PRIFYSGOL BANGOR UNIVERSITY

RESEARCH ETHICS POLICY

Rev	Date	Purpose of Issue/Description of Change	Equality Impact Assessment
1.	16th December 2005	Initial Issue	
2.	13th July, 2007	Revision	
3.	12th November, 2009	Revision	
4.	18th June, 2012	Review and approval by the University Ethics Committee	
5.	6th March, 2013	Review and approval by the University Ethics Committee	
6.	9th November, 2015	Review and approval by the University Ethics Committee	
7.	10th November, 2016	Review and approval by the University Ethics Committee	
8.	9th November, 2018	Review and approval by the University Ethics Committee	
9.	1st November 2021	Updating Committee title and Appendix 1	
10.	4th February 2022	Review and approval by the University Research Governance and Ethics Committee	
11.	24th May 2022	Review, revision and approval by the University Research Governance and Ethics Committee	
12.	15th September 2022	Further review and revision	
13.	10th July 2023	Amendments to update roles and responsibilities	

Policy Officer	Senior Responsible Officer	Approved By	Date
Senior Research Governance and Policy Officer	Head of Legal Services	University Research Governance and Ethics Committee	15 September 2022

1. INTRODUCTION

This document sets out the policy for managing research ethics and the research ethics review process within Bangor University.

The Policy applies to all members of staff and students involved in research at Bangor University including its staff and students conducting research either within the University where the research participants are members of University staff and / or students, or outside the University, as well as any persons not employed by the University but with permission to carry out research at the University (all referred to as Researchers).

The University subscribes to nine key principles relating to ethical research and expects all researchers to abide by these principles. The Policy sets out the way in which the University will ensure that these key principles are adhered to.

2. PRINCIPLES

i. The Declaration of Helsinki[1] documents important ethical principles for medical research involving human subjects which must be carried out in accordance with the requirements of the Declaration. Additionally, in all research involving human participants the consent, dignity, rights, safety, and well-being of participants, as outlined in the Declaration, must be ensured.

ii Research should be designed, reviewed, and undertaken to ensure integrity and quality as stated in the UK Concordat for Research Integrity[2].

iii With the exception of observational research, participants must be fully informed about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved subject to the one exception set out in 5.1 [b] (iii) and to approval by the AREC as set out in 5.1 [a].

iv. The confidentiality of materials and information supplied by research participants and, where appropriate, anonymity must be respected in accordance with relevant guidelines, legislation, and professional guidelines (see below).

v Human research participation will normally be voluntary and should adhere to the requirements of Section 4.1[e] on consent. In those exceptional cases where participation is not voluntary, research must be carried out in accordance with all relevant research ethics, governance, and professional guidelines (see below).

vi Risk to human research participants must be minimized and be proportional (i.e. balanced against the benefits of any research outputs.)

vii The independence of research must be clear, and any conflicts of interest or partiality must be explicit.

viii All research involving animals must adhere to the principles of Replacement, Reduction and Refinement.

ix Approval for carrying out research with ethical implications is by independent peerreview.

3. RESPONSIBLITIES

3.1 Individual Responsibilities

[a] Pro Vice-Chancellor (Research)

The Pro Vice-Chancellor (Research) is responsible for the overall management and ethics of research.

[1] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[2] https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-research-integrity

[b] Deans of College (and other staff roles)

Deans of College are responsible for local ethical review arrangements as advised and supported by Directors of the three College Research Institutes and School Directors of Research in accordance with this Policy, supported by the Associate Pro Vice-Chancellor Research Governance and Governance Services. Deans must ensure that at least one Academic Research Ethics Committee (AREC) that meets the needs of their college and its constituent Schools has been established with an appropriate membership, appropriate terms of reference and a process for monitoring and review. Otherwise, appropriate agreements must exist to operate ethical review for that College or School through other appropriate ARECs. Deans of College must also ensure that any research that requires review by external research ethics committees are adequately assessed as suitable for sponsorship by the university.

3.2 Committee Responsibilities

(See Appendix 1 for the Composition and Terms of Reference of these committees)

[a] University Research Governance and Ethics Committee

The University's Research Governance and Ethics Committee is a standing committee of Senate and is responsible for setting policy on research governance and ethical matters. The Research Governance and Ethics Committee also advises on broad strategies for research governance and ethics and monitors the University's overall performance rather than considering individual matters such as research proposals.

The Research Governance and Ethics Committee has devolved responsibility for research governance and ethics processes to the relevant ARECs. The Chairs of ARECs provide the Research Governance and Ethics Committee with regular reports which will include submitting an annual report to the first meeting of the academic year. They can refer any matters raising research governance and / or ethics to the Secretary of the Committee who will make arrangements to establish a subcommittee of the Research Governance and Ethics Committee to consider the matter and make recommendations.

[b] Animal Welfare and Ethical Review Body (AWERB)

The Animal Welfare and Ethical Review Body is responsible for the ethical review and approval of all research involving animals at the University as set out in the *Animal Welfare and Ethical Review Process*. The AWERB reports to the University Research Governance and Ethics Committee.

[c] Academic Research Ethics Committees

An Academic Research Ethics Committee (AREC) is defined as a multidisciplinary, independent body which is responsible for reviewing research involving human participants to ensure that their dignity, rights, and welfare are upheld. They should be constituted and operate in accordance with the core principles (independence, competence, facilitation, transparency & accountability) and guidance provided by the UK Research Integrity Office (UKRIO & ARM&A) Research Ethics Support and Review in Research Organisations; and other appropriate professional bodies[3].

The independence of an AREC is founded on its membership, on strict rules regarding conflict of

[3] https://ukrio.org/wp-content/uploads/Research-Ethics-Support-and-Review-in-Research-Organisations-UKRIO-ARMA-2020.pdf

interest[4] and on regular monitoring of and accountability for its decisions. The composition of an AREC will reflect a range of expertise and breadth of experience necessary to provide competent and rigorous review of the range of research activities in the relevant schools and colleges. ARECs report to the University's Research Governance and Ethics Committee but reports should also be available to the relevant College Research Committee and College Director of Research (where relevant).

There should be at least one AREC established in each College (which meets the need of that College, its Research Institute, and its constituent Schools) or, in cases where it is envisaged that the number of research proposals within a College, its Research Institute and constituent Schools will be low, an agreement should be reached with another College / School AREC to consider requests where required. Any such agreement should be notified to and agreed by the University Research Governance and Ethics Committee.

ARECs are responsible for:

i. Reviewing university-sponsored research involving human participants (with the exception requiring review by external research ethics committees; see Section 4.1.b) conducted by individuals employed by or registered as students within Bangor University;
ii. Ensuring ethical review processes are independent, competent andtimely;
iii. Protecting the dignity, rights and welfare of researchparticipants;
iv. Drawing up their own local policies and arrangements in accordance with thisPolicy;
v. Appointing lay members[5]. At least one student member[6] would also be desirable;
vi. Ensuring that procedures are established and are known for both peer review and expedited review;
vii. Ensuring that relevant policies, guidance and forms appropriate for that AREC are readily available on the College / School website and are made known to both staff and students.
viii. Ensuring that clear procedures exist in relation to the reporting of unforeseen events which might challenge the ethics conduct of the research or which might provide grounds for discontinuing the study.

An AREC may seek advice and assistance from experts outside the committee in considering a research proposal. When this happens, the Chair is responsible for ensuring that the experts have no conflict of interest in relation to the proposal.

AREC's should normally meet at least twice per academic year. The dates of AREC meetings and the deadlines for submission of applications to be considered should be available well in advance.

[d] Sensitive Research Approval Group

Having been initially considered by the Chair of an AREC, research judged to involve military, security or legal issues can be considered by the Sensitive Research Approval Group, is responsible for the approval and registration process for sensitive research projects undertaken by members of staff and postgraduate students at the University, as set out in the *Procedure for Approval and Registration of Sensitive Research Projects*[7].

[4] As set out in the University's Declaration of Interest Policy available on the University's website
[5] Lay members can be former members of University staff as long as they have not worked for the University in any capacity in the five years prior to their appointment to the Committee.
[6] ARECS may wish to consider appointing a PhD or post-doc student representative as they would normally be students at the University for longer than one year.
[7] https://www.bangor.ac.uk/governance-and-compliance/governance.php.en

4. MANAGEMENT OF RESEARCH ETHICS

This section gives expanded guidance on ethical principles relating to both research on human participants and research involving animals, as well as guidance on clinical trials, research outside the United Kingdom, sponsorship, and the environmental consequences of research.

4.1 Research involving Human Participants

The following guidance sets out the principles that must be adhered to for all research involving human participants, their observation, biological material or human data.

[a] Primary Consideration

In any research involving human participants the consent, dignity, rights, safety, and well-being of participants is the primary consideration. Researchers have a duty of care towards the individuals participating in the research and are accountable for their well-being. Chairs of ARECs may, when presented with a particular ethical concern, refer to the Chair of the University's Research Governance and Ethics Committee.

Efforts should be taken to:

- Minimise the number of human participants used based on statistical goodpractice
- Minimise all the potential risks to the well-being of the researchparticipants
- Maximise the quality and impact of the research and the relevance of theresearch.

[b] Ethical review by an appropriate research ethics committee.

All research involving human participants must be reviewed by the appropriate AREC or external research ethics committee, streamed by the 5 categories below. The Senior Research Governance and Policy Officer, Governance Services is available to answer queries about individuals projects.

Category A. Research involving human participants, their observation, biological material or data (directly or indirectly collected) (including commercially purchased human material), but excluding National Health Service (NHS)/Health and Social Care (HSC) patients, their families, patient records, research involving Her Majesty's Prison & Probation[8] or Ministry of Defence (MoD)[9].

The vast majority of projects with human participants sponsored by Bangor University fall within this category and should be seen an appropriate school or college AREC.

Category B. As specified by Gafrec (2021)[10], research involving NHS patients or Health & Social Care (HSC) service users, families and patient records, nursing and/or residential homes, HM Prison & Probation; as well as research involving use of previously collected data or tissue from which past or present users of these services could be identified or involving exposure to ionising radiation.

Following sponsorship checks (see below), projects within this category should be submitted to the NHS or HSC research ethics committees

Category C. Clinical Trials of Investigational Medicinal Products (CTMPS), of any design, or clinical investigations of medical devices involving patients or healthy volunteers. (Experimental medicine studies (with licensed or unlicensed drugs) that are not CTMPs most usually belong in Category B).

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[8] Gafrec, Governance arrangements for Research Ethics Committees, H.R. Authority, Editor. 2021.

[9] MoD JSP 536, JSP 536 Governance of Research Involving Human Participants Part 1, M.o.Defence, Editor. 2021

[10] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/

Following sponsorship checks (see below), projects within this category should be submitted to the NHS research ethics committees.

Category D. As specified by JSP 536, projects conducted in the UK or overseas that are funded or sponsored by the MOD or involve MOD-employed staff and/or participants including cadets. (Projects with veterans, their dependents or families are normally excluded unless MOD-funded.)

Following sponsorship checks (see below), projects within this category should be submitted to the MOD research ethics committees.

Category E. Projects that involve the use of human tissue or personal data from publicly available tissue banks or research databases. These databases come with generic ethical approval from a recognised Research Ethics Committee (i.e. NHS/HSC REC or an equivalent) and/or with their own data management toolkits (e.g. https://www.dsptoolkit.nhs.uk/).

Sponsorship checks (see below) and checks that study protocols fall within remit of the database can allow projects to proceed.

[c] Sponsorship

Sponsorship is presumed for Category A research approved by an appropriate AREC. Research in Categories B, C and D should secure sponsorship from the university before submission to any external research ethics committee. Sponsorship checks should confirm that;

i sufficient funding and other resources are in place;

ii adequate scientific quality assessment;

iii all external permissions have been secured (e.g. from the Health Research Authority (HRA), a health board's R&D departments or a care organisation);

iv an appropriate ethical review process is being undertaken (or has been completed) and that the research will not commence until formal approval is provided;

v that appropriate indemnity is in place;

vi that all external and professional regulatory arrangements are in place (e.g. data management protocols) and;

vii for CTMPs, the trial is supported by a Clinical Trials Unit with a Clinical Trials Authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) (as well alignment with the Medicines for Human Use (Clinical Trials) Regulations 2004) or Medical Devices Regulations 2002).

Authority to allow sponsorships is the responsibility of Deans of College but can be devolved to the directors of Research Institutes but can be devolved to be School Directors of Research as appropriate.

[d] Legal Requirements

All university research must adhere to all legal requirements, external regulatory frameworks and guidelines produced by the appropriate professional bodies. The requirements of the General Data Protection Regulation and the Data Protection Act 2018 states that all information gained from research regarding individuals should be kept strictly confidential and securely stored for the length of time required by legislation or by guidance produced either by funding bodies,

professional bodies, or the University's *Records Retention Schedule*[11], whichever is the most onerous. Unless the individuals provide informed and explicit consent in advance, research data should not be presented in a manner that could potentially identify any individual.

All Bangor University research should adhere to the University's Data Protection and Safeguarding Policies. The confidentiality of research participants may only be broken in exceptional circumstances where there is reason to expect risk to the health, welfare or safety of themselves or others (including children or other vulnerable groups) that outweighs the need for the personal information to be kept confidential; or where there has been a breach of professional standards. Where such circumstances are likely, research participants should be informed of the limits of any confidentiality; and researchers should raise any concerns with the appropriate authority which can include academic supervisor, Head of School, Associate Pro Vice-Chancellor Research Governance or the Senior Research Governance and Policy Officer, Governance Services as soon as possible.

[e] Consent

Freely given, specified, informed and unambiguous indication of an individual's wishes to participate in a research activity is required from all participants in research with the exception of research necessarily involving deception as set out in 5.1 [b] (iii) and subject to approval by the AREC as set out in 5.1 [a].

Research participants should be aware of the potential risks and benefits, if any, associated with their involvement. They must also understand that their involvement is entirely voluntary and that they are free to withdraw at any time. When research participants are patients or users of a health or educational service, they must be informed that withdrawal from a research project will in no way affect the quality of any care, treatment, or provision they are receiving. There should be no coercion to participate. In accordance with the Data Protection Act 2018, use of personal data in research should be fair and transparent. Participants must be informed about the use, storage and sharing, of their personal data, along with appropriate information about their rights in relation to the data. All use of personal data should be in line with participants' expectations. Members of staff should discuss any concerns about the appropriate use or reuse of personal data with Governance Services..

Research involving deception must adhere to the stringent guidelines set out by the relevant professional body and relevant AREC and it must have full ethical approval from the relevant AREC as set out in 5.1 [a].

Where Schools require student participation in research as part of the learning experience, protocols should involve minimal risk (see 5.1 [b] below).

[f] Children, Young People and Adults at Risk

Research on children, young people, and adults at risk, e.g. those with mental health problems or learning disabilities, should be undertaken with greatest care and will always require the approval of an AREC or an appropriate external research ethics committee. Researchers must satisfy themselves that there is a real need to involve these groups in the research and be able to justify this to the relevant ethics committee. Researchers must bear in mind that there are a number of specific consent issues relating to research on children, young people, and adults at risk (including the requirement for consent of carers or guardians) and briefings should be clearly and carefully drafted. It is important that those giving consent are involved at all stages, but especially if problems arise during the research.

[11] Available from the Governance Services Office web pages

Advice on these issues will be available from Governance Services and from relevant associations and support groups. The requirements of the University's *Safeguarding Policy* should also be considered[12].

Researchers must, in line with the requirements of the Mental Capacity Act 2005, evidence a person's mental capacity to give consent at the time that consent is sought and must only undertake research involving an adult who lacks mental capacity if it is related to their incapacity or its treatment. If in any doubt the researcher should request a formal assessment from a suitably qualified professional. Adults who lack mental capacity should not be involved in research if the same or similar research could be undertaken by involving only people with capacity.

Researchers, with guidance from the AREC, must also comply with legal obligations before proceeding with the research (such as obtaining clearance from the Disclosure and Barring Service prior to commencing research involving children, young people, or adults at risk). The role, responsibilities, and rights of individuals on whom the research participant is dependent (e.g. parents, carers, and supporters) must be clearly explained and recognised. Further guidance on the considerations relating to children and young people can be found in the University's *Safeguarding Policy*.

4.2 Research Involving Human Tissue

Since the establishment of the Human Tissue Authority (HTA), there have been strict legally binding parameters to be followed when storing and using human tissue. The Human Tissue Act (HT Act), 2004 provides a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specific health related purposes and public display.

Any activity within the University that involves the use of organs, tissues and cells (including saliva, blood etc. which contain cells), has to follow strict Standard Conditions and, in accordance with *Governance Arrangements for Research Ethics Committees* (GAfREC)[13] and whether appropriate, researchers must ensure that their use of human tissue has been ethically approved through the NHS research ethics committee as above (see 4.1.b above and that the appropriate consent is in place. Researchers wishing to undertake research involving human tissue must consult with the University's Human Tissue Designated Individual (DI) prior to the commencement of any research.

4.3 Research Involving Animals

The following guidance sets out the principles that must be adhered to for all research involving animals.

Research involving animals must be carried out in accordance with the Animals (Scientific Procedures) Act 1986 and must have the approval of the Animal Welfare and Ethical Review Body. It should also comply with the University's *Animal Welfare and Ethical Review Process.*

Alternatives to the use of animals in research should be sought wherever possible, and researchers should be able to demonstrate that all alternatives have been considered. All legal requirements and guidelines produced by other appropriate bodies must be adhered to, in particular Home Office controls. Research involving animals requires Home Office licenses for the researcher, the project and, where appropriate, the premises. The requirements of the license must be complied with at all times. Information relating to the Home Office's procedures can be found on the Home Office website.

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[12] Available from the University website

[13] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/

4.4 Bangor University Research outside the UK

Research to be undertaken outside the UK or involving partners from outside the UK, carries an additional level of responsibility and scrutiny and researchers should ensure that they have considered fully any legal requirements and those of any relevant professional bodies. Researchers should bear in mind the differences in the civil, legal, and financial position of national and foreign researchers and academics. Where the research is carried out entirely overseas, researchers should familiarise themselves with the legislative and other requirements of the country in question. All research involving human participants outside the UK should be approved by an AREC or appropriate external research ethics committee; also referencing the University's Overseas Policy Standard and Procedures and the Overseas Travel Checklists both of which are available from the University's Health and Safety web pages. Researchers travelling abroad to undertake research must ensure that a suitable risk assessment has been undertaken and approved at the appropriate level within their School / College. Where these arrangements are unclear, researchers should seek the advice of the university governance team.

All proposed research activities in countries or organisations which are subject to political and / or economic sanctions by the United Nations Security Council[14] and / or the United Kingdom[15] must be risk-assessed initially by the chief investigator to identify whether, by undertaking the research and working in or with a sanctioned country or organisation, the individual(s) or the University may be inadvertently breaking sanction restrictions. A risk assessment should be completed, first, with the relevant Head of School or Dean of College and then, shared for approval with Senior Research Governance & Policy Officer, Governance Services, the Associate Pro Vice-Chancellor Research Governance and the Head of Health and Safety *before any travel is undertaken*. In certain circumstances, approval by the Pro Vice-Chancellor for Research or the Vice-Chancellor may be required. There are both civil and criminal enforcement options, which may be utilized by various government agencies to remedy breaches of financial, economic and travel sanctions.

All research sponsored by Bangor University undertaken at an overseas institution requires approval by an AREC or, where available and appropriate, an external research ethics committee at the host institution. Where external research ethics approval is preferred, members of staff should seek to obtain all relevant information about the institution's research ethics and governance arrangements and make this information available for a risk assessment (prior to the university signing off as sponsor) by the School or Research Institute Directors of Research, and Governance Services.'

4.5 Nagoya Protocol

The Nagoya Protocol is 'a framework for the effective implementation of one of the three objectives of the Convention on Biological Diversity: the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. It recognises that benefits derived by users of genetic resources should be shared with those who provide them, with the ultimate objective being the conservation and sustainable use of biodiversity'[16].

The UK is a signatory so that all proposed research on non-human genetic resources (plants, animals, and microorganisms) from non-UK countries along with their associated traditional knowledge (aTK) should be conducted in accordance with the Nagoya Protocol and the UK Access and Benefit Sharing (ABS) Regulations. This means researchers wishing to use a genetic resource

[14] The current list can be obtained from the United Nations Security Council https://www.gov.uk/government/collections/financial-sanctions-regime-specific-consolidated-lists-and-releases

[15] The current list can be obtained from the Office of Financial Sanctions Implementation (HM Treasury) https://www.gov.uk/government/organisations/office-of-financial-sanctions-implementation, or the Foreign and Commonwealth Office

[16] https://www.gov.uk/guidance/abs#overview

and / or aTK from a country signatory to the Nagoya Protocol are legally obliged to exercise due diligence and show compliance with the relevant country requirements. Depending on the country, researchers may need to demonstrate prior informed consent to access the genetic resource and assent to mutually agreed terms for undertaking research and development.

The ABS Clearing House (ABSCH) is an online platform for exchanging information on ABS measures countries have established[17]. It is a valuable asset assisting Nagoya Protocol implementation and compliance since all signatories are required to place national legislation on it to provide unambiguous legal clarity. Researchers using non-human genetic resources should use this information source as part of their due diligence process at the pre-application stage in their research proposals.

4.6 Ethical Approval from other institutions/organisations

Approval by the research ethics procedures of other universities, institutions, or organisations, both within the UK and overseas, can be acceptable where a research project or activity is sponsored by that institution and the institution can demonstrate adequate research governance arrangements (see section 4.7 below). It is envisaged that this would normally be relevant where, for example, Bangor University is a contributor to a project, or where researchers from another institution or organisation wish to collect research data from staff and/or students at the University.

4.7 Conduct of research involving other universities/organisations

Researchers should not accept nor imply acceptance of conditions that are contrary to their professional code of ethics or competing commitments under their employment contract. The terms of the research being undertaken on behalf of any external sponsor must be agreed in advance. Wherever the work is undertaken in collaboration with other institutions, either in the UK or abroad, it is essential to ensure that the policies of those institutions meet the standards of the University's Ethical Policy Framework and the requirements of this document. The terms will usually include the specification of the research and the roles and responsibilities of the researcher. The need for confidentiality or non-disclosure agreements must be negotiated in advance. Researchers are still required to work in accordance with the UK Concordat for Research Integrity.

Intellectual property arrangements must be in accordance with the University's Intellectual Property Rights Policy. Intellectual Property Rights agreements should be made clear at the outset.

When submitting research papers for publication the authors must declare any relevant funding sources or other issues that constitute a possible conflict of interest, or which may compromise the objectivity of the research[18].

In response to expectations from UK Research & Innovation (UKRI), funding bodies, and the wider general public, Bangor University encourages its staff to meet the Open Access requirements for publicly funded research as laid out in the Bangor University Open Access Policy[19]. These expectations are waived; however, where ethical or contractual restrictions apply.

4.8 Environmental Consequences of Research

Researchers should be mindful of the impact of their work on the environment. Researchers

[17] https://absch.cbd.int/en/

[18] Further guidance on conflict of interest can be found in the University's Declaration of Interest Policy available from the University's web pages.

[19] https://www.bangor.ac.uk/library/OpenAccess.php.en

should, where appropriate, carry out environmental assessments to ensure that their projects are not likely to have a significantly adverse impact on the environment. For further guidance on this matter researchers should contact the relevant AREC within their College or School.

The Policy assumes that research projects comply with University environmental policies and guidance, e.g. guidance on the Control of Substances Hazardous to Health Regulations (COSHH) and Disposal of Hazardous Wastes both of which can be obtained from the University's Department of Health and Safety. Researchers should also consult the University's Sustainability Policy where issues of environmental impact are discussed

5. ETHICAL REVIEW PROCESS

This section provides researchers with guidance on the University's ethical review process. Processes should be constituted and operate in accordance with the core principles (independence, competence, facilitation, transparency & accountability) and guidance provided by the UK Research Integrity Office (UKRIO & ARM&A) Research Ethics Support and Review in Research Organisations; and other appropriate professional bodies[20].

Bangor University has established a two-stage process for the ethical review and approval of research proposals – expedited review and full committee review. Both are carried out either by an AREC (human participants) or the Animal Welfare and Ethical Review Body (research involving animals).

Clinical research and any other form of research involving NHS Patients must be referred to an NHS ethics committee where it falls under the requirements of the *Governance Arrangements for Research Ethics Committees* (GAfREC)[21] for specific research projects.

All approved university-sponsored applications for ethical review to an NHS Research Ethics Committee in the UK must be submitted on the standard national application form, available from the Integrated Research Application System (IRAS) website[22].

Where a proposal for funding is being submitted research proposals should normally be submitted for review by the AREC immediately after receiving the notification that funding has been granted. However, researchers may also wish to submit the proposal to the AREC prior to a pilot study so that participants' interests are protected; prior to seeking the agreement of potential research sites and gatekeepers so they can be assured of its good standing; or prior to the main data collection commencing.

5.1 Approval by an AREC

[a] ARECs are responsible for ethical review of all research involving human participants that has more than a minimal risk[23]. In undertaking ethical review AREC's should act independently of the researchers whose proposals they consider and from the personal or financial interests of their members. The composition of an AREC is set out in Appendix 1.

[b] The following research activities would normally be considered as involving more than minimal risk and, consequently, would require full ethical review by the relevantAREC:

[20] https://ukrio.org/wp-content/uploads/Research-Ethics-Support-and-Review-in-Research-Organisations-UKRIO-ARMA-2020.pdf

[21] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/

[22] https://www.myresearchproject.org.uk/Signin.aspx

[23] Researchers may also wish to consult their appropriate professional Codes of Practice for further guidance.

i) Research involving vulnerable groups – for example, children and young people, vulnerable adults, such as those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship.
ii) Research involving sensitive topics – for example participants' sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.
iii) Research necessarily involving deception, or which is conducted without participants' full and informed consent at the time the study is carried out.
iv) Research involving access to records of personal or confidential information, including genetic and other biological information, concerning identifiable individuals.
v) Research involving intrusive physiological or psychological interventions likely to be carry risks of harm or discomfort..

[c] ARECs are responsible for ensuring that a comprehensive record keeping system is maintained outlining the method of decision-making used, the rationale for the decision, and clearly recording the final decision. The ARECs decision and any associated feedback to researchers should be clearly recorded and open to scrutiny, and procedures should ensure openness and accountability of AREC decisions while maintaining confidentiality where this is required.

5.2 Approval by the Animal Welfare and Ethical Review Body (AWERB)

The Body is responsible for ethical review of all research involving animals. The Body should undertake ethical review thoroughly and independently. The composition and terms of reference of the Animal Welfare and Ethical Review Body are to be found in Annex 2. Researchers are also encouraged to read the University's *Animal Welfare and Ethical Review Process*[24]

5.3 Expedited Review

The ARECs can, where required, carry out a process of expedited ethical review. Expedited review of research proposals can only occur where the potential for risk of harm or discomfort to participants and others affected by the proposed research is minimal, as confirmed by peer review of the proposal, or for research projects that have a short lead in time and are commissioned in response to a demand of pressing importance.

ARECs must have clear procedures in place for expedited review. These must include:

- Criteria for identifying research which involves minimal risk of harm or discomfort
- A sub-committee or chair responsible for reviewing the research and the scope of their authority
- Forms and procedures for submitting applications for expeditedreview
- Procedures for reporting decisions to the main committee

ARECs should undertake yearly audits of a small random sample of those proposals which were dealt with under Expedited Review and the outcome of such audits should be reported to the next meeting of the AREC.

5.4 Approval by the Sensitive Research Approval Group

[24] https://www.bangor.ac.uk/governance-and-compliance/EthicsRevProc-J.php.en

The Group is responsible for ethical review of all sensitive research as defined by the *Procedure for the Approval and Registration of Sensitive Research Projects*[25]*.* Where the Chair of the relevant AREC considers that the research proposal falls into one of the categories outlined in Section 2 of the Procedure, or where there is any uncertainty as to its sensitivity, they should contact the Senior Research Governance and Policy Officer, Governance Services as soon as possible and should include the application / research proposal submitted by the researcher to the AREC.

6. TRAINING AND GUIDANCE

6.1 Training

The University will offer training and briefing sessions for relevant staff, coordinated, and facilitated by Governance Services.

The training, where required, will also be available for individual researchers, members of the University's Research Governance and Ethics Committee, the Animal Welfare and Ethical Review Body and ARECs including lay members of the committees, and any students whose projects may potentially require ethical review.

6.2 Guidance

Guidance and support will be provided by the University through the provision of policies, procedures and web-based resources that can be accessed from the Governance Services web pages.

7. RESEARCH ETHICS MISCONDUCT

The procedure for dealing with suspected research ethics misconduct can be found in the University's Research Integrity Policy available in the Governance Policy List[26] under Process for Investigating Research Misconduct. In taught programmes, failure to obtain relevant ethical permissions is also deemed to be unfair practice and is included as such in the Unfair Practice Procedure[27].

[25] https://www.bangor.ac.uk/governance-and-compliance/governance.php.en
[26] https://www.bangor.ac.uk/governance-and-compliance/governance.php.en
[27] https://www.bangor.ac.uk/regulations/procs/proc05.php.en

Appendix 1

Composition and Terms of Reference of Relevant Committees

1. University Research Governance and Ethics Committee

Composition and Terms of Reference

The University Research Governance and Ethics Committee is the overarching Committee at Bangor University for the consideration of research governance and ethical issues. It also receives the minutes and an Annual Report from the Animal Welfare and Ethical Review Body.

Composition

Chair: Pro Vice-Chancellor (Research) or nominee

Ex-officio:

Chair, Animal Welfare and Ethical Review Body
Chairs of Academic Ethics Committees
Associate PVC's (Research)
Associate PVC (Research Governance)
President of the Students Union
Deputy Secretary / Head of Governance Services / Head of Legal Services
Senior Research Governance & Policy Officer (Secretary)

Appointed:

One academic member of staff from each College, appointed by the relevant Dean
Two members of Senate, appointed by the Senate Nominations Committee

The Committee shall have the power to co-opt no more than two additional individuals who may be drawn from either within or outside the University. Co-opted members shall serve in that capacity for a period of 3 years and may be re-appointed for one further term of 3 years.

Terms of Reference

1. To recommend to the Senate such policies as may be required on matters of research governance, ethics, and clinical research governance, and to establish related procedures in line with such policies, ensuring alignment with associated statutory, regulatory, and legal requirements and the University's Research Strategy, consulting with other University committees as appropriate.

2. To provide the Senate with periodic reports on the work of the Committee and on the operation of relevant University research governance and ethics policies and procedures.

3. To review, as required, the University's Ethical Policy Framework and the Research Ethics Policy and to recommend to the Senate proposals for their approval and amendment.

4. To establish a general framework for the operation of Academic Ethics Committees and to ensure that where such Committees are created, they work within the general guidelines and standards set by the Committee.

5. To receive the reports of the Animal Welfare and Ethical Review Body, as a sub-committee, and to advise the Senate thereon.

6. To receive regular reports on the activities of the Academic Ethics Committees established to oversee procedures to approve and monitor research activities with potential ethical implications.

7. To receive an Annual Report, at its first meeting of the academic year, from each Academic Ethics Committee.

8. To act as the final body of appeal against decisions of the Academic Ethics Committees to reject research on ethical and/or reputational grounds.

9. To support the Academic Ethics Committees in the event of a regulatory inspection relating to research governance, clinical research governance and ethics.

10. To act on any other matter consistent with the above as may be required by the Council, Senate or Executive.

11. To report to Senate, including providing the Senate with an Annual Report.

12. To meet at least twice per academic year.

2. Animal Welfare and Ethical Review Body (AWERB)

The AWERB will have the following membership (as required in Schedule 3, Part 2, paragraph 6 of the Act)

Core Membership

- The Named Veterinary Surgeon (NVS)
- The Named Animal Care and Welfare Officer(s) (NACWO)
- At least one or up to two Project Licence and / or Personal Licence Holders

The following individuals will also be invited:

- The Establishment Licence Holder
- A senior member of Animal Care Technical Staff
- Up to 3 Co-opted members who do not hold a licence under the Act
- A Lay member who has an interest in animal welfare and / orethics
- A member of Corporate Services responsible for compliance with the Act and the associated guidance, policy, and processes.

The Establishment Licence Holder (when present) will normally chair the AWERB, in their absence the Named Animal Care and Welfare Officer will take the chair. The Home Office Inspector shall also have the right to attend any meeting of the AWERB.

The AWERB shall be quorate if the core membership are present or have been included in any decision.

Any person who is co-opted shall serve as a member of the Committee for an initial term of three years, and may be re-appointed to serve one further term of 3 years

The membership of the AWERB includes those with defined responsibilities and obligations specified in the Premises Establishment Licence. The co-opted members will have an interest in animal welfare and / or ethics but they will not be engaged in work under the Act.

The work of the AWERB will be as set out in Schedule 3, Part 2, paragraph 6(3) of the Act namely:

a) advise staff dealing with animals in the licensed establishment on matters related to the welfare of the animals, in relation to their acquisition, accommodation, care and use;
b) advise on the application of the 3Rs, and keep it informed of relevant technical and scientific developments;
c) establish and review management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment;
d) follow the development and outcome (retrospective review) of projects carried out in the establishment, taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs; and
e) advise on re-homing schemes, including the appropriate socialisation of the animals to be re- homed.

These aims will be achieved by the AWERB performing the three main functions of the animal welfare and ethical review process (as set out in the *Animal Welfare and Ethical Review Process*).

3. Academic Research Ethics Committee

Each College should have at least one AREC (see proviso under section 3.2.[c]).

Composition

Membership of an AREC should reflect the following:-

a) ARECs should have a pre-designated Chair appointed by the relevant Dean of College[30].

b) ARECs should where possible be multidisciplinary and seek to include a wide ranging and diverse representation (e.g. gender and ethnicity)
c) AREC members (with the exception of the lay member) should cover all necessary experience of and expertise in the areas of research regularly reviewed by the AREC and should have the confidence and esteem of the research community.
d) It is recommended that ARECs include at least one lay member from the local community with no affiliation to the University and possessing the skills relevant to that particular AREC.
e) It is desirable that an ARECs should have at least one student member.

Officers who can attend:-
A member of Corporate Services with responsibility for ethics.

It is suggested that the AREC have at least seven members, and that the minimum attendance for a quorum should be 5. The AREC should also have a procedure in place for meetings which are not quorate.

[30] An AREC Chair should serve for a period of three years, and may be re-appointed to serve one further term of 3 years by agreement with the relevant Dean of College.