, University policies and guidelines and discipline specific best practice concerning research data and records management.

Researchers are responsible for the meticulous recording, quality assurance and management of their research data. At the proposal stage Researchers must consider how they will actively manage their research data and records in whatever format throughout the project lifecycle, to ensure they remain secure, retain integrity and authenticity and remain available throughout the designated period of

retention. Due regard must also be given to the provision of access to the research data. As good practice, all research projects that are creating or capturing data should include these considerations in a formally documented data management plan (DMP). The DMP should be implemented, and updated where required throughout the project lifecycle. As part of their DMP Researchers should ensure that they have assessed the risks relating to confidentiality, integrity, availability and compliance with respect to their data and have employed appropriate security controls. Relevant resources are available through the Information Security Framework programme website (refer to [Annex 1](#)).

As per the Information Security Framework, the Director of Research and Innovation Services (RIS) is the Information Asset Owner for Research Information including research data. The Information Asset Owner is responsible for providing the Senior Information Risk Owner with assurance that the security controls in place to protect the asset are consistent with the University's risk appetite and that information risk is being managed effectively for their assigned information asset.

The University will provide a significant amount of secure electronic storage to support researchers. Each School/Research Institute is responsible for identifying where storage beyond this amount will be required and for making appropriate provision to accommodate both secure paper and electronic storage space.

#### **Metadata and Documentation**

Researchers must ensure that research data and records are created with sufficient high quality metadata and documentation to explain their origin, content and context, and where being made accessible externally, discoverable to others for future re-use.

Researchers will be expected to register details of their research data, and the provisions for accessing it in line with funder requirements and in accordance with any University designated method. Where funders do not have requirements concerning the registration of data, Researchers are still encouraged to log details with the University.

#### **Retention**

Research data must be retained in line with the University's retention requirements (as set out in the University's records retention schedule (refer to [Annex 1](#))) and any retention periods specified by the funding organisation.

Research data obtained from Clinical Trials of Investigational Medicinal Products must be managed and retained in line with the relevant University Framework-Standard Operating Procedures (refer to [Annex 1](#)).

#### **Access to Data and Data Preservation**

At the end of any publicly funded project, subject to any legal, contractual and ethical considerations, data shall be made openly available in a timely and responsible manner. Researchers are entitled to a limited period of privileged access to work on their data, to prepare publications and to conduct commercial explorations but it is expected that data will be made available no later than publication of research outputs.

Research data that substantiates research findings or is likely to be of interest for future research shall be deposited for preservation to a University, national or international data service or repository, where legal, contractual and ethical considerations allow. Research data shall be deposited with the appropriate metadata and documentation.

Where data is deposited externally care must be taken to ensure that rights are not assigned without retaining the right to make the data openly available for re-use, unless this was an original condition

of the research project funding award. Where data cannot be made widely available, Researchers should provide access to third parties under appropriate legally enforceable confidentiality agreements to enable them to verify results.

### **Leaving the University**

Research staff leaving the University must ensure that appropriate provisions are made within their School, Institute or Department for the continued retention, storage and where applicable, provision of access to their research data and records. A member of School/Institute/Department staff shall be identified to take on responsibility for the research data and records. By default this responsibility will revert to the Head of School, Department or Research Institute should no other member of staff be identified.

Students leaving the University must ensure that appropriate provisions are made within their School, Institute or Department for the continued retention, storage and where applicable, provision of access to their original research data and records/or copies. A member of School/Institute/Department staff shall be identified to take on responsibility for the research data and records. By default this responsibility will revert to the student's supervisor if no other member of staff is identified.

Students wishing to retain original research data and records or copies after they have left the University must ensure that there are no restrictions in their funding agreement or assignments which they have made with the University which would prevent them from doing so. Students must consult with their supervisor and seek their consent before taking away original research data and records. Where personal data is included in the records, students must consult with the University's Data Protection Officer prior to the removal of originals or copies (for contact details see [Annex 1](#)).

### **3.3 Data Protection Act 1998**

Researchers must comply with the terms of the Data Protection Act 1998 whenever they are holding information from which a living person can be identified. This is known as 'personal data'. The Act requires Researchers to have proper grounds to enable them to use personal data for research purposes and it sets out principles that must be applied to the use, storage and disclosure of that personal data (storage of research data is covered in section 3.2). The Act defines a special category of personal data as 'sensitive' and the lawful use of this data is further restricted under the Act. Sensitive personal data includes the state of individuals' mental or physical health; their religious, philosophical or political beliefs; trade union membership; their criminal record; their racial or ethnic origin and details of their sexual life.

A series of guidance notes for Researchers explaining the requirements of the Data Protection Act in relation to research (including valid consent and who is competent to give valid consent) are available (refer to [Annex 1](#)).

### **3.4 Publications and Authorship**

Researchers have a responsibility 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. Research results should be disseminated widely in an appropriate form, thereby allowing the community at large to view, challenge and develop research results. All publications should contain enough information to allow other Researchers to accurately repeat the procedures originally used.

Research should be published wherever possible, taking into account conditions specified by the funding body and protection of any intellectual property or confidential information (refer to section 4.1). It is important that research output is peer reviewed through accepted scientific and

professional channels. An exception to the standard rule of first publishing through a recognised channel would be when serious public health or safety issues are involved. The safety of the general public would take precedence in these instances. It follows on from this that healthcare research findings in particular must be published as soon as possible.

Published research should always include 'Cardiff University' in the author address field. In the majority of cases supporting data should be made available and published research should include a short statement outlining how and on what terms the data may be accessed.

Authors should not publish more than one paper based on the same set of data, except where there are full and thorough references and acknowledgements made to the earlier paper(s). A publication must contain appropriate references if it is substantially similar to another article(s) on the same research. Any author who submits similar work to more than one publisher must ensure each publisher is aware of this at the time of submission.

Authors are required to deposit the full text of the final, peer-reviewed, author's version ("post-print") of their journal articles and published conference proceedings in the institutional repository no later than 3 months after acceptance. Where publishers' copyright permissions allow and there are no confidentiality or commercial constraints, these versions will be made Open Access. Outputs subject to an embargo will not be released publicly until the embargo period has expired (refer to [Annex 1](#)).

Authorship is the foremost method of allocating credit for intellectual advances. An author can be defined as someone who has had a major input into a publication's creation. This can be by:

- i. helping conceive the research project and its procedural framework;
- ii. being involved in the study and the interpretation of research data;
- iii. drafting the publication, or revising its content in a critical matter to perceive its actual worth;
- iv. giving approval for the final version of article which is to be published.

Assisting in acquiring funding or data is not sufficient to earn the title of author. Neither is general supervision of a research team. Contributions of this kind should be acknowledged in the text, but not as authors. The practice of honorary authorship is not acceptable.

An author is responsible for reviewing and taking responsibility for his/her contribution to the output prior to the publication and thereby ensuring that he/she is familiar with its contents and his/her contribution to it. Once published, the authors should collectively support the findings of the research: any person listed as a co-author on a publication is deemed to endorse every part of that output.

In every aspect of research, the roles and contributions of collaborators and other supporters of the work must be acknowledged. This extends to attributing thanks to the body funding the project, if it is appropriate to do so. This should apply when publishing research findings, and whenever making a statement regarding the research. Where data from third parties has been used the source of the data shall be acknowledged.

Failure to properly acknowledge all direct or indirect contributions made by other persons is unprofessional conduct and could amount to academic research misconduct.

### 3.5 Training

It is the personal responsibility of Researchers to participate in training in current good practice and statutory requirements relevant to their research area. It is the responsibility of the University to ensure that there are adequate provisions for training and development to enable research staff and research students to attain necessary skills for their current role, and to support their future career development. The University is fully committed to the principles of the 2008 Concordat to Support the Career Development of Researchers (refer to [Annex 1](#)) which provides 'a single, unambiguous statement of the expectations and responsibilities of Researchers, their managers, employers and funders with regard to how research careers should be managed and supported in higher education institutions (p2).'

It is University policy that Researchers receive adequate supervision from their supervisors/principal investigators, along with regular reviews of their progress. The identification of training and development requirements and the provision of careers advice constitute key components of the appraisal (for staff) and progress review (for students). It is the responsibility of the Lead Investigator/Research Degree Supervisor to work with research staff/students to identify their training needs and document agreements about how these needs will be met.

It is vital that supervisors/principal investigators develop the appropriate skills in respect of their staff development and managerial responsibilities. For further information on Supervisor Training and the Cardiff University Leadership and Management Framework refer to [Annex 1](#).

Training in research related skills will generally be provided at a School, Research Institute or Research Group level, as appropriate. Particular attention should be paid to providing inexperienced Researchers with training in all the necessary skills to undertake their research work.

The Staff Development Team is responsible for supporting staff training across the University, and there is a designated member of staff responsible for research staff. The 'Cardiff Researcher' Programme covers all cross-discipline, transferable skills workshops provided for research staff by the University's central staff development section. This training is organised around the four domains set out in the 'Researcher Development Framework' (developed by Vitae): knowledge and intellectual abilities; personal effectiveness; research governance and organisation; and engagement, influence and impact. Research staff also have access to the general Staff Development Programme, which is issued annually to all members of staff. For further information on training and career development for research staff refer to [Annex 1](#).

As outlined in the Code of Practice for Research Degrees, Academic Schools are responsible for ensuring that their research students have access to appropriate training. To this end, Schools are responsible for delivering or procuring the research skills, methods and techniques that are specific to their discipline and local research context.

The University Graduate College provides research students with generic research skills, professional and transferable skills and career development opportunities, which are organised around the four domains set out in the 'Researcher Development Framework' (developed by Vitae): knowledge and intellectual abilities; personal effectiveness; research governance and organisation; and engagement, influence and impact. For further information on training and career development for research students refer to [Annex 1](#).

### **3.6 Equality and Diversity**

Cardiff University has a public sector duty under the Equality Act 2010 to eliminate unlawful discrimination, harassment and victimisation, advance equality of opportunity and foster good relations in everything it does, including research. The Equality Act also provides rights to individuals in relation to discrimination, harassment and victimisation on the grounds of the 'protected characteristics' under the Equality Act 2010<sup>1</sup>. Researchers must recognise the specific duties of the Equality Act 2010 which require the University as a public body to promote equality and diversity, eliminate unlawful discrimination and strive to ensure that no one is unlawfully disadvantaged by the way we carry out our functions. Researchers must abide by the Equality Act and the University's policies and guidance on equality and diversity in every aspect of their work.

Specific guidance on considering equality and diversity issues in research can be found on the Governance and Compliance Division (GOVRN) website (refer to [Annex 1](#))

In addition to the above, RCUK expect those in receipt of Research Council funding to:

- promote and lead cultural change in relation to equality and diversity;
- engage staff at all levels with improving the promotion of equality and diversity;
- ensure all members of the research workforce are trained and supported to address disincentives and indirect obstacles to recruitment, retention and progression in research careers;
- provide evidence of ways in which equality and diversity issues are managed at both an institutional and department level.

Furthermore, the University requires that those in leadership positions maintain a thorough awareness of Equality and Diversity requirements and share that knowledge with those under their leadership.

### **3.7 Ethical Requirements**

#### **3.7.1 Research Involving Human Participants, Human Material or Human Data**

The responsibility for ensuring the ethical conduct of research resides with the Researcher. The following guidance sets out the principles that should be adhered to for all research involving human participants, human material or human data.

Research must adhere to all legal requirements and guidelines produced by appropriate bodies, including but not limited to, this Code of Practice, and Code of Practice for Human Tissue Research, the Data Protection Act 1998, The Human Tissue Act 2004, guidelines from relevant professional bodies or relevant research ethics committees. It is legally and ethically paramount that all information gained from research regarding individuals must be kept strictly confidential and securely stored.

The University requires that research involving human participants, human materials or human data be reviewed according to the relevant School Research Ethics Committee (SREC) procedures unless the research:

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<sup>1</sup> Under the Equality Act 2010 protected characteristics are the grounds upon which discrimination is unlawful. The protected characteristics (section 4) under the Act are: age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief (including lack of belief), sex and sexual orientation.

- i) is being reviewed by a mandatory external ethics committee e.g. animal research or research involving the NHS where external ethics committees already exist to consider research proposals, and their use for such research is mandatory. In such cases neither the SREC nor University Research Ethics Committee (UREC) is empowered to give the research proposal ethical approval;
- ii) uses only information that is publicly and lawfully available e.g. census data, population statistics published by government departments and personal letters / diaries in public libraries.

All ethics committees are dependent on the information supplied by the Researcher to inform their decision-making. It is therefore the responsibility of the Researcher to ensure information provided to those committees is complete and accurate.

If the Researcher is unsure if ethical review is required all queries should be addressed in the first instance to the appropriate Chair of the SREC or School Ethics Officer (SEO), who will consult, if necessary, with UREC or the National Research Ethics Service (NRES).

The requirements of ethics review at Cardiff University are designed to demonstrate that Researchers have given consideration to ethical issues surrounding the design of their research and its future conduct. This system will therefore enable Researchers to apply for funding from those bodies that require such review and publication in journals that likewise require evidence of ethical review. The University will endeavour to support Researchers in reflecting upon ethical issues in research by providing support through the UREC, the SRECs, the SEOs and through providing opportunities for training.

For further information refer to the University's policy and procedures for ethical requirements for non-clinical research involving human participants Refer to [Annex 1](#)).

### **3.7.2 Research Involving Human Participants: Basic Principles**

In any research involving human participants, the safety, rights and dignity of the participant must be the primary concern.

The University recognises the breadth of research methodologies in use across the academic disciplines and that ethical issues and practices may vary within the context of the methodologies as well as within context of a discipline. In all research disciplines the Data Protection Act 1998 requires a lawful ground for collecting and using information on living identifiable human participants in research (refer to section 3.2.1). Valid and informed consent is one of these lawful grounds and will normally be necessary where sensitive personal data is collected. For the consent of the research subjects to be valid it must be fully informed and freely given.

Whilst the principle of informed consent is an important method of helping to ensure the ethical conduct of research in many methodologies and disciplines, the University recognises that it is not always necessary or appropriate, for example, where the individuals are not identifiable (and the Data Protection Act therefore does not apply). Where the individuals are identifiable but consent is not necessary (because another lawful ground as specified in the Data Protection Act applies) then the use of that personal data must still be 'fair' and ethical considerations will be central in assessing fairness. Whenever research on identifiable individuals is contemplated without the consent and/or knowledge of the research subjects and advice must be sought from the University's Data Protection Officer who is based in the Governance and Compliance Division. For information on consent relating to the Human Tissue Act, refer to section 3.9.4.

Research with children and vulnerable adults, e.g. those who are vulnerable in particular contexts on account of physical or mental disabilities, should be undertaken with care. Researchers should comply with the Mental Capacity Act 2005 in all cases where research participants may not have capacity or may lose capacity to provide valid consent during the course of the study. Researchers should also be familiar with and adhere to the University's Safeguarding Children and Vulnerable Adults policy. Where appropriate, Researchers must comply with any additional obligations such as obtaining a Disclosure and Barring Service clearance. The Lead Investigator has a responsibility to determine (with HR) whether these checks are required for all researchers under their supervision/management and then to ensure that these individuals are adequately vetted and trained. The research protocol should detail the role and responsibilities of individuals on whom the research participant is dependent (e.g. parents, carers, 'gate keepers'), and should indicate how consent is being sought from the participant ('real consent') or how the provisions of the Mental Capacity Act 2005 are being applied.

If Researchers consider that human participants in research are subject to unreasonable risk or harm, or if there are concerns relating to the improper and/or unlicensed use or storage of human material, or the improper use or storage of personal data, they must report their concerns to their manager or other appropriate person in the University and where required, to the appropriate regulatory authority.

### **3.7.3 Research Involving Animals**

Alternatives to the use of animals in research must be sought wherever possible, and Researchers should be able to demonstrate that all alternatives have been considered. If animal involvement is unavoidable, animal welfare concerns must be weighed against the potential gains in knowledge and understanding brought about by the research. Additionally, when designing the research protocol to be followed, the possible replacement, reduction or refinement of animal involvement should be continuously considered. This means:

- i. the replacement of animals by non-animal methods wherever possible;
- ii. the reduction of numbers necessary to obtain valid results if replacement is not possible;
- iii. the refinement of all procedures to minimise harms and adverse effects.

Research involving animals requires prior approval from the relevant ethics and regulatory committees. All legal requirements and guidelines produced by other appropriate bodies must be adhered to, in particular Home Office controls via the Animal (Scientific Procedures) Act. Details of regulation of animal use in scientific procedures, and current legislation, can be located at the Home Office website (refer to Annex 1).

Research involving animals will require Home Office licences for the University, investigator and project, application forms for which are also available on the website. All Researchers and support staff have a duty to maintain high standards of care for the animals involved in the research. Exemplary levels of animal husbandry and welfare under veterinary supervision are required, and must be maintained. University guidelines on the care and use of animals in research and advice regarding Home Office Licences can be obtained from the Biological Standards Officer.

If Researchers consider that animals involved in research are subject to unreasonable risk or harm, they must report their concerns to their manager, or other appropriate person in the University, and where required, this will be reported to the appropriate regulatory authority.

### **3.8 Clinical Research**

#### **3.8.1 Research Governance Framework for Health and Social Care (RGF)**

The RGF is relevant to research conducted by the NHS or using NHS resources that might have an impact on the quality of NHS services. NHS resources means NHS patients (including those recruited through their association with NHS e.g. patients' relatives, those recruited through virtue of their status as former patients), patient tissues or data, staff, facilities or support.

For the full requirements of the RGF and further guidance on conducting research involving the NHS refer to [Annex 1](#).

#### **3.8.2 Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)**

The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments impose a number of legal responsibilities on Researchers and research institutions active in any investigation in human participants intended to:

- i. discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
- ii. identify any adverse reactions to one or more such products, or;
- iii. study absorption, distribution, metabolism and/or excretion of one or more such products with the object of ascertaining the safety or efficacy of those products.

Under the Regulations, it is illegal to start a Clinical Trial of an Investigational Medicinal Product in the UK until:

- i. the trial has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA); and
- ii. an ethics committee has given favourable approval of the protocol; and
- iii. a Sponsor for the trial has been agreed.

For further information on Clinical Trials refer to [Annex 1](#).

#### **3.8.3 The Human Tissue (HT) Act 2004**

The Human Tissue Act 2004 (HT Act) came into force on 1 September 2006 and established the Human Tissue Authority (HTA) to regulate and advise on the provisions of the Act. The HT Act refers to *Relevant Material*, which is any material, other than gametes, removed from the body that consists of or includes human cells (including waste products and fluids containing human cells, such as blood, urine and saliva). The HT Act provides a framework for regulating the removal (where appropriate), storage and use of human tissue for specific Scheduled Purposes, including research. The HTA has developed several Codes of Practice that must be followed when collecting, using or storing human tissue.

All research at Cardiff University that involves the use of human tissue must be registered with the Human Tissue Act Compliance Team and adhere to the Cardiff University Code of Practice for Human Tissue Research, the HTA Codes of Practice and all other relevant legal requirements and guidelines produced by appropriate bodies.

It is the researcher's responsibility to ensure a) all human tissue studies or collections are registered with the Human Tissue Act Compliance Team, and b) that the Cardiff University Codes of Practice for Human Tissue Research and all relevant HTA Codes of Practice and are followed.

The University HTA website (refer to [Annex 1](#)) provides specific information relating to the standards expected for the collection, use and storage of human tissue and provides access to the University's Standard Operating Procedures related to use of human tissue. Further information can be sought from the Human Tissue Act Compliance Team ([HTA@Cardiff.ac.uk](mailto:HTA@Cardiff.ac.uk)).

## **4. Intellectual Property**

### **4.1 Definition and Importance**

Intellectual property (IP) is the product of thought, creativity and intellectual effort. In the course of their research, consultancy and teaching, academic members of staff often generate IP (e.g. technical discoveries and methods, drawings, designs, experimental outcomes, pieces of prose and music). Funding bodies expect universities to commercialise IP arising from research they have funded (refer to [Annex 1](#)).

It is important therefore that IP generated by the University is commercially exploited, where appropriate, in order to:

- i. propagate research findings and help realise their fullest value;
- ii. aid local and national economic prosperity;
- iii. generate additional income for the University and its academic staff;
- iv. gain prestige for the University.

Although there is no guarantee of a financial return from the commercialisation of IP, where such return is realised Researchers can benefit financially through the University's revenue-sharing arrangements. Other advantages include:

- v. more opportunities for collaborative research;
- vi. entrepreneurial status and recognition;
- vii. the satisfaction of making a positive contribution to society.

At the earliest opportunity Researchers should bring to the attention of Research and Innovation Services any IP that may have commercial value.

### **4.2 Ownership**

IP generated through research and teaching activities conducted during employment at the University belongs to the University, and staff must notify the University of any invention or other intellectual property with potential commercial value.

Undergraduate and postgraduate students are not employed by the University and, as such, may own IP which they are solely responsible for producing. In some circumstances, however, a student will be required to assign his or her ownership interest in IP to the University or to a third party. This usually relates to postgraduate research students where the terms of the funding for their studentship requires such assignment. In other circumstances, the student's supervisor and/or other members of the research group in which the student is based will contribute to the creation of IP. In order to maximise the prospect of successfully commercialising the IP, the student will be encouraged to assign ownership rights to the University on the same basis as academic staff (which will include a share of any revenues generated from successful commercialisation).

The University will normally allow the author to own the copyright on any work to be published, and waive any claim it may have to benefits arising from publication. There are exceptions to this:

- i. copyright in course materials for the purpose of a course being run or to be run by the University;
- ii. copyright in any software program generated during the normal course of employment;
- iii. copyright in any works which may be necessary to protect rights in commercially exploitable IP;
- iv. copyright in any works commissioned by an external organisation where the terms and conditions of the commission require copyright to be transferred to that organisation.

IP or University expertise can also be exploited by creating spin-out companies. The University encourages and supports the establishment of appropriate spin-out companies and has developed a number of funding mechanisms for this purpose. Research and Innovation Services will work with staff in developing business proposals and obtaining the necessary University approvals. Research and Innovation Services will also assist in locating sources of finance for spin-out companies. For further information on establishing spin-out companies and similar enterprises, contact Research and Innovation Services.

### **4.3 Protection**

Researchers should safeguard their own interests, those of the University and those of any funder or collaborating body in relation to IP. In most countries of the world, prior disclosure will invalidate any patent application and harm potential commercial benefits. Researchers should not, therefore, disclose an idea to any party not employed by the University, either verbally or in writing, until steps have been taken to protect the IP. After obtaining the appropriate protection, the idea or results may then be published in the normal way.

When a piece of research is believed to have commercial potential, immediate steps can be taken to protect the idea through filing a patent application. To be patentable, an invention must be novel, include an inventive step not immediately obvious and be capable of industrial application. Research and Innovation Services is responsible for managing the University's patent budget and it will discuss and agree with the inventor(s) the best means of protecting and exploiting the IP.

University College Cardiff Consultants Ltd (UC3) is the University's patent holding company, and is the vehicle for exploiting on behalf of the University, patents and other Intellectual Property Rights. When a licensing or similar commercialisation agreement has been secured with a company, Research and Innovation Services will ensure its terms are complied with, monitor the receipt of royalties to the University and arrange the distribution of income to inventors, Schools and the University.

## **5. Conflicts of Interest**

A conflict of interest is a conflict between the private interests and the official responsibilities of a person in a position of trust. The initial responsibility for managing conflicts of interest rests with the individual Researcher. Researchers should recognise that conflicts of interest may have a negative impact on research. The fundamental requirement is that conflicts of interest, whether actual or potential, should be identified, declared and addressed as soon as they become apparent. Responsibility for identifying and declaring conflicts of interest lies with all individuals involved in research. Researchers should comply with the University's policy for addressing conflicts of interest, as well as any external requirements relating to conflicts of interest. This disclosure will usually be made to the relevant Head of School and the individual concerned will then comply with their

direction. If in doubt, it should be considered best practice in the first instance to disclose any potential conflicts of interest and seek advice from Research and Innovation Services.

For further information refer to the University's Policy and Guidance on Conflicts of Interest (refer to [Annex 1](#)).

## 6. Concluding Statement

This Research Integrity and Governance Code of Practice aims to enhance the professional, open and honest research culture already apparent within the University, whilst not infringing upon the fundamental pursuit of greater knowledge and understanding.

All external standards applicable to the research and any relevant stakeholder requirements must be complied with as well as the University's common law and statutory obligations.

<b>Acknowledgements</b>	
Cardiff University gratefully acknowledges the following organisations producing some aspects of this Code of Practice:	
Edinburgh University	Code of Research Practice
RCUK	RCUK Policy and Code of Conduct on the Governance of Good Research Conduct
NISCHR	Research Governance Framework for Health and Social Care in Wales
UK Research Integrity Office	Code of Practice for Research: Promoting good practice and preventing misconduct
Universities UK	The Concordat to Support Research Integrity

If you require further information regarding this Code of Practice, please contact [resgov@cardiff.ac.uk](mailto:resgov@cardiff.ac.uk)

## **Annex 1: Source Material and Related Policies and Guidelines**

### **2.2 Honesty & Integrity**

- The University's 'Procedures for **Dealing with Allegations of Misconduct** in Academic Research'  
<http://www.cardiff.ac.uk/govrn/cocom/academic/index.html>

### **2.3 Openness**

- Research Councils UK Policy on Open Access  
<http://www.rcuk.ac.uk/research/openaccess/>
- Research Councils UK Data Policy  
<http://www.rcuk.ac.uk/research/datapolicy/>

### **2.4 Accountability & Responsibility**

- University **Safety Health & Environment** Policy Statement  
<http://www.cf.ac.uk/osheu/safety/index.html>
- University's **Finance Regulations**  
<http://www.cardiff.ac.uk/fince/resources/FinRegs2012.pdf>

### **3.1 Leadership & Supervision**

- UK Research Integrity Office Recommended checklist for researchers  
<http://www.ukrio.org/wp-content/uploads/UKRIO-Recommended-Checklist-for-Researchers.pdf>

### **3.2 Research Data & Records Management**

- The University's guidance for **Managing Research Data and Records**  
<http://www.cardiff.ac.uk/govrn/cocom/recordsmanagement/guidanceleaflets/index.html>
- The **Information Security Framework** Programme  
<http://sites.cardiff.ac.uk/isf/>
- The University's **Research Data & Information Management Programme's** webpages  
<http://www.cardiff.ac.uk/insrv/researchdata/index.html>
- **Records Retention Policy**  
<http://www.cardiff.ac.uk/govrn/cocom/recordsmanagement/recordsretention/recordreten.html>
- **University's Framework-SOPs** for Clinical Trials of an IMP  
<http://www.cardiff.ac.uk/racdv/resgov/forms/forms-procedures-sops-and-guidelines.html>

### **3.3 Data Protection Act**

- The University's **guidance on Data Protection for Researchers**  
<http://www.cardiff.ac.uk/govrn/cocom/accinf/dataprotection/datap/dpresearchers/dpresearch.html>
- Contact details for Data Protection Officer  
<http://www.cardiff.ac.uk/govrn/cocom/accinf/dataprotection/datap/index.html>

### **3.4 Publication & Authorship**

- University's Institutional Repository (ORCA)  
<http://orca.cf.ac.uk/>
- The University's policy on **open access publications**  
<http://www.cardiff.ac.uk/insrv/forresearchers/openaccess/policy/index.html>
- The University's guidance on putting your thesis online  
<http://learning.cf.ac.uk/quality/pgr/code/thesis-preparation-and-examination/uploading-your-thesis-to-orca-important-information/>

- Committee on Publication Ethics (COPE)  
<http://publicationethics.org/>

### **3.5 Training**

- **Concordat to Support Career Development of Researchers**  
<http://www.vitae.ac.uk/policy-practice/505181/Concordat-to-Support-the-Career-Development-of-Researchers.html>
- The University's **Progress Review Procedures**  
<http://www.cardiff.ac.uk/humrs/training/perfreview/index.html>
- **Leadership & Management Framework**  
<http://www.cf.ac.uk/humrs/training/perfreview/appraisal/Cardiff%20University%20Leadership%20&%20Management%20Framework.pdf>
- **Researcher Development Programme**  
<https://www.vitae.ac.uk/researchers-professional-development/about-the-vitae-researcher-development-framework>
- **Training for Research Staff**  
<http://www.cardiff.ac.uk/researchstaff>  
<http://www.cardiff.ac.uk/humrs/training/programme/index.html>
- **Training for Postgraduates**  
<http://www.cardiff.ac.uk/ugc/training>

### **3.6 Equality and Diversity**

- **University Equality and Diversity web pages and policy**  
<http://www.cardiff.ac.uk/govrn/cocom/equalityanddiversity/index.html>
- **Equality and Research**  
<http://www.cardiff.ac.uk/govrn/cocom/equalityanddiversity/equalityandresearch/equality-and-research.html>

### **3.7 Ethical Requirements**

- **Research Involving Human Participants, Human Material or Human Data** at Cardiff University  
<http://www.cardiff.ac.uk/racdv/ethics/index.html>
- **Cardiff University Research Ethics Committee Procedures**  
<http://www.cardiff.ac.uk/racdv/ethics/urec/index.html>
- **Research Involving Animals**  
<https://www.gov.uk/research-and-testing-using-animals>

### **3.8 Clinical Research**

- **Research Governance Framework for Health and Social Care (RGF)**  
<http://www.cardiff.ac.uk/racdv/resgov/governance/index.html>
- **Medicines for Human Use (Clinical Trials) Regulations 2004**  
<http://www.cardiff.ac.uk/racdv/resgov/clintrials/index.html>
- University **Human Tissue** website  
<http://www.cf.ac.uk/govrn/cocom/humantissueact/index.html>

## **4. Intellectual Property**

- The University's **Research and Innovation Services**  
<http://www.cardiff.ac.uk/racdv/techtransfer/index.html>

## **5. Conflicts of Interest**

- The University's **Guidance on Conflicts of Interest**  
<http://www.cf.ac.uk/humrs/staffinfo/disclosure/index.html>

## **Annex 2: Research Integrity Responsibilities at Cardiff University**

[Organogram to be inserted when available]