Aston University Research Ethical Principles and Procedures

Contents

1. Introduction:

Aston University expects research to be undertaken in accordance with commonly agreed standards of good practice such as those laid down in the Declaration of Helsinki.

Aston University and the University Research Ethics Committee (UREC) recognise and endorse the 'Concordat to support research integrity' as published by Universities UK.
UREC is committed to maintaining the highest standards of rigour and integrity in all aspects of research. The core elements of this 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: 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 conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting the work to other researchers and to the general public.' and

Care and respect - 'for all participants in and subjects of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations'.

1.1 Purpose

The purpose of the UREC is, through the Research Integrity Committee, to provide advice to the Research Committee and Senate on the development, implementation and review of institutional procedures and guidelines relating to ethical issues arising from research and other related activities, taking into account emerging issues of institutional, national or international significance.

The ethical standards which apply to academic activities (including research, teaching, consultancy and expert services and outreach work) arise from the basic principle that

such activities should neither include practices which directly impose a risk of serious harm nor be indirectly dependent upon such practices. Serious harms include, for example, failure to protect the reputation of the University, failure to respect the welfare and interests of the wider community and damage to items of cultural value or the natural environment. Ethical practice also requires that the use of animals in academic work is fully justified and that statutory controls and codes of practice are observed at all times.

1.2 University Research Ethics Committee (UREC) Terms of Reference and constitution

1.2.1 Terms of Reference

i. To consider all research related issues arising within the University which involve considerations of an ethical nature;

ii. To prepare a set of principles and procedures in relation to ethical issues which may arise from research activities within the University;

iii. To be available for consultation on such ethical issues by the Senate or any other corporate body, and by individual members of staff or students of the University;

iv. To consider, and in appropriate cases grant a favourable ethical opinion, specific representations and research protocols submitted to it by members of staff and students of the University, or representatives of certain external bodies working in collaboration with members of the University;

v. To report on the exercise of the UREC's functions, and make recommendations to the Senate as appropriate on key matters relating to ethics policy and strategy.

vi. To ensure research is carried out in accordance with the University's research values as outlined below.

vii. To have oversight of and support Protocol and Ethics Review Boards to promote and disseminate good practice in accordance with Aston University Ethical Principles and Procedures

1.2.2 Constitution of the University Research Ethics Committee

a) **Chair** - to be appointed for a period of **three years** by the Senate on the nomination of the Pro Vice-Chancellor research.

b) **Deputy Chair(s)** – to be appointed for a period of up to **three years** through agreement of the Committee members (can be from the below).

c) **Co-opted** – At least three members, at least one of whom should be medically qualified, and at least one of whom should be a lay person.

d) **Student Representation** – At least one member.

e) **Ex officio** – Chairs of the Protocol and Ethics Review Boards (PERBs) and director of governance and a Health and Safety representative.

f) **In Attendance** – Research Integrity Office (AURIO)

1.2.3. Modus Operandi

a) UREC shall meet at least 4 times a year and may increase this as needed.

b) UREC shall review research applications that meet any of the criteria in section 2.5.1. It may also review other research application through other routes subject to chair's agreement.

c) UREC shall issue a favourable ethical opinion (FEO), ask the Project Team to respond to comments raised by members of the Panel, which may necessitate the submission of revised documentation, or issue an unfavourable ethical opinion.

d) UREC will have the right to de-escalate application to PERBs or reject reviewing applications where the scientific validity and/or governance checks have not met the university standards.

e) Newly formed PERBs must be ratified by UREC the prior to them commencing operations.

f) A quorum is at least three members including the Chair OR Deputy Chair of the Committee, in addition to the Ethics Committee Secretary.

g) Subject to the Chair's agreement, review of applications may take place by correspondence.

h) The Panel may decide to seek further specialist technical or professional advice from outside the committee (e.g. a medical or legal specialist). Should a project require external legal or expert opinion, it may be necessary to charge the applicants for the specialist advice obtained.

i) Responses to comments raised by the committee and/or revised documentation may be reviewed and signed off by delegated members including the chair and/or deputy chair of UREC .

j) Service evaluations involving the NHS and/or amendments may be reviewed and signed off by the Chair of the committee or their nominee through Chair's Action. This will also include research projects that have been reviewed by other UK based academic research ethics committees.

k) Projects that are reviewed and have a FEO through NHS ethics will by default have UREC FEO. However, the Committee reserve the right to consider any application.

l) In certain situations, UREC may invite the research applicants to attend the committee meeting to provide clarifications related to their project.

m) Appeals and complaints on UREC's decisions can, in the first instant, be raised to Aston University Research Integrity Office.

1.3 Protocol and Ethics Review Boards (PERBs)

1.3.1. Terms of Reference

The purpose of the PERBs is to review research applications and approve the scientific validity and research governance aspects and, where research fall under any of the criteria specified 2.5.3, the ethical acceptability of the project, in line with Aston University's guidelines and procedures.

1.3.2. Constitution of the Protocol and Ethics Review Boards (PERBs)

a) **The formation of a PERB** must be approved by school's/college's Executive Dean and ratified for operation by the UREC.

b) **Chair** - to be appointed for a period of **three years** by the school's/college's Executive Dean.

c) **Deputy Chair(s)** – to be appointed for a period of up to **three years** through agreement of the PERB members, but must be of different area of expertise and research interest of the Chair.

d) **Co-opted** – At least **two** academic members of Aston University with no upper limit.

1.3.2. Modus Operandi

a) PERBs shall meet at least 4 times a year and may increase this as needed.

b) shall review research applications and approve the scientific validity and research governance aspects.

c) for research applications that meet any of the criteria in section 2.5.3, shall issue a favourable ethical opinion (FEO), ask the Project Team to respond to comments raised by members of the Panel, which may necessitate the submission of revised documentation, or issue an unfavourable ethical opinion.

d) shall escalate to UREC any research applications the meet any of UREC review criteria as specified in 2.5.1

e) shall escalate to AURIO any research applications that meet the criteria in section 2.5.2.

f) PERBs may pass applications back to Principal Investigators for improvement where the scientific validity and/or governance checks have not met the university standards.

g) newly formed PERBs must be ratified by UREC the prior to them commencing operations.

h) All members of the PERBs will need to undertake a form of training in research integrity and ethics and familiarise themselves with the processes and systems available.

i) A quorum is at least **four** members including the Chair OR Deputy Chair of the Committee.

j) Subject to the Chair's agreement, review of applications may take place by correspondence.

k) The Panel may decide to seek UREC input where further specialist opinion is needed

l) Responses to comments raised by the committee and/or revised documentation may be reviewed and signed off (within the authority of the PERBS) by delegated members including the chair and/or deputy chair of the relevant PERB .

m) In certain situations, the PERB may invite the research applicants to attend the committee meeting to provide clarifications related to their project.

n) Appeals and complaints on the PERB decisions can, in the first instant, be raised to Aston University Research Integrity Office.

1.4 National and International guidance on ethics

All teaching experiments and research carried out in, and by members of, the Aston University should conform with the 'Universal Declaration of Human Rights and Covenants on Human Rights' (UN General Assembly, December 1984) and with the University's ethical principles and procedures. Researchers are also required to observe the ethical principles and procedures advocated by their own appropriate Society or Professional Body.

1.5 Responsibilities

1.5.1 Responsibility of Deans of Schools and Heads of Department

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

1.5.2 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 approve the content of 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 submission to the ethics committee.

The responsibility for 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 should be free to withdraw from research.

Although researchers may not abnegate from their responsibility, the Executive Dean of the School/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 are 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 academic staff who should be the principal applicant, giving details of the student involved, including the name, course and year. For postgraduate research students, the registered supervisor must be the principal applicant. For applicants from outside the University, a member of academic staff must be the principal applicant.

2. When is an Ethical Review Required?

All research requires a form of **ethical assessment**, however, if research involves data that are not in the public domain, and/or involves using other human participants (e.g. in questionnaires, interventions or interviews), human tissue, or animals, then some form of ethical review of the research would normally be required.

2.1. Ethical review by external bodies

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**.

2.1.1 NHS Research Ethics review

Review by an NHS Research Ethics Committee (REC) is required for certain research projects, for example, but not limited to, studies that involve NHS patient groups, characterised by a specific disease or disorder, or their carers, adults lacking capacity to consent for themselves, investigational medicinal products/devices and ionising radiation. Please consult the Health Research Authority (HRA) website for more information.
UREC recognises a favourable ethical opinion (FEO) from the NHS. If your study requires sponsorship from Aston University under the UK Framework for Health and Social Care Research, please contact AURIO.

2.1.2 Research with the HMPPS

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).

All student applications below doctoral level need to be supported by an MOJ/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.

These kind of studies will require sponsorship from Aston University under the UK Framework for Health and Social Care Research, please contact AURIO on research_governance@aston.ac.uk.

2.1.3 MODREC Research Ethics review

The Ministry of Defence Research Ethics Committee (MODREC) ensures that all research involving human participants either undertaken, funded or sponsored by MOD meets nationally and internationally accepted ethical standards. UREC recognises a favourable ethical opinion (FEO) or approval from the MODREC.

2.2. Ethical opinion from collaborating organisations

2.2.1 Hospitals and Clinics

Research protocols which involve access to subjects under the day to day care of a hospital or clinic will need to produce evidence that the investigator has the agreement of the appropriate Ethical Committee governing the hospital(s) or clinic(s) concerned. Similarly, protocols which use hospital or clinical premises, other than those which are available within the University, will normally need to produce such evidence. Additional legal and ethical approvals may need to be obtained **(see section 3).**

2.2.2 Higher Education Institution (HEI)

Research that requires or has external review by another Higher Education Institution (HEI) may require an ethical review by the UREC, but this will be decided on a case by case basis. Researchers are advised to contact AURIO by email prior to commencing their research study.

2.3. Reviewing protocols from associated institutions

The UEC is prepared to consider and grant an ethical opinion to protocols from those of the University's Associated Institutions that do not have Ethics Committees of their own, provided that the protocols arise directly or indirectly from undergraduate or postgraduate programmes, or staff which are validated by the University. In these circumstances, UREC (or representative thereof) reserves the right to inspect the appropriate premises and facilities within the institution.

2.4. Research conducted outside of the UK

The 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 UREC (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 also regularly check the British Foreign Commonwealth Office website for further details and travel advice for the country they are planning to visit.

2.5. Criteria for ethical review by UREC

All research involving human participants or their data should be evaluated against the criteria listed below before recruitment of study participants begins. Researchers at the University can carry out this evaluation using the Research Ethics Submission Tool (REST).

Research should be reviewed on a project basis. An FEO is normally given for an individual project rather than a general procedure or research method. An application may cover a complete study in all of its different phases or stages, or submissions may be made for each individual stage or phase separately. The FEO will cover all activities that will be carried out in the specific application.

2.5.1. UREC review criteria

Full UEC review is required for projects meeting one or more of the following criteria:
a) Studies that involve the inducement of MORE than minimal stress to the participant? Such as:

- Procedures involving more than minimal risk or stress to a participant's health or well-being.

- Procedures involving the use of surveys, questionnaires and any research, the nature of which might be offensive, distressing or deeply personal for the particular target group even if individuals are not identifiable.

- Questions on identifiable (at the point of collection) sensitive data, i.e. ethnicity, political views, religion, physical or mental health/condition, sexual life/orientation and alleged offences.

b) Procedures involving children under the age of 16 or other vulnerable groups, or those who may feel under pressure to take part due to their connection with the researcher.

c) Research involving prisoners or young offenders. *If the research requires Her Majesty's Prison and Probation Service (HMPPS) approval.*

d) Research protocols which require participants to take part in the study without their knowledge and/or consent at the time *For example, covert observation where adults might reasonably expect that their behaviour would not be observed by third parties. This* ***does not include*** *observational research taking place in public venues, either physical (e.g. a town square, conference, or meeting open to the public), or virtual (e.g. a public chat room).*

e) Research associated with illegal activity in the UK or country(s) it is being conducted in.

f) Research which involves deception other than withholding information about the aims of the research until the debriefing.

g) Research where the procedures or findings could lead to public controversy and/or significant **ethical or reputational** concerns may arise.

h) Where an external funding body or sponsor requires full ethical review to be undertaken.

i) Research activities taking place in a country against Foreign and Commonwealth Office advice for travel.

J) Research protocols to be carried out by persons unconnected with the University, but wishing to use staff and/or students as participants.

2.5.2 Studies involving new collection or donation of Human Tissue Samples

The collection and storage of human tissue is governed by the Human Tissue Act 2004. Ethical review may be required for projects meeting one or more of the following criteria:

a) Research involving the new collection or donation of human tissue from a living person or the recently deceased as defined by the Human Tissue Authority (HTA).

b) Research involving previously collected human tissue.

The research may need review by an Ethics Committee 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 for advice on any necessary approvals.

2.5.3 a Protocol and Ethics Review Boards (PERBs)

All research not meeting UREC review criteria, will be assessed by the Protocol and Ethics Review Boards. In addition to the scientific and governance review, the PERBs will ensure the below criteria are adequately addressed and satisfied:

a) The handling, accessing of records and/or the collection of **personal identifiable data**, concerning identifiable individuals as defined by data protection legislation.

b) Linking or sharing of personal data, special category data (sensitive data) or confidential information beyond the initial consent given (including linked data gathered outside of the UK).

c) The collection or access of audio, video recordings, photographs or quotations within which participants may be identifiable.

d) Incentives that may unduly influence participants' decision to participate.

e) Activities where the safety/wellbeing of the researcher may be in question.

f) Behavioural/physiological intervention could possibly lead to discovery of ill health or concerns about wellbeing in a participant incidentally.

g) Investigations of existing working or professional practices among participants, identifiable to the researcher at their own place of work.

2.6. Media and Filming

UREC does not normally review activities for media programmes. However, for programmes that are looking to reproduce research outputs, UREC would welcome invitations to offer advice from Research Ethics perspective, mainly focusing on informed consent and burden on participants.
Where there are elements involving human tissue samples, the DI's review/approval must be sought.

3. Additional approvals and considerations required

3.1 Health and Safety approval

All researchers are expected to adhere and comply with all local Health and Safety policies are in place. More detailed guidance on available Health and Safety available on Aston University webpages.

3.2 Additional ethical or legal approval

It is the researcher's responsibility to ensure they obtain any additional ethical, legal or other approvals. These approvals can be from institutions hosting the research and/or approval from local organisations or gatekeepers. The need for additional permissions should also be considered if the research is being conducted outside the UK.

3.3 Pilot studies

Any pilot studies that require participants to take part in a procedure that would qualify a study for review should be submitted through REST for the relevant review.

3.4 Translation of documents

UREC and/or the PERBs will consider and assess the method of translation and may accept the researcher's own signed translation provided that it was accompanied by the original document. Where applicable, the supervisor/Principal Investigator should also sign to agree the accuracy of the translation and this would be acceptable. UREC might also request further information and evidence from the researcher for the translated documents.

3.5 Amendments and the expiry of a Favourable Ethical Opinion

The Ethics committee and/or the relevant PERB should be notified of any changes to the protocol, any adverse reactions/events, or if the study is to be repeated using a different group of research participants or lead researcher/s.

If changes are required by external bodies, these changes should be referred back to the ethics committee as an amendment. Amendments should not be implemented before the appropriate confirmation of acknowledgement from the relevant ethics committee or a new Favourable Ethical Opinion (FEO) has been obtained.

A further submission through REST will be required in the event that the study is not completed **within five years of** the date of the FEO. Also, AURIO should be advised when a research project has not proceeded according to the timescale specified in the original application, for example if it has been terminated early or if still collecting data after the proposed end date of the study.
If a study has not started within 12 months of the FEO, researchers must update the ethics giving the reasons why.

4. University Ethics Committee Procedure

4.1. Auditing of protocols

A sample of all research protocols received by UREC and PERBs are audited. The University uses the audit process to identify any gaps in processes or sharing of information across the University. Where any concerns are raised by the auditors, these are initially discussed informally with the researcher to provide advice on how to proceed, although the potential exists for such cases to be referred for investigation under the provisions of research misconduct policies.

4.2. Confidentiality and conflict of interest

Chatham House Rule shall apply. In order to encourage and foster open and candid discussion at their meetings, members of the UREC or PERBs shall keep confidential any and all information relating to discussions, unless compelled by legal process to disclose such information, or as otherwise agreed by the UREC.

It is expected that members of UREC and the PERBs will treat material submitted for review as confidential and not make use of it to gain an unfair academic advantage. Any type of peer review is in itself a learning process, however, members must never derive academic or commercial competitive advantage from information they acquire in the process of reviewing applications.

It is vital that all reviewers are seen to be impartial at all stages of the review process. Reviewers should not take part in the review of any proposal where a conflict of interest may be experienced or perceived and are required to declare any conflict of interest if they should inadvertently be invited to take part in a review where such a conflict of interest exists.
These points are summarised in Aston University Research Ethics Committees 'Conflict of Interest and Confidentiality Statement' in Appendix I.

Appendix I: Aston University Research Ethics Committees Conflict of Interest and Confidentiality Statement

Conflict of Interest

This statement serves to assist members of Aston University Research Ethics Committees in identifying whether they may have a conflict of interest in relation to an application they are asked to review and whether it would be advisable to decline reviewing this particular application.
It is vital that all reviewers are seen to be impartial at all stages of the review process. Not all conflicts are obvious from the information available. Members of the committees should not take part in the review of any proposal where a conflict of interest may be **experienced or perceived**. All declared conflicts of interest will be recorded against applications. **If you consider you may have or be perceived to have a conflict of interest you must contact Aston University Research Integrity Office (AURIO) before proceeding with the review.** It is important that you ensure you are eligible to review the proposal before undertaking the review. A list of possible conflicts that may exclude you from assessing a proposal is included below. **This is not an exhaustive list; if you are in any doubt about whether or not you should assess a proposal, please contact AURIO, who may refer to the Chair of the relevant ethics committee for a decision**. Lay members are under the same duty to identify and report potential conflicts of interest as members from within the University and should refer any concerns in this regard not covered by the criteria listed below to AURIO on a case-by-case basis.

Examples of Conflicts of Interest for Aston University Research Ethics Committees' members conducting reviews

A conflict of interest may occur or be perceived when you:

- Are a relative of the applicant or have another significant personal relationship with the applicant (e.g. close friendship or romantic).
- Have a significant professional relationship with the applicant (e.g. are currently the PhD supervisor or line manager for one or more applicant(s)) or had such a relationship in the past.
- Are directly involved in the work that the applicant proposes to carry out and/or have assisted the applicant with their application.
- Have a vested interest in the outcome of the application, whether that be negative or positive, e.g. the current project competes for the same funding or you would benefit from the applicant's work to progress your own research.
- Have collaborated on a research project, or worked closely with the applicant in the last **three years**. In the interest of maintaining sufficient expertise to fulfil review adequately, simply working in the same Department or School as the applicant does not necessarily exclude you from reviewing the application, unless one or more of the other exclusions apply.
- Have been approached and agreed to be a member of a committee or group connected with the research project. If, for example you are a member of an advisory group or steering committee, you should not - if approached - also act as a reviewer for that project.
- Feel you may otherwise have a bias towards the outcome of the application.

Please note that, **the restrictions which apply to the Principal Investigator or Applicant, apply equally to any Co-Investigator(s) on an application.**

Confidentiality

It is expected that members of Aston University Research Ethics Committees will treat material submitted for review as confidential and not make use of it for any other purpose. Members must never derive academic or commercial competitive advantage from knowledge they acquire in the process of reviewing applications.