

Research Ethical Principles & Procedures

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Aston University Research Ethical Principles and Procedures

0. Introduction

Aston University and the University Research Integrity and Ethics Committee (URIEC) recognise and endorse the 'Concordat to support research integrity' as published by Universities UK. URIEC is committed to maintaining the highest standards of rigour and integrity in all aspects of research. The core elements of the concordat, and which URIEC support, are:

Honesty - 'in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.'

Rigour - 'in line with prevailing disciplinary norms and standards, and in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.'

Transparency and open communication - 'in declaring potential competing interests; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes publishing or otherwise sharing negative or null results to recognise their value as part of the research process; and in presenting the work to other researchers and to the general public.'

Care and respect - 'for all participants in research, and for the subjects, users and beneficiaries of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the integrity of the research record.' and

Accountability – 'of funders, employers and researchers to collectively create a research environment in which individuals and organisations are empowered and enabled to own the research process. Those engaged with research must also ensure that individuals and organisations are held to account when behaviour falls short of the standards set by this concordat.'

1. Ethical Principles

The University Research Ethics Principles and Procedures are based upon widely accepted principles and practices governing research and other academic activities (including teaching, consultancy and expert services and outreach work). The key elements are as follows:

- Minimal risk of harm to participants and researchers, including emotional and mental distress, and possible damage to financial and social standing, as well as to physical harm.

Health and safety issues should always be considered, and risk assessments completed if necessary.

- Minimal risk of harm to the environment.
- Potential for benefit by society.
- Voluntary informed consent by participants. Enough information should be given to participants such that they can understand what the research involves, that they are not coerced into taking part, and can withdraw if they want to. Where this is not possible, for instance in studies where covert observation is employed, or deception is involved, special safeguards or measures should be put into place.
- Confidentiality of information supplied by research participants and anonymity of respondents (unless explicit consent is given to the contrary). Issues of lack of privacy and anonymity should always be considered and addressed. Research should conform to Data Protection legislation, including around the keeping, sharing and disposal of personal data.
- Maintenance of the dignity of participants.
- Independence and impartiality of researchers. Research integrity should be high, research being sound, accountable, and supervised by appropriately qualified and experienced people. Conflicts of interest should be declared. There should be transparency in declaring funding sources.
- Appropriate publication and dissemination of research results, in line with the relevant University research governance policies.

1.1 Use of animals in research

Ethical practice also requires that the use of animals in academic work is fully justified, and that statutory controls and codes of practice are always observed. Where no alternatives exist and where their use is essential for medical research, Aston University undertakes research using animals. The ethical standards that apply to research work with animals are derived from the Animals (Scientific Procedures) Act 1986 as revised in the EU harmonisation of animal legislation Directive 2010/63/EU, which was implemented in 2012.

Under ASPA, Aston University operates as a regulated Establishment and complies with the regulatory regime through liaison between named office holders and the Animals in Science Regulatory Unit (ASRU). All research work undertaken at Aston University takes place within the personal and project licensing system as specified under ASPA.

At the University level, Aston's Animal Welfare Ethical Review Body (AWERB) oversees all projects involving animals and reviews all project work undertaken by researchers. The AWERB examines proposed projects to evaluate the balance between harms (potential or actual) to animals and the expected benefits (to animals or man) of the proposed work. AWERB approval is a mandatory requirement for licence approval by ASRU.

A second major role of Aston's AWERB is to provide a forum for consideration of 3Rs aspects of research on animals to ensure that:

- animals are **replaced** with non-animal alternatives wherever possible;

- that the number of animals is **reduced** to the minimum needed to achieve the results sought; and
- that, for those animals which must be used, procedures are **refined** as much as possible to minimise their suffering.

Aston University is a signatory to The Concordat on Openness on Animal Research (<https://concordatopenness.org.uk/>), and pledges to offer the public greater information about research that involves animals. Aston also follows the ARRIVE (<https://arriveguidelines.org/>) guidelines on reporting of animal research. ARRIVE approaches ethical considerations on the use of animals through ensuring that detail, consistency, and clarity of scientific publications based on investigations using animals is sufficient for them to add to the knowledge base.

2. Responsibilities

2.1 Responsibility of Deans of Colleges, Heads of Schools, and Heads of Department

Deans of Colleges, Heads of Schools and Heads of Department are responsible for teaching and research carried out within their own College/School/Department and under the supervision of their own staff.

2.2 Responsibility of Research Supervisors

It is the responsibility of all supervisors to ensure that any students involved as researchers or in conducting experimentation are aware of the ethical principles and procedures in this document. It is also the role of the supervisor to review and have oversight of the content of ethics application submissions from researchers under their supervision and to check the researcher's documentation, ensuring that any inaccuracies including spelling and grammar are corrected, before signing the application off and authorising its submission to the ethics committee.

2.3 Responsibility of Researchers

The responsibility for good research practice and the ethical conduct of research always rests with the researcher; it never falls on the research participants even after their consent is obtained. At any time during the course of research the research participants or their guardians can cease their participation and withdraw their data after participation (for as long as that data remains identifiable). Although researchers may not abnegate from their responsibility, the Executive Dean of the College concerned also has responsibility for ensuring that practice by those under their direction is irreproachable. The Executive Dean also has the right to prevent research from taking place that is not in accordance with the corporate mission, objectives and rules of governance.

In the case of investigations performed by an undergraduate or taught postgraduate student, the project must be supervised by a member of Aston University academic staff who will take overall responsibility for the conduct of that research. For applications received which originate outside of the University, a member of Aston University staff must be the principal applicant.

A decision by URIEC or a CREC to give ethics approval to a research project does not 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 address themselves to ethical matters and are dependent upon information supplied by the researcher. This information is

expected to be properly researched, full, truthful and accurate. Researchers who fail to follow the University's policy and procedures on ethical review of research may be regarded as engaging in research misconduct.

Researchers conducting research which does not involve human participants, but which is high risk or has potential for negative impacts on the environment or society should contact the Research Integrity Office for advice. This includes research where the research is involved with endangered, vulnerable or threatened species or populations, introduces material into an environment of a species or type not previously present, constitutes significant intrusion or destruction into an environment, disturbance to an ecosystem, causes deliberate damage or harm, pollution, removes plants or animals from an environment, is culturally or socially controversial or potentially infringes the rights of others.

2.4 Responsibility of College Research Ethics Committees (CRECs) and URIEC

All research requires a form of ethical assessment: where research involves using human participants (e.g., in questionnaires, interventions or interviews, observation studies, etc.) and/or their data, human tissue, or animals, then some form of ethical review of the research would normally be required. Researchers are asked to continually reflect upon any ethical issues which may arise during the course of their research and seek advice from the Research Integrity Office if needed.

A decision to change the University's policies or procedures for ethical review of research does not imply that previous policies or procedures were inappropriate, and any such changes do not invalidate ethical approval that has been given.

URIEC and CRECs recognise that the definition and perceived significance of ethical problems may be subject to change and difference of opinion. In this light, URIEC will conduct an annual review of its work, reporting annually to Research Committee on the management of the Committees, indicating any suggested or agreed change in policy or procedures. URIEC will also report on any outstanding or anticipated difficulties. Each CREC will provide a report to URIEC for these purposes. A list of all submissions and the decision taken in respect of them together with any major issues arising and a record of applications considered outside formal meetings will be required as part of the annual report. Each CREC annual report will also be presented to the appropriate College Research Committee for information.

It is not the responsibility of the CRECs to consider and give advice on wider legal issues which might affect whether, and how, the research should be permitted to go ahead. However, they may request additional information on legal aspects of the research to assist in their deliberation if needed, as research which does not comply with legal requirements cannot be ethical. CREC members can seek advice from AURIO as necessary.

CRECs should provide independent, competent, and timely review of the ethics of proposed research studies. In their decision-making, research ethics committees need to have independence from political, institutional, profession-related or market influences. They need similarly to demonstrate competence and efficiency in their work. CRECs are constituted therefore to ensure the competent review and evaluation of all ethical aspects of the research projects they receive, and to ensure that their tasks can be executed free from bias and influence that could affect their independence in reaching decisions. There is provision for representation on committees from qualified people from outside the University. The University will expect the membership of

committees to be inclusive, recognising the diversity of the research community in terms of the gender, age, ethnicity and background of members.

The operational details of URIEC and CRECs are set out in the respective Terms of Reference, available on the Aston University Research Integrity webpages.

3. Research

For the purposes of various statutory returns (such as research income figures returned under the Research Activity Survey and published by the Higher Education Statistics Agency), research is defined by the conventions set out in the Frascati Manual.

The Frascati Manual is the internationally recognised methodology for collecting and using R&D statistics.

3.1 Definition of Research

Research and experimental development (R&D) comprise creative and systematic work undertaken to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge. To qualify as R&D, an activity must be all of the following:

- novel;
- creative;
- uncertain;
- systematic; and
- transferable and/or reproducible.

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.

R&D must be distinguished from a wide range of activities relating to R&D with a scientific and technological basis; such activities are excluded from the definition of R&D unless they are carried out solely or primarily for R&D purposes. Pure R&D activities should have an element of novelty and the resolution of scientific and/or technological uncertainty, i.e. when the solution to a problem is

not readily apparent to someone familiar with the basic stock of common knowledge and techniques for the area concerned.

Ethics approval is needed for research activities – defined above. This includes research which involves human participants, human data, human tissue, secondary analysis of an existing dataset. There is a process of applying for ethics approval through your College – for more information see the Research Integrity webpage.

4. External Ethics Review

If the study is being led by Aston University, researchers must contact Aston University Research Integrity Office (AURIO) by email before making an application to any external review body (e.g., NHS or Ministry of Defence).

Review by an NHS Research Ethics Committee (REC) is required for certain research projects, for example:

- clinical trial of an investigational medicinal product (CTIMPs) “drug trials”;
- a non-CE marked medical device; or a CE marked device, which has been modified or is being used, outside of its current intended purpose?;
- research participants identified in the context of, or in connection with, their past or present use of services; and
- adults lacking capacity to consent for themselves.

This list is not exhaustive and any researchers are asked to visit the [Health Research Authority \(HRA\) website](#) and the [Aston University Research Integrity Office](#) for advice and guidance. If a study requires sponsorship from Aston University under the UK Framework for Health and Social Care Research, again, researchers should contact AURIO.

All research involving staff and/or offenders in prison establishments, National Probation Service (NPS)/Community Rehabilitation Companies (CRC) regions or within Her Majesty’s Prison and Probation Service (HMPPS) Headquarters are required to formally apply for research approval to the HMPPS National Research Committee (NRC). For such studies, all student applications below doctoral level must be supported by a Ministry Of Justice/HMPPS business lead in order to be considered. This business support needs to come from a senior member of staff, working in MOJ/HMPPS Headquarters who is willing to state that they believe the research is going to be of benefit to MOJ/HMPPS and will have minimal resource demands. Studies of this nature will require sponsorship from Aston University under the UK Framework for Health and Social Care Research, and researchers should contact AURIO on research_governance@aston.ac.uk.

The Ministry of Defence Research Ethics Committee (MODREC) ensures that all research involving human participants either undertaken, funded, or sponsored by the MOD meets nationally and internationally accepted ethical standards. Applications to MODREC require a Sponsor; for Aston University students and staff, the Sponsor would usually be Aston University. Researchers should contact AURIO on research_governance@aston.ac.uk for more information. URIEC recognises a favourable ethical opinion (FEO) or approval from the MODREC.

For research that has or will be considered by a research ethics committee external to Aston University, other than those described above, a judgement will be made by the Chair and/or Deputy

Chair of the CREC, in consultation with other members of the CREC and URIEC if necessary, as to whether a full review is necessary or whether the application can be processed by Chair's action alone. Advice may be provided to the applicant regarding any shortcomings and steps that will be necessary to obtain ethics approval from Aston University.

5. Research Carried Out Overseas

A researcher should, where possible, refer to country-specific guidelines for the location where research is being carried out. The International Compilation of Human Research Standards is a listing by the US Department of Health and Human Services of over 1,000 laws, regulations, and guidelines (including ethics committees) on human subjects' protection in over 100 countries and from several international organisations. Details of country-specific requirements and how these are met should be included in protocol submissions to CREC/URIEC (even if this is to confirm that additional action is not necessary). It is also recommended that researchers confirm they are covered by the University's travel insurance, and they should ensure that their visa will allow for research to be conducted. Researchers going abroad should follow the University Travel Policy/Procedures and regularly check the British Foreign Commonwealth Office website for further details and travel advice for the country they are planning to visit.

6. Research Involving Human Tissue

The collection and storage of human tissue is governed by the Human Tissue Act 2004. Ethical review will be required for projects meeting one or more of the following criteria: a) Research involving the new collection or donation of human tissue (whether relevant material or non-relevant material) from a living person or the recently deceased as defined by the Human Tissue Authority (HTA); or b) Research involving previously collected human tissue (whether relevant or non-relevant material).

The research may need review by a CREC or URIEC, and a separate approval is required from the University HTA Designated Individual. Research must not commence until after the researchers have contacted the Research Integrity Office by email (research_governance@aston.ac.uk) for advice on any necessary approvals.

Note: Research must not commence until confirmation of ethics approval has been received by e-mail from an Aston University REC (CREC or URIEC). The REC should be notified of any intended changes to a research protocol following ethics approval, as well as any adverse reactions or events during the course of the research. Amendments must not be implemented before appropriate confirmation of acknowledgement from the REC or until a new ethics approval letter has been obtained.

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