Research Ethics Policy, Terms of Reference and Operating Procedures for University Ethics Sub Group and Faculty Research Ethics Committees

This document sets out the policy and procedures for the establishment of ethics review processes at the University of South Wales (USW). Research integrity is at the core of high quality research and science. All research at USW should adhere to the highest ethical standards and **where necessary must be submitted for independent ethical review.**

The University is required by the Concordat to Support Research Integrity (2012) as well as the health focused UK Policy Framework for Health and Social Care Research (2018) to have appropriate procedures for ensuring the integrity of research, and compliance is a condition of receiving HEFCE funding. Researchers are also expected to carry out research in accordance with the USW Code of Good Research Practice.

For staff and students the USW approach is based upon the ethical scrutiny of individual research projects by the Faculty Research Ethics Committees (FREC) which have been established in each of the faculties of the University. These operate to standard terms of reference, composition and procedures as described within this document.

It is the researcher's responsibility to identify the potential risks their research may pose for participants and to address these in both the ethics application and the health and safety risk assessment. Separate guidance on risk assessment can be found on the University's Health and Safety webpages.

This policy applies to all faculties and corporate departments, as well as external individuals or organisations undertaking research under the auspices of the University.

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Each criterrion has been obtained from either or all of the following guidelines - NICE (NG100), MSK Foot Health Standards, ARMA inflammatory arthritis, NWCEG Guidelines

Contents

1 What Types of Research Require Ethical Review?

When considering the potential ethical implications of proposed research activity, three key elements must be considered:

- Risks to participants (balanced against whether the research might help any participants)
- Risks to the Research team (could the proposed locations or subject matter potentially harm the researcher/s?)
- Risk to the reputation of the University?

All research, practice based research, and service evaluation involving any of the below is required to seek ethical approval. Externally funded research must as a minimum meet the standards expected of funding bodies.

1. human participants*
2. human data* (including personal identifiable data covered by the GDPR 2018)
3. is culturally or socially controversial or has the potential to infringe the rights of others
4. research with animals
5. research related to the study of security issues or implied in the PREVENT legislation
6. has potential for negative impacts on the environment or society
7. contains risk for the researcher or the University reputation

*Secondary analysis of data from such studies must also seek ethical approval

Research is defined below in 'definition 2.1'

1.1 No Research Ethics Application Required

If your research **does not** meet the criteria to seek research ethics review then your research does not need to formally apply for research ethics approval. For example, a literature review would normally not require formal research ethics approval, but this would still be dependent on the subject matter. Caution must be taken, and advice should be sought where there is any uncertainty. In this example, a literature review that intends or might require access to illegal material, or highly sensitive or contentious subject areas (e.g. but not limited to - paedophilia, violence, or crime) would still require ethical approval.

PLEASE NOTE - all activities conducted under the auspices of USW must be conducted in accordance with accepted ethical practice (minimisation of harm, benefit not harm, and confidentiality) as well as recognised professional codes of conduct.

If your research **does** meet the criteria for research ethics approval please refer to section 1.2 to determine if your research is considered **HIGH** or **LOW RISK**.

1.2 Is Your Research High Risk or Low Risk?

If your research involves any of the items listed below then your research is considered **HIGH RISK** and should proceed to obtain Research Ethics approval via the High Risk pathway for the USW lead researcher's faculty.

1	Involves anyone considered vulnerable*, such as: • Anyone under 18 • Adults at risk* Unless in an accredited setting and accompanied by a carer or professional with a duty of care

2	Involves: • Adults or children with diagnosed mental illness/terminal illness/dementia/in a residential care home • Adults or children in emergency situations • Adults or children with limited capacity to consent*
3	Involves those who are "dependent" on others (such as school children or students) Unless in an accredited setting associated with normal working conditions or routines and within normal operating hours, such as a cultural institution, pre-school, school, university, or youth club where the research is carried out as part of professional practice such as curriculum development
4	Requires full external ethical approval, for example the NHS via IRAS. However, in some cases the Faculty Research Ethics Chair can review via Chair's action.
5	Requires a Human Tissue Act license
6	Involves "covert" procedures as in covert observation studies
7	Involves anything considered "sensitive". For example, does carry a risk of those involved disclosing information which compromises the research (e.g., illegal activities; activities where moral opinion may differ, potential professional misconduct – work errors).
8	Induces significant psychological stress or anxiety, or produce humiliation* or cause more than fleeting harm / negative consequences beyond the risks encountered in the normal life of the participants (and where the potential for fleeting "harm" is clearly detailed in the participant information sheet). If in doubt regarding definition of the above terminology please contact the research governance office.
9	Involves administration of drugs, placebos or other substances (such as food substances or vitamins) as part of this study.
10	Involves invasive procedures (including but not limited to blood sampling, collection of biological samples, or passing current through a participant's body, etc.).
11	Offers any financial inducements to participate in the study.
12	Intends to recruit serving prisoners or serving young offenders via HMPPS.
	* Defined in section 2

If your research requires ethical approval but does not involve any of the above, then it is appropriate to consider the activity **LOW RISK**.

For the avoidance of doubt always seek advice from the Faculty Research Ethics Chair.

1.3 Animal Research

Research on 'protected animals' is strictly regulated by the Home Office under the Animal Scientific Procedures Act 1986 see:
https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986

"A protected animal" for the purposes of this Act means any living vertebrate other than man and any living cephalopod. Research with live (or the killing of) such animals is only permitted under licence. USW does not hold a licence and therefore research with animals on USW premises is not currently permitted.

1.4 Human Tissue

The University does not currently have a Human Tissue Authority (HTA) License, and any activity utilising samples derived or obtained from humans must comply with the conditions enforced by not having a license. Therefore, the regulations state that all samples that are on the premises for any time period (longer than a few days) must be covered by either a

HTA license, or current/valid NHS Ethics Approval. Samples that are not covered must be discarded in accordance with the relevant laboratory standard operating procedures. Samples that have been processed to be 100% acellular are exempt from HTA regulation.

1.5 General Data Protection Regulation (GDPR) 2018

The GDPR 2018 legislation is relevant to **ALL** research that seeks to collect or process personal data. The data can be obtained directly from a participant or obtained via a third party. The GDPR adopts a "broad" definition of research, encompassing the activities of public and private entities alike. The GDPR aims to encourage innovation, as long as organisations implement appropriate safeguards.

The University has produced a guidance document titled 'GDPR for Research' which provides practical guidance on the new legislation with respect to research involving personal data.

It should be noted that actions required to comply with the GDPR do not replace or supersede actions that would be required under any other framework such as ethical approval – **they must exist together**.

All research that intends to collect and store personal data (including special category data) must adhere to, and comply with the GDPR (2018) and ensure that they are familiar with the expectations and requirements of all related legislation.

For more information: http://uso.southwales.ac.uk/ig/dp/index.html

1.6 Data re-use (secondary data)

The University will **not normally** require formal ethical review for **secondary data analysis** as long as **all** below apply:

- The data set is completely anonymous with no personal information being present or collected (this does not include datasets that are already owned but require anonymisation).
- The data is not considered to be sensitive or confidential in nature.
- The data poses no risk to USW's or other organisation's reputation.
- The data is freely available via public means. If the data is freely available on the Internet, books or other public forum, permission for further use and analysis is implied. However, the ownership of the original data must be acknowledged.
- You are able to prove that the data will be used for a purpose which falls within the remit of the original consent provided by data subjects (this will be clear for publicly available data sets) and that additional consent is not required.

Otherwise, researchers must seek ethical approval in accordance with the appropriate approval pathway described within the University Research Ethics Policy. Researchers should determine which approval route is most appropriate using the USW definitions of High, Low and Zero Risk research as contained within the USW Research Ethics Policy.

A data producer such as the Office of National Statistics or other government departments may have restrictions relating to access and re-use which must be complied with. The fact that an original piece of research has gone through ethics review for its collection does not rule out ethics issues arising from its re-use.

1.7 Course/Module Evaluation OR Evaluation of Teaching Methods/Practice

The University will **not normally** require formal ethical review for these activities as long as:

- It is not research (see definition in 3.1)
- It is only related to teaching practice, teaching methods, or evaluation of an academic module or course
- The data set is completely anonymous with no personal information being collected (this does not include datasets that you possess currently that require anonymisation)
- The data is not considered to be sensitive or confidential in nature
- The activity is low risk in accordance with the University Research Ethics policy
- The evaluation is not likely to upset or disturb participants

Please note - If you intend to publish your findings or think there will be a possibility that you will want to publish your findings, then a low risk application should be submitted via the low risk pathway. If the low risk committee approves your evaluation, this would satisfy the requirements of publishers

1.8 Forbidden and permitted activities prior to ethical approval

The following are forbidden prior to ethical approval being granted (not exhaustive): data collection, data analysis, and contact with or recruitment of participants.

It is therefore permissible to design the study, design data collection tools, contact gatekeepers for permission to approach their participants once ethical approval is granted, and conduct literature reviews.

2 Definitions

2.1 Research

In the context of Ethical Approval '**Research'** is any activity that meets the definition of research as described by the Frascati Definition (summarised below), or is an activity that intends to be published which may also include **'Service Evaluation'** or **'Audit'**.

Research and experimental development (R&D) comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.

The term R&D covers three activities: basic research, applied research and experimental development.

Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.

Applied research is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.

Experimental development is systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially

those already produced or installed. R&D covers both formal R&D in R&D units and informal or occasional R&D in other units.

Further information is available: http://www.oecd-ilibrary.org/science-and-technology/frascati-manual-2015/concepts-and-definitions-for-identifying-r-amp-d_9789264239012-4-en

2.2 Capacity to Consent

Capacity is the ability to understand, retain and use information to make a decision, and to communicate any decision made. Capacity is time and decision specific, which means that every decision needs to be considered separately at the time the decision is required. Some people have capacity for some decisions but not for others, this can change over time and is never diagnosis specific. People's capacity can fluctuate and can be impaired by many things. People with capacity can consent to take part in research. The Mental Capacity Act makes special provisions to allow people with impaired capacity to participate in research.

The Mental Capacity Act (MCA) 2005 is a law (legislation) for England and Wales that is designed to protect and empower individuals who may lack capacity to make their own decisions. It facilitates the inclusion of individuals with impaired or fluctuating capacity in research. The Act applies to any research involving people who are unable to give their consent within England and Wales, wherever it takes place, except for clinical trials of investigational medicinal products, which are covered by different legislation.

The MCA has five guiding principles:

- All adults are presumed to have sufficient capacity to make decisions unless there is evidence this is not the case.
- Individuals must be helped to make their own decisions as far as practical.
- Irrational decision making does not imply an individual lacks capacity as long as they understand the reality of their situation.
- All decisions should be in the best interest of the person lacking capacity.
- All decision and actions must represent the least restriction to the individual's rights and freedoms.

An individual's interests must always be more important than those of the research project, and any objection made by a person who lacks capacity must be respected.
It is the responsibility of the researcher, with appropriate consultation, to decide whether someone has the capacity to consent for research. Capacity can change and it should be assessed at the time a decision is required.

Assessment should be undertaken by an appropriately qualified health professional or researcher. In this case, appropriately qualified means someone who has, within the last three years, undertaken training or refresher training in taking and obtaining consent in research with adults lacking capacity. It would be expected that evidence of training would be provided in the ethics submission.

For further information please consult:
https://www.healthandcareresearch.gov.wales/uploads/News/research_and_impaired_mental_capacity_in_adults-guidance_for_researchers.pdf

2.3 Humiliation

Humiliation: Make (someone) feel ashamed and foolish by injuring their dignity and/or pride. (https://en.oxforddictionaries.com/definition/humiliate)

2.4 Vulnerability / Children / Adults at Risk (of harm)

The Oxford dictionary defines Vulnerable as '(of a person) in need of special care, support, or protection because of age, disability, or risk of harm, abuse, or neglect'.

Vulnerable groups include children (under the age of 18), and adults at risk (of harm). While an exact definition is difficult to obtain, researchers should be mindful of the context within which participants exist and to remember that in any situation, an individual may be vulnerable despite a researcher's inability to determine their vulnerability.

Researchers should be mindful of an individual's ability to understand what is being asked of them, institutional contexts (where some sense of coercion may be felt), individual circumstances, and the sensitivity of the issues/themes being explored.

To that end, the definitions here are in accordance with UK legislation and in reference to a framework of contextual considerations. In accordance with current UK legislation that may be subject to amendment or change, and in reference to a framework of contextual considerations. Where legislation changes part way through a study or investigation, it is the responsibility of the Principle Investigator to comply with any new definitions, changes or caveats.

Research that is conducted abroad would need to ensure that in-country norms and safeguarding are maintained.

Children

The Children Act 1989 defines a 'child' as a person under the age of 18.The Health and Safety at Work Regulations 1999 (Reg 19) defines the term "children/child" to apply to persons between birth and 16 years. Individuals of 16 and 17 years are 'young persons', anyone over 18 is considered an adult.

The term 'child' is used within this document to refer to anyone under the age of 18.

"Young person" can be used to refer to someone who might not perceive themselves as a child, but who is still legally defined as a child being under 18.

Adults at Risk (of harm)

In Wales, *'the Social Services and Wellbeing Act 2014'*, describes an "adult at risk" as:
'A person who is 18 years of age or over, and who is experiencing or is at risk of abuse or neglect, has needs for care and support (whether or not the local authority is meeting any of those needs), *and* as a result of those needs is unable to protect himself or herself against the abuse or neglect or the risk of it.'

People with learning disabilities, mental health problems, older people and disabled people **may** fall within this definition. Other legislation such as that governing DBS checks may give different variations of the definition and should be applied accordingly.

What to do if abuse is reported or suspected?
Staff and students should familiarise themselves with the USW Safeguarding Policy (V3 Jan 2019). Appendix 1 of the policy outlines what should be done if abuse is suspected or disclosed during the course of a USW related activity, such as research.

Full USW safeguarding policy:
https://www.southwales.ac.uk/documents/1085/Safeguarding_Policy_v3_Jan_19.pdf

3 Establishment of Ethics Committees

The University has established the University Ethics Sub Group (UESG) which reports to the University Research Committee (RC) chaired by the DVC (Academic), and to the Quality Assurance Committee (QAC) which is chaired by the PVC (Learning, Teaching & Student Experience).

Each Faculty has a Faculty Research Ethics Committee (FREC). The composition, terms of reference and procedures have to be approved by the University Ethics Sub Group (UESG) and therefore are sub-groups of UESG.

3.1 Faculty Arrangements

The faculty of **Faulty of Creative Industries (FCI)** utilise their Faculty Research Committee as a Faculty Research Ethics Committee (FREC) for reviewing and approving high risk research ethics applications and audit/oversee low risk ethics arrangements within the faculty:

The **Faculty of Life Science and Education (FLSE)** uses a designated Faculty Research Ethics Committee to review and approve high-risk applications, and audit/oversee arrangements for low risk review and approval. School Research Ethics Sub Committees specifically review and approve low risk applications.

The **Faculty of Business and Society (FBS)** and the **Faculty of Computing, Engineering and Science (FCES)** uses a designated Faculty Research Ethics Committee to review and approve high risk research ethics applications, and audit/oversee low risk ethics arrangements.

The Terms of Reference of the UESG and FRECs are provided in Appendix 1 and 2 of this document.

FRECs are chaired by a **Faculty Research Ethics Chair** whose role is outlined in appendix 3.

3.2 Corporate Departments

All corporate departments that intend to conduct research or work which meets the criteria for Research Ethics Review (such as evaluations, or work intended for publication) must seek ethical approval.

If the target population is pan University, or using one or more corporate departments then an ethics application must be submitted to the Secretary of the University Ethics Sub Group, the route to review will depend on the risk rating of the research as in section 5.1.

If the research carried out by a Corporate Department intends to target individuals within a single specific faculty, applications should be made to that single Faculty Research Ethics Committee. For further guidance see section 5.1 ‘Routes to high risk / low risk ethical approval’.

3.3 Partner Colleges and distance learning courses

Where partner colleges are engaging in research that meets the requirements for ethical approval, approval should be sought from the Faculty to which their courses belong. Advice and guidance is available to partner colleges, and Faculty Research Ethics Chairs should be consulted where there is any doubt or where advice is required.

Courses that are being carried out either under the auspices, or in the name of USW which are administered remotely as part of distance learning or online learning are required to comply with USW policy and process, including this one which covers research ethical approval. These courses are expected to undergo comparable levels of ethical scrutiny in the same way as projects or studies that are being completed by staff and students who attend the University routinely.

3.4 Overseas Research and ethical approval

Despite taking place overseas USW is still responsible for all such research activity – including the safety, management of risk, suitability of researchers, and ethical scrutiny. Research that is intended for overseas locations must therefore adhere to USW policy and obtain ethical approval from USW if the activity meets the criteria for research ethics approval.
Researchers should be mindful that there may also be 'local' requirements for ethical approval at the destination which cannot be overlooked before the research can commence.

NB. Research ethics approval from USW is required to confirm that the proposed research meets our institutional expectations and standards but can never constitute 'permission' for any research to commence where there might also be local requirements for approval.

Proposed research that encompasses either overseas data collection or risk to the institution should seek preliminary institutional support at the earliest possible opportunity, via the **Research Risk Matrix** process. In this context, support should be gained prior to any funding application being submitted, for example.

4 Composition and Membership

The committee reviewing research ethics applications should provide independent, competent and timely review of the ethics of proposed research studies. In their decision-making, research ethics committees need to be mindful of being independent from political, institutional, profession-related or market influences. Membership of committees should recognise the diversity of the research community and research interests.
Members should declare any conflict of interest that may colour or affect their decision making or judgement against any application.
Any appointed member is expected to preserve confidentiality with regard to any aspect of research that is under review, the meeting deliberations or agenda items.

The time required to undertake the role of a committee member or the associated training must be protected by the University. Therefore, it should be acknowledged that participation in ethics committee membership is a fundamentally important role. This is further emphasised by the Universities commitment to uphold the *Concordat to Support Research Integrity (2012)* which also commits the University to resource this function appropriately.

Member training

Members of Ethics Committees will require training upon appointment and as continuing education. Therefore, members must agree to undergo initial training and continuing training. It is particularly important that Faculty Research Ethics Chairs and Deputies are up to date

with current ethical issues and considerations and will therefore agree to undertake any additional training identified for them by the University.

The role and responsibilities of Faculty Research Ethics Committee members are set out in Appendix 4.

4.1 Formation of additional or new Research Ethics Committees within a Faculty

It is feasible that over time the forming of new Research Ethics Committees within a Faculty may be required. All such additional committees must always feed into the existing Faculty Research Ethics Committee.

The justification for an additional Research Ethics Committee within a faculty can only be based on:

1. Improving the potential quality of ethics reviews (such as where applicants are currently applying to a committee that does not hold relevant expertise),

or

2. Where the volume of applications could be managed more efficiently by forming a new committee.

Where a faculty identifies the need to form a new research ethics committee the following process should be followed:

Where there is a justified need, a panel comprising of the Dean of Faculty, Head of Research and the Faculty Research Ethics Chair must agree to the formation of a new faculty committee and identify the individuals who will potentially make up the membership.

Once agreed, the intention to form a new committee must be reported the Pro Vice Chancellor Research as Chair of the University Ethics Sub Group who will consider final approval.

5 Approval of Research Applications by the Faculty Research Ethics Committees

All research that requires research ethics approval in accordance with this policy must do so. **Failure to follow the University's policy and procedures on ethical review of research may be regarded as research misconduct**. See SECTION 11: USW Research Misconduct Policy.

Supervisors (and students) should be reminded that gaining ethical approval cannot be guaranteed and that some applications can take time to progress through the risk-based committee structure. Therefore, research projects cannot rely on meeting scheduled assessment deadlines while applying for ethical approval.

5.1 Routes to High Risk / Low Risk approval

Where research requires ethical approval, the university operates an ethical review system that distinguishes whether research is low or high risk. The pathways for approval are illustrated appendix 5 & 6.

Type of research project	Proposer	Approval route

FBS / FCI / FCES		
No further ethics review required	All staff, all students	No requirement to seek research ethics approval, sign off by the academic supervisor (students), or principal investigator/lead researcher (staff research)
Low risk research projects	Staff	To be submitted to the Faculty Research Ethics Chair for review. The Faculty Research Ethics Chair may use subject experts to contribute to any review where additional expertise are deemed necessary.
	Undergraduate student	Supervisors will help to review the ethical issues of a project but approval and sign off must be from members of the module team who are not the dissertation supervisor – this is to protect the lead supervisor and ensure there is external scrutiny. **ALL approval activity including application paperwork must be reported and sent to the Faculty Research Ethics Committee as part of the audit trail.**
	Postgraduate taught (MSc, MA)	Supervisors will help to review the ethical issues of a project but approval and sign off must be from members of the module team who are not the dissertation supervisor – this is to protect the lead supervisor and ensure there is external scrutiny. **ALL approval activity including application paperwork must be reported and sent to the Faculty Research Ethics Committee as part of the audit trail.**
	Postgraduate Research (MRes, MPhil, PhD / Doctoral)	Applications should be submitted to the Faculty Research Programmes Committee (FRPC) who will consider the application in conjunction with the Faculty Research Ethics Chair.
High risk research Projects	All staff, all students	All high risk research must be submitted to the Faculty Research Ethics Committee for review.
FLSE		
Zero risk (no ethics review required)	All staff, all students	No requirement to seek research ethics approval, sign off by the academic supervisor (students), or principal investigator/lead researcher (staff research)
Low risk research projects	Staff	Applications must be submitted to the relevant School Ethics Sub Committee.
	Postgraduate (MSc, MA, MRes, MPhil, and PhD/Doctoral research degrees)	Applications must be submitted to the relevant School Ethics Sub Committee.
	Undergraduate student	Applications must be ethically approved by members of the module team who are not their dissertation supervisor – this is to protect the lead supervisor and ensure there is external scrutiny.

		Where there are any doubts, the Faculty Research Ethics Chair should be contacted for advice. **ALL approval activity including application paperwork must be reported and sent to the School Low Risk Ethics Committee as part of the audit trail.**
High risk research projects	All staff, all students	Applications must be submitted to the Faculty Research Ethics Committee for review.
Corporate Departments		
Pan University research / or research using one or more corporate departments		
Low Risk		Applications must be submitted to the Secretary of the University Ethics Sub Group for Chairs Action review
High Risk		Applications must be submitted to the Secretary of the University Ethics Sub Group for Committee review. Please note timescales can be long depending on availability of members
Research intended to target individuals within a single specific faculty only must submit an application to the appropriate Faculty Research Ethics Committee.		

5.2 Role of the student supervisor

All student research must be supervised and the supervisor is responsible for the conduct of the research and to ensure that the appropriate level of ethical review has taken place before any data collection commences. If helpful, reviews should utilise a **Faculty Ethics 'Guidance for reviewers'** sheet to ensure that the range of issues considered are consistent for all projects.

A supervisor should request additional ethical scrutiny by the Faculty Research Ethics Committee for any student project if they have ethical concerns. The Faculty Research Ethics Chair should be contacted for advice if required.

A supervisor must raise concerns to the Faculty Research Ethics Chair if they have concerns around the conduct of the student or the project being carried out, as soon as possible.

Undergraduate Student Research

Supervisors should not be put under pressure to sign off student projects. Any supervisor who is unsure of whether additional scrutiny is needed should speak with their line manager or the Faculty Research Ethics Chair.

Where possible, undergraduate students should normally only undertake research that is considered to **not require ethical approval** or at most is **low risk research**. This helps to protect the participants, researchers, and the reputation of the University. Exceptions should be discussed as early as possible with the Faculty Research Ethics Chair.

5.3 Role of the Faculty Research Ethics Committee

The primary task of the Faculty Research Ethics Committees lies in the ethical review of research ethics applications and their supporting documents, with special attention given to - the nature of any intervention, safety and protection for participants and researchers, to the informed consent process, documentation, and to the suitability and feasibility of the proposal.

A decision by an ethics committee to give ethical approval to a research project does not imply an expert assessment of all possible ethical issues or of all possible dangers or risks involved, **nor does it detract in any way from the ultimate responsibility which researchers must themselves have for all research which they carry out and for its effects on human participants**. The Committees are dependent upon information supplied by the researcher. This information is expected to be properly researched, full, truthful and accurate.

In order to give ethical approval for human participant research, the ethics committee should be adequately reassured about such issues as:

- The design and conduct of the study
- The recruitment of research participants
- The informed consent process
- The care and protection of research participants and others affected by the research
- The right of research participants to withdraw
- The protection of research participants' confidentiality
- Research data management plans and data security
- Research data sharing arrangements or data disposal, including General Data Protection Regulation (2018) and Data Protection Act (2018) requirements
- Storage arrangements for human derived materials (acellular materials only)*
- Any community considerations both within and externally to the University
- That the researchers are clearly qualified to carry out their roles within the study

* The University does not have a Human Tissue Authority (HTA) License, and any activity utilising samples derived or obtained from humans must comply with the conditions enforced by not having a license. Therefore, the regulations state that all samples that are on the premises for any time period (longer than a few days) must be covered by either a HTA license, or current/valid NHS Ethics Approval. Samples that are not covered must be discarded in accordance with the relevant laboratory standard operating procedures. Samples that have been processed to be 100% acellular are exempt from HTA regulation.

A decision to grant ethical approval to a research project does not constitute a precedent for similar research and each application will be considered individually, on its own merit and in light of present circumstances.

A Faculty Research Ethics Committee may offer four outcomes:

1. Approval
2. Resubmission for Chair's Action addressing feedback provided from the review.
3. Resubmission to a future meeting, addressing feedback provided from the review. (Where the amendments required are considered significant enough to warrant discussion by the committee again, at the Chair's discretion).
4. Escalation to the Pro Vice Chancellor for Research and the University Ethics Sub Group

5.4 Required components of a research ethics application

- Completed ethics application form (mandatory)

- An overview of the current qualifications and training undertaken by the research team, including all USW and external team members to confirm they are qualified and competent to undertake their role in the project[1] (mandatory)
- Risk assessment (mandatory)
- Supporting documents such as consent forms and participant information sheets (where being used)
- Data collection tools such as questionnaires, surveys, interview schedule (where being used)
- Evidence from the gatekeepers of participants or data (e.g. such as a head teacher of a school, or coordinator of a patient support network, director of a charity), to confirm that they give permission for the individuals or data they are responsible for to be used in the research
- Where there are non-USW research team members, such as external academics, confirmation that they understand their role in the research and confirmation that they are happy to take part

5.5 NHS / Other External Agency Ethical Approval

It is sometimes the case that researchers are required to seek ethical approval from external organisations, such as an NHS Research Ethics Committee, Prison Service, or the Research Ethics Committee of a collaborating University. This will always be in addition to the University ethics approval process.

Where the University is taking responsibility for research, the research ethics application requires internal review by the appropriate Faculty Research Ethics Chair. Only **AFTER** approval from the Faculty Research Ethics Chair should the ethics application be submitted to the external organisation. The Faculty Research Ethics Chair may request that the application to submitted for full ethical review at faculty level before being submitted for external consideration.

In accordance with the 'UK Framework Policy for Health and Social Care Research' all research intended for the NHS requires a **sponsor**. Before USW will act as a sponsor for your study you are required to seek **Sponsorship from USW.** This process can be found on the USW research ethics intranet pages.

The ‘representative of the sponsor’ is the Director of Research and Business Engagement.

Where USW is not the organisation taking responsibility for the research, the researcher will be expected to provide evidence of any ethics approval given by an external ethics committee to the appropriate Faculty Research Ethics Chair for ratification by that Faculty Research Ethics Committee and **the research data collection phase cannot begin until internal ratification has been granted.**

5.6 Legal Issues

It is the researcher’s responsibility to ensure that the research conforms to relevant legal or regulatory requirements and to seek appropriate guidance through the Faculty Research Ethics Chair or Research Governance Officer, or where appropriate from other University departments.

Researchers have ultimate responsibility for all research which they carry out and for its effects on human participants.

[1] This will be underpinned by the ***USW Research Training Passport*** concept.

6 Processing Ethics Applications

The Faculty Research Ethics Committees shall make decisions at scheduled meetings at which a quorum is present. The regularly scheduled meeting dates shall be announced in advance so that the submission of applications can be planned.

- For the University Ethics Sub Group to be quorate, one third of the membership must be in attendance, including the University Ethics Committee Chair or a nominee.

- For Faculty Research Ethics Committees to be quorate, one third of the membership must in attendance, including the Faculty Research Ethics Chair or a nominee.

In exceptional circumstances, ethics applications can be considered between meetings and the Faculty Research Ethics Chair is responsible for ensuring that an appropriate level of scrutiny informs the decision. Applications should be reviewed in the same level of detail as any other ethics application. The decision will be reported to the next available meeting of the Committee for ratification.

In respect of a proposal being put forward by a member of the reviewing Committee, those involved in the research submission should withdraw from the meeting while the submission is considered.

Meetings shall be recorded in minutes and there shall be an approval procedure for the minutes, utilising the Committee to agree the record is accurate.

All ethics committees shall keep a register of all proposals (and outcomes) that come before them.

The Faculty Research Ethics Committees shall retain all relevant records, applications and documents for a period of at least six years or longer if required for legal, regulatory or insurance purposes. Advice should be taken from the University Officer responsible for record retention and management before records are destroyed. Records shall be made available upon request to any member of the Vice-Chancellor's Senior Management Team.

The Faculty Research Ethics Committees should always be able to demonstrate that they have acted responsibly in reaching a particular decision. When the faculty ethics committees reject research proposals, the reasons for that decision shall be made available to the applicant and, where appropriate, opportunities for resubmission provided. Where approved, the basis for that decision should be recorded.

The Faculty Research Ethics Committees shall consider valid applications, reach a decision and communicate the outcome to the applicant in a timely manner.

Any adverse events which occur as a result of the research should be notified immediately to the Faculty Research Ethics Chair that approved the research.

Where the research is terminated prematurely, a notification should be provided to the approving Faculty Research Ethics Chair within 14 days, indicating the reasons for early termination.

7 Audit

The University needs to be confident that its ethical review policies and procedures are robust and appropriately implemented. Being able to demonstrate this is part of quality management in relation to educational provision but also an important aspect of good research governance and ensuring that human participants in research have ethical protection. Faculties therefore have an important responsibility to ensure that there is an auditable process relating to the review of student research projects. Each Faculty will be expected to hold a register of Staff, Undergraduate, and Postgraduate level student projects that have sought research ethics approval. Inter faculty auditing can be employed to ensure independence.

8 Appealing the Decision of an Ethics Committee

There is no appeal against the decision of a Faculty Research Ethics Committees. Complaints on procedural grounds should be sent to the Chair of the University Ethics Sub Group

Complaints on grounds of procedural failing should provide:

- A clear statement of the issue/procedure that has not been acted upon appropriately.
- A clear rationale that underpins the complaint.
- A clear overview of the project in question and an overview of the interactions between the parties involved.

9 Requesting Changes to an Already Approved Research Ethics Application

Where amendments are made to the research protocol after ethical approval has been granted the research data collection must be paused until research ethics approval has been granted for the proposed changes.

The lead researcher (staff research) or/and supervisor (for student research) is responsible for notifying the ethics committee and requesting approval of amendments to the existing research protocol. A full justification for the change(s) must accompany the amended documentation.

Requests for amendment to an already approved protocol shall normally be dealt with through Chair's Action unless the amendments are considered significant enough to warrant discussion by the committee again. This is at the discretion of the reviewing committee. Changes to an already approved research protocol will void the current ethical approval for that project.

10 External research - seeking participants from USW

External organisations/institutions may wish to recruit USW staff or students as participants in their research. Such organisations must NOT approach USW personnel until ethical approval from the University has been given to their projects.

Where participants from a single faculty are required, approval from that faculty research ethics committee is required. This does not permit recruitment from across USW.

Where participants from across USW are required, ethical approval from the University Ethics Sub Group must be sought.

Unsolicited requests for participation that are posted on electronic noticeboards will be removed. All external requests and related recruitment material must state that the work has been given ethics approval by USW, including the committee that awarded approval and the date it was awarded.

11 Research Misconduct

The University Research Misconduct policy applies to all members of the institution involved in research. This will include staff and undergraduate and postgraduate students. It also applies to those who are not members of the institution, but who are conducting research under the auspices of the University, on the institution's premises, or using the institution's research facilities.

Research misconduct includes the following, whether deliberate, reckless or negligent:

- failure to obtain appropriate permission to conduct research
- deception in relation to research proposals
- unethical behaviour in the conduct of research, for example in relation to research subjects
- unauthorised use of information which was acquired confidentially
- deviation from good research practice, where this results in increased risk of harm to humans, other animals or the environment
- fabrication, falsification or corruption of research data
- distortion of research outcomes, by distortion or omission of data that do not fit expected results
- dishonest misinterpretation of results
- publication of data known or believed to be false or misleading
- plagiarism, or dishonest use of unacknowledged sources
- misquotation or misrepresentation of other authors
- inappropriate attribution of authorship
- fraud or other misuse of research funds or research equipment
- attempting, planning or conspiring to be involved in research misconduct
- inciting others to be involved in research misconduct
- collusion in or concealment of research misconduct by others
- failure to meet ethical, legal and professional obligations

The full policy is attached as section '12.7 - Appendix 7'.

12 Appendix

12.1 Appendix 1 Terms of Reference University Ethics Sub Group (UESG)

Purpose

To be responsible to the Quality Assurance Committee for the protection of research participants and the promotion of and continuation of ethical research practice and standards across the University.

It is responsible for the development and review of policy, procedures and guidelines for ethical review of all research involving human participants, their data or tissue, conducted by staff and students. The Committee has oversight of Faculty Research Ethics Committees and considers an annual report from these committees.

Terms of Reference

1. To develop, review, and evaluate procedures, policy, and guidelines for the UESG and FRECs for the ethical review of all research conducted by academic staff and students and to provide appropriate research ethics support.
2. To ensure the implementation of arrangements to ensure that the University is in compliance with the Universities UK Concordat to Support Research Integrity, UK Research Integrity Office Code of Practice for Research, Research Councils UK Policy and Guidelines on Governance of Good Research conduct.
3. To issue guidelines on the proper conduct of research investigations in order to promote good ethical practice.
4. To monitor and audit research investigations carried out by undergraduate and postgraduate students, and staff within the University with respect to ethical practice.
5. To ensure that an effective programme of staff development and training is delivered to support the University's ethics policy and guidelines.
6. To receive, consider and give ethical approval for research where;
    - it is not appropriate for the application to be delegated to a FREC
    - a FREC refers the application to the UESG for advice
    - the applicant is proposing research that encompasses or implicates more than one faculty
    - the applicant is external to USW but is seeking access to USW students, staff or premises
7. To seek clarification from expert bodies, as necessary on matters of ethical review policy and practice and advise where necessary on compliance with external regulations
8. To consider any matters referred to the committee by FQACs, FRPCs, QAC or RPSG.
9. To consider any matters referred to the committee by Quality Assurance Committee.
10. To advise FRECs on how to comply with external regulations and/or guidance.
11. To receive reports from FRECs annually or more frequently if required, and to make the report available for discussion at QAC meetings.

Appointment Criteria

1. Those appointed should have received training in research ethics reviewing. Potential candidates should be offered any necessary supplementary training upon appointment.

Composition

1. Pro Vice Chancellor – Research (Chair)
2. Faculty Research Ethics Chairs
3. Director of CELT
4. Chairperson of Research Programmes Sub-Group
5. Other members as required
6. Members independent of the research and teaching activities of the University (if required)

7. Representative of Postgraduate Research and Undergraduate students
8. Secretary: Nominee of the Director or Research and Business Engagement

12.2 Appendix 2 Terms of Reference Faculty Research Ethics Committee (FREC)

Purpose
To act under the authority and guidance of the University Research Ethics Committee (UREC) and provide feedback to the UREC concerning matters and procedures for the ethical protection of human participants.

Terms of Reference
1. To disseminate guidelines produced by the UESG on the proper conduct of research investigations in order to promote good ethical practice.
2. To review and approve, high risk research ethics applications from members of the Faculty, staff and students that meet the requirements for high risk ethics review.
3. For multi-faculty research projects ethical approval is to be sought from the FREC of the lead investigator/project manager in the first instance but also from the faculty that owns the premises, laboratory, location (if different from lead investigator)
4. To monitor and audit research investigations carried out by undergraduate and postgraduate students and staff within the Faculty with respect to ethical practice.
5. To encourage a culture within the Faculty which recognises the central importance of ethical considerations in the design and performance of research.
6. To identify and advise UESG of appropriate training on ethical review for members of FREC.
7. To advise on and, where necessary, comply with external regulations and/or guidance on the ethical conduct of research with particular reference to the research culture within the Faculty.
8. To report to the UESG annually or more frequently if required, and to make the report available for discussion at UESG meetings.

Appointment Criteria
1. The Faculty Research Ethics Chair and Deputy Chair of FRECs shall be proposed by the Dean of Faculty, and agreed by the Chair of the UESG and the Pro Vice Chancellor for Research.
2. The appointees for Chair should normally have at least one year's experience of the work of the FREC or equivalent research ethics committee.
3. Those appointed as Chair should have received training in research ethics reviewing, and possess the relevant chairing skills. Potential candidates should be offered any necessary supplementary training upon appointment.
4. Appointments of any member of a FREC will normally be for a maximum period of five years. Appointments will be staggered to ensure staged turnover of membership. In exceptional circumstances a member may be invited to continue beyond this five year period.
5. Each FREC will appoint a named member of staff, normally the Chair of the Committee, to act as the designated officer with responsibility for reporting to the UESG. This designated officer will also be a member of the UESG.
6. The FREC designated officer will conduct an annual review of the FREC operations, and report to the UESG on the findings.
7. The FREC (usually the Chair) will refer cases to the UESG that require advice or opinion. Referral to the UESG for a review will be in exceptional circumstances only.

Composition
The FREC must have sufficient members to guarantee the presence of a core group at each meeting and to allow for a sufficiently broad range of experience and expertise that the committee is likely to encounter. If possible, membership should contain at least one person who has been trained in safeguarding children.

As a minimum, all FRECs shall comprise the following:

1) Faculty Research Ethics Chair
2) Deputy Chair
3) At least 2 members of staff representing each discipline area
4) A member from another Faculty
5) External expertise if deemed appropriate

12.3 Appendix 3 – Role of Faculty Research Ethics Chair

The role holder is responsible for managing the Faculty's ethical review procedure and operational processes in order to ensure the integrity of research activity (in particular research) are of the highest ethical standards. The Faculty Research Ethics Chair is expected to advise the Dean, Faculty Executive, and Faculty regarding ethical review and practice.

The Faculty Research Ethics Chair will assist the Faculty Executive and Chair of the University Research Ethics Sub Group (UESG) in ensuring that research activity meets the guidelines and requirements of the University Research Ethics Policy and as well as external policies including:

- Universities UK Concordat to Support Research Integrity.
- UK Research Integrity Office Code of Practice for Research.
- Research Councils UK Policy and Guidelines on Governance of Good Research conduct.
- Higher Education Academy guidance regarding partnerships with students in learning and teaching.

The Faculty Research Ethics Chair will also assist staff and students in complying with relevant law regarding the ethical review of research involving NHS patients and their relatives and carers, social care research, research involving the criminal justice system, MoD research, and work falling under the Human Tissue Act or Mental Capacity Act.

Key Responsibilities:

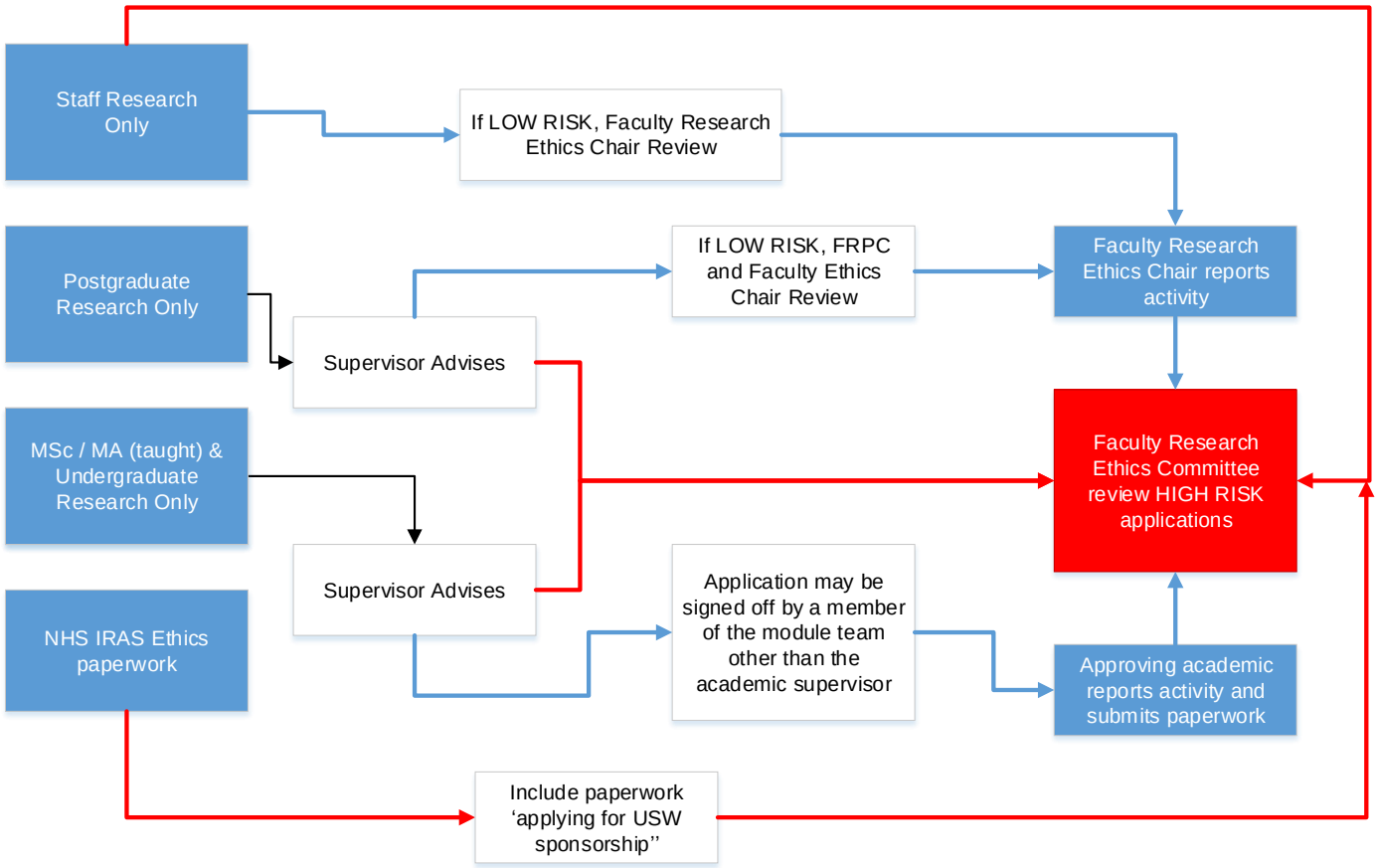
1. Oversee Faculty Research Ethics Committee in accordance with the agreed terms of reference and the University Ethics Policy.
2. Contribute as a member of the University Ethics Sub Group.
4. Chair Faculty Research Ethics Committee meetings (either in person and/or online) ensuring that ethical issues are explored and debated. Responsible for reading applications, taking part in the ethical review, leading or directing the review where necessary, and responsibility for the time management of the Committee's business.
5. Work with Faculty Administrators to ensure accurate records are maintained, and communications with committee members and submitting researchers managed.
6. Ensure that during the meetings a decision is reached, recorded and communicated to applicants.
7. Review responses and queries from applicants and consider amendments in a timely manner.
8. Ensure effective dissemination of University communications at FREC meetings.
9. Support the Faculty in managing the membership of the Committee including:
    a. Assisting or leading in the recruitment and selection of new members
    b. Providing guidance to committee members regarding potential conflicts of interest
10. Ensuring two reviewers are identified as per agreed local process for new applications and amendments.
11. Engage with professional development and training in the area of research ethics
12. Attend University training in Research Ethics when invited to do so.
13. Offer informal and formal advice and guidance relating to research ethics when called upon via one to one or faculty workshops.
14. Treat all ethical reviews and discussions about applications as confidential
15. They will represent the Faculty and report to the University Ethics Sub Group and any other committees as agreed.
16. They will be members of, and contribute to the following committees and sub groups:

Faculty Research Ethics Committee (to chair and advise on research), Faculty Research Committee, Faculty Research Programmes Committee (to advise on Postgraduate Research), and Faculty Quality Assurance Committee (to advise on matters related to teaching).

12.4 Appendix 4 – Role and Responsibilities of the FREC Members

1) Attend FREC meetings.
2) Receive ethics applications for scrutiny and complete and submit scrutineer report within agreed timescales.
3) Promote research ethics culture within the faculty
4) Act as a contact person for staff and students seeking advice on research ethics
5) Assist in disseminating good practice around research ethics
6) Assist in raising awareness and understanding of USW Ethics policy and procedures.
7) Contribute to research ethics policy development.
8) Attend training on research ethics – both internal and external events
9) Assist in delivering training around research ethics to staff and students.
10) Contribute expertise on specialist areas of research
11) Represent the faculty at UESG when appropriate.
12) Work closely with staff in Research Administration to ensure effective communication around ethics approvals.
13) Report on departmental concerns relating to research ethics policy and procedures.
14) Keep updated on research governance policies at USW.
15) Be aware of related policies on data protection, safeguarding, disclosure and barring, health and safety as they apply to research.
16) Provide advice on research ethics to module leaders delivering research training.
17) Support PGR research supervisors, and taught course supervisors as appropriate.
18) Assist in the monitoring and audit of research activity within the Faculty.
19) Lead by example of good research practice.

12.5 Appendix 5 – Overview of Ethical Approval Pathways FBS, FCI & FCES



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Prifysgol De Cymru

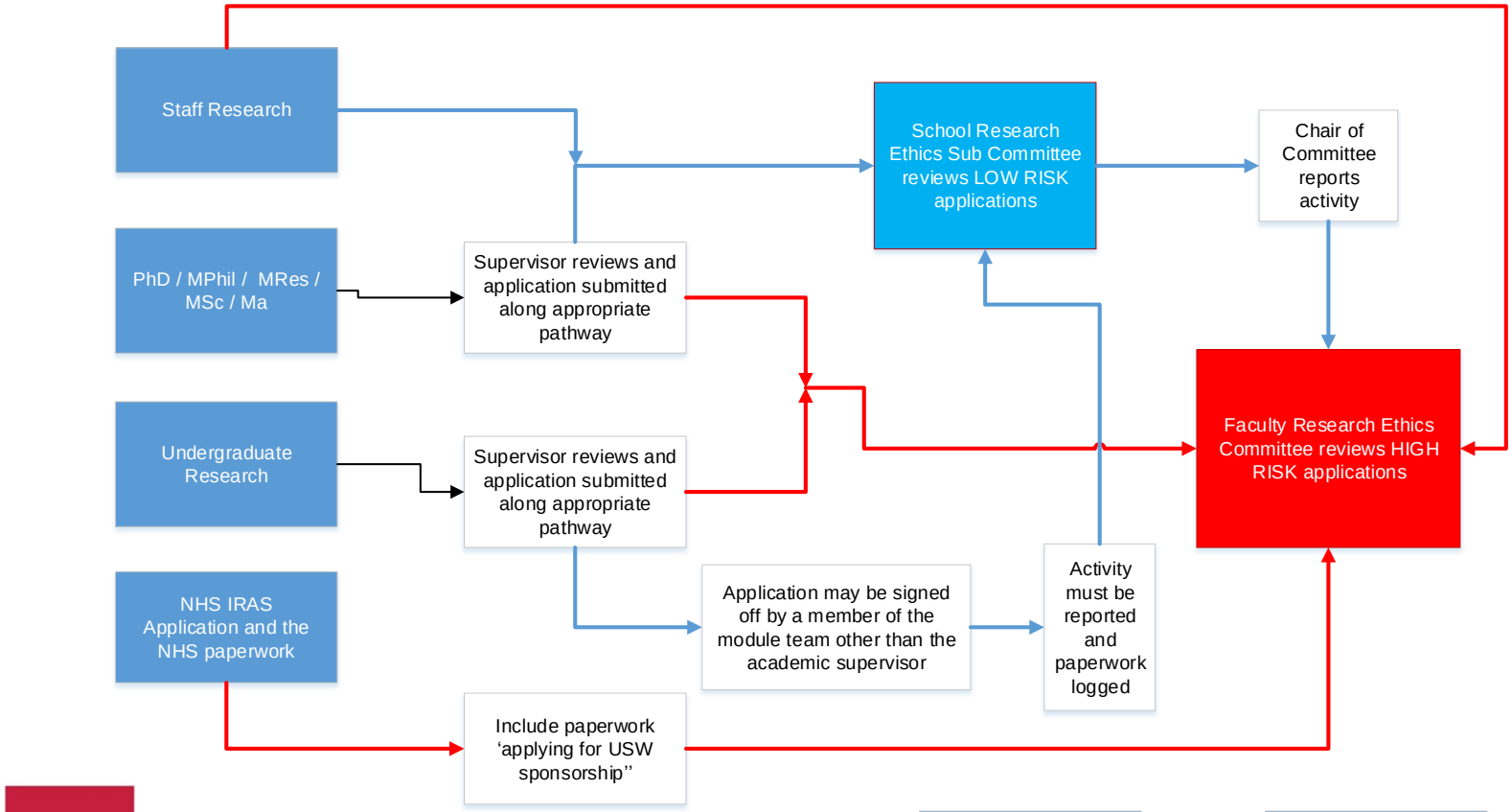
Indicates pathway for LOW RISK submission
Indicates pathway for HIGH RISK submission
Version 1, Approved June 2018

Ethical Approval of Teaching Modules → Faculty Quality Assurance Committee (FQAC)

12.6 Appendix 6 – Overview of Ethical Approval Pathways FLSE

FLSE Research Ethics Approval Pathways

Indicates pathway for LOW RISK submission
Indicates pathway for HIGH RISK submission



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Prifysgol De Cymru

Version 2, 02/05/2019

12.7 Appendix 7 - Research Misconduct Policy

Regulations on Research Conduct
These regulations apply to all members of the institution involved in research. This will include staff and undergraduate and postgraduate students. It also applies to those who are not members of the institution, but who are conducting research on the institution's premises or using the institution's research facilities.

For the purpose of these regulations, the Vice-Chancellor and other officers may act through their properly appointed nominees.

Principles of good conduct in the conduct of research
All those to whom the regulations apply are expected to:
- maintain professional standards
- be familiar with guidance on best research practice, for example in relation to matters of policy, ethics, finance and safety
- observe legal and ethical requirements laid down by the institution or other properly appointed bodies involved in the research field
- recognise the importance of good leadership and co-operation in research groups
- take special account of the needs of young researchers
- document results and keep secure primary data
- question findings
- attribute honestly the contribution of others
- take steps to ensure the safety of all those associated with the research
- report any conflict of interest, actual or prospective, to the appropriate person

Definition of research misconduct
Research misconduct includes the following, whether deliberate, reckless or negligent:
- failure to obtain appropriate permission to conduct research
- deception in relation to research proposals
- unethical behaviour in the conduct of research, for example in relation to research subjects
- unauthorised use of information which was acquired confidentially
- deviation from good research practice, where this results in unreasonable risk of harm to humans, other animals or the environment
- fabrication, falsification or corruption of research data
- distortion of research outcomes, by distortion or omission of data that do not fit expected results
- dishonest misinterpretation of results
- publication of data known or believed to be false or misleading
- plagiarism, or dishonest use of unacknowledged sources
- misquotation or misrepresentation of other authors
- inappropriate attribution of authorship
- fraud or other misuse of research funds or research equipment
- attempting, planning or conspiring to be involved in research misconduct
- inciting others to be involved in research misconduct
- collusion in or concealment of research misconduct by others

Fraud or other misuse of research funds or research equipment may be dealt with under separate financial regulations.

Procedure in the case of suspected research misconduct

The institution has a responsibility to investigate allegations of research misconduct fully and expeditiously. It also has a responsibility to protect researchers from malicious, mischievous or frivolous allegations.

All those to whom these regulations apply should report any incident of misconduct, whether witnessed or suspected. Members of staff and students are encouraged to raise concerns about suspected research misconduct in confidence with their Dean, The Pro Vice Chancellor (Research) or the Research Governance Manage. Those who raise concerns in good faith will not be penalised in any way for doing so. Allegations should normally be made in writing, accompanied by any available supporting evidence.

In the event that serious allegations are made they will be referred to the Vice Chancellor through the University Secretary under the appropriate disciplinary regulations – those relating to employees or those relating to students. For the purposes of this procedure any researcher who is not registered as a student at this University will be subject to the disciplinary procedure applicable to employees.

In cases where the outcome of the implementation of disciplinary regulations is the implication of someone who is not subject to the institution's disciplinary procedures, the Vice Chancellor shall bring the information to the attention of any appropriate disciplinary or other body.

Where the research is funded in whole or part by an outside grant, the institution shall have regard to the guidance issued by the relevant funding body. The institution shall ensure that any such body is given appropriate and timely information as to the instigation and progress of an investigation and any referral under disciplinary regulations.

In the event of a finding of misconduct, where the person responsible is subject to the regulation of a professional body such as the General Medical Council, the institution shall consider whether it is appropriate to inform the professional body of any finding.

Where the person responsible has published research, especially research to which the misconduct relates, the institution shall consider whether it is appropriate to inform journal editors or others of any finding.