1. **Scope of policy**

1.1 All academic activity at the University of Worcester should be conducted according to good ethical practice and with the highest standards of integrity. This Policy, however, sets out the principles and procedures for research. Ethical issues arising from learning and teaching should be addressed by the programme or module leader seeking advice as appropriate from the Institute Ethics Coordinator.

1.2 For the purpose of this policy the term *research* refers to:
- original investigation leading to the creation of knowledge
- replication of an investigation for the purposes of developing the researcher – this will include undergraduate independent studies and postgraduate dissertations, but also smaller scale projects that form part of a module’s assessment
- evaluation
- audit

1.3 For the purpose of this policy, the term *researcher* refers to:
- any member of staff at the University of Worcester engaging in research
- any student at the University of Worcester
- any individual who is not a member of staff or student at the University, undertaking research using University premises and facilities, and/or in the University’s name (hereafter referred to as an associate researcher)

1.4 It is important that all research at the University of Worcester is conducted to the highest standards of integrity. All researchers are expected to consider the ethical implications of their research and to submit their research for ethical review as appropriate. This policy is particularly focused on research with:
- Humans - that is research with
  - living human beings
  - human beings who have died (cadavers, human remains and body parts)
  - embryos and fetuses
  - human tissue, DNA and bodily fluids
  - data and records relating to humans
  - human burial sites
• Animals

1.5 This policy sets out the principles for ethical research and the procedures for ethical review. It is expected that this policy will be read in conjunction with the relevant subject-specific and professional codes and guidance on ethics and research conduct as well as taking into account all relevant legislation.

1.6 This policy will be reviewed by the University’s Ethics and Research Governance Committee on an annual basis.

2. Ethical Principles

2.1 The University’s stance on ethical issues is underpinned by the following key principles:
• Research must be justified
• Informed consent must be given by participants
• Participation in research must be voluntary
• Confidentiality must be ensured
• Participants and the researcher(s) should not come to any harm during the research

2.2 Justified
Researchers should be able to demonstrate that the research they undertake is worthwhile and necessary. They should be able to show that the study will add new knowledge and not simply replicate research that already exists. The value of the new knowledge gained should outweigh the potential disruption and inconvenience caused to those involved in the research. In the case of students undertaking an undergraduate independent study or postgraduate dissertation it is, however, permissible for them to replicate existing research as part of their development as researchers.

2.3 Informed consent
2.3.1 Those involved in research whether as participants or researchers should be informed of the nature and purpose of the research, and any potential benefits, risks, obligations or inconvenience associated with the research before they choose to participate. It is therefore normal practice to provide an information sheet or similar to potential participants that sets out the details of the research in a form accessible to the non-expert and in a format appropriate to them.

2.3.2 Wherever possible, and proportional to the nature of the research, evidence of consent (either written consent, or oral consent witnessed by another) should be obtained and retained as appropriate. Participants should be informed that they are free to withdraw this consent at any time without adverse consequences, and that any data provided by them will be destroyed should they request it.
2.3.3 Where consent is being sought to collect sensitive personal data explicit consent must be given by the participant to collect this data. Sensitive personal data is defined in the Data Protection Act 1998 as personal data consisting of information relating to:
   a. the racial or ethnic origin of the data subject
   b. his/her political opinions
   c. his/her religious beliefs or other beliefs of a similar nature
   d. whether he/she is a member of a trade union
   e. his/her physical or mental health or condition
   f. his/her sexual life
   g. the commission or alleged commission by him/her of any offence
   h. proceedings for any offence committed or alleged to have been committed by him/her, the disposal of such proceedings or the sentence of any court in such proceedings

2.3.4 Particular care is needed in gaining consent from vulnerable groups, such as: children, persons lacking mental capacity, and persons whose first language is not English.

2.3.5 For research involving children, researchers should seek to gain the consent or perhaps more appropriately the assent of the child in keeping with Article 12 of the United Nations Convention on the Rights of the Child which states that children who are capable of forming their own views should be granted the right to express their views freely in all matters affecting them, commensurate with their age and maturity. The consent of the child's parent/legal guardian should normally also be obtained when this is feasible.

2.3.6 For research involving persons lacking mental capacity, researchers, in keeping with the Mental Capacity Act 2005, should:
   • assume a person to have capacity to consent unless it is established that he/she lacks capacity
   • not treat a person as unable to make a decision unless all practicable steps to help him/her to do so have been taken without success
   • not treat a person as unable to make a decision merely because they make an unwise decision

2.3.7 When access to participants is controlled by a ‘gatekeeper’, researchers should adhere to the principle of gaining informed consent/assent from the participants themselves, whilst respecting the legitimate interests of the gatekeeper.

2.3.8 In the case of research in educational settings, the researcher must consider carefully the need to gain parental consent for participation

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1 Gatekeepers are those who have the power and authority to grant the researcher access to a group of (normally vulnerable) participants, for example: a head-teacher or a care home manager would be considered as ‘gatekeepers’.
in addition to that of the child. The school acts *in loco parentis* but it must not be assumed that this always negates the need to ask parents to consent to their child’s participation. This will particularly be the case where the research is of a sensitive nature or where the research requires children to undertake activities beyond those normally asked of them.

2.3.9 There may be some types of research design (e.g. deception studies or covert research) that require the research to be undertaken without informed consent. Such design should be carefully considered and fully justified with procedures put in place to provide post research full debrief and/or granting of post hoc consent.

2.4 **Voluntary Participation**

2.4.1 As well as being informed, consent should also be freely given. Researchers should ensure that participants are taking part in the research voluntarily, that they do not feel pressured or obliged to participate, and are not subject to coercion.

2.4.2 Researchers should be aware that where there is a power relationship between the researcher (or representative of the researcher, e.g. a gatekeeper) and the participant - such as between a lecturer and his/her students or a doctor and his/her patients – a person may feel compelled to participate. In these circumstances, a researcher should endeavor to find ways of ensuring voluntary participation, e.g. by using a neutral intermediary to gain consent.

2.4.3 Researchers should also be aware that the use of incentives to encourage participation may be viewed as coercion if such incentives are any more than a token. For example, giving those who complete a questionnaire access to a free prize draw will not normally be seen as coercive. On the other hand, paying individuals more than reasonable expenses to take part in an interview *would* normally be seen as coercive.

2.5 **Confidentiality**

2.5.1 Except where explicit written consent is obtained to the contrary, researchers should protect the confidentiality and anonymity of all human participants and their data relating to them at all times.

2.5.2 Researchers should be aware of the risks to anonymity, confidentiality, privacy and security posed by the data they collect and store, and take measures to prevent accidental breaches of confidentiality. The collection, storage, use and disclosure of data must comply with the [Data Protection Act 1998](https://www.legislation.gov.uk/ukpga/1998/29).

2.5.3 It is important to note that the duty of confidentiality is not absolute in law and may, in exceptional circumstances, be over-ridden by more compelling duties, such as the duty to protect individuals from harm.
2.6 **Avoidance of harm**

2.6.1 Researchers should seek to minimize the risk of harm to any individual (the participants, the researcher him/herself, other researchers) or organisations arising from the research.

2.6.2 Harm is broadly conceived to include physical injury and psychological distress (beyond that encountered in daily life), but also negative impacts on economic or social standing.

2.6.3 Researchers should assess potential risks prior to the commencement of a project and accordingly make adjustments to the project design and make provisions to provide help and support for any individual who suffers harm.

2.6.4 Most fundamentally, researchers must always ensure that participants and other researchers are fully aware of any potential risk of harm. This will enable the individual to make their own risk assessment before choosing to participate and, if fully informed, the individual is best placed to make this judgment.

3. **Ethical Review Procedures (Students)**

3.1 **Application for Ethical Approval**

3.1.1 All students are required to complete an Application for Ethical Approval *before* commencement of any research.

3.1.2 The application requires the student initially to complete a checklist designed to highlight any potential ethical issues with the research. The student should always answer the questions honestly, taking into account the ethical principles outlined in Section 2 of this document.

3.1.3 When a student answers ‘no’ to all questions, he/she submits the form to the supervisor/tutor/module leader. If the supervisor/tutor/module leader is satisfied with the answers in the checklist, he/she submits the approved form to the relevant Institute Ethics Coordinator. The research is not normally subject to any further review.

3.1.4 It is important to note that students should keep their answers to the checklist questions under review. If the student believes at any point during the research that he/she would now answer ‘yes’ to a question where he/she had formerly answered ‘no’, the student should immediately inform their supervisor/tutor/module leader who will advise the next course of action.

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2 For the purposes of this policy, a member of staff undertaking research as part of a higher degree at the University of Worcester should follow procedures for students.
3.1.5 When a student answers ‘yes’ to one or more questions in the checklist he/she must progress to complete a full application for ethical approval.

3.1.6 If the student has answered yes to question 20 of the checklist, he/she should liaise with Dr John-Paul Wilson (ethics@worc.ac.uk) before completing a full application to establish if NHS approval is required for the research.

3.1.7 The completed application should be submitted to the student’s supervisor/tutor/module leader for consideration. The supervisor/tutor/module leader should work with the student to ensure that all ethical issues have been identified and addressed.

3.1.8 If the student has answered ‘yes’ to one or more of questions 1-7 (but ‘no’ to all other questions) on the checklist, the supervisor/tutor/module leader may, once he/she is happy that all ethical issues have been identified and addressed, approve the research.³ The completed and approved form should be submitted to the relevant Institute Ethics Coordinator.

3.1.9 If a supervisor/tutor/module leader feels unable to approve the research for whatever reason, he/she must refer the Application for Ethical Approval to the relevant Institute Ethics Committee via the relevant Institute Ethics Coordinator.

3.1.10 If the student has answered ‘yes’ to one or more of questions 8-20 on the checklist, the supervisor/tutor/module leader must refer the Application for Ethical Approval to the relevant Institute Ethics Committee via the relevant Institute Ethics Coordinator.

3.1.11 If the research is externally funded or external funding is being sought the Institute Ethics Coordinator may be required to refer the application to the Ethics and Research Governance Committee automatically.

3.1.12 The Institute Ethics Committee will review applications and contact the student and supervisor/tutor/module leader with the outcome normally within 4 weeks. There are four possible outcomes:

- the application is approved without any changes needed
- the application is approved subject to revisions being made to the satisfaction of the committee
- the application is not approved
- the application is referred to the Ethics and Research Governance Committee

³ The exception to this is if the research is externally funded or external funding is being sought for the research then the Application for Ethical Approval must be referred to the Institute Ethics Coordinator.
3.1.13 The Ethics and Research Governance Committee will review applications and contact the student and supervisor with the outcome normally within 4 weeks. There are three possible outcomes:

- the application is approved without any changes needed
- the application is approved subject to revisions being made to the satisfaction of the committee
- the application is not approved

3.1.14 If a student wishes to deviate from the approved research at any time, he/she should discuss this with his/her supervisor/tutor/module leader and/or the Institute Ethics Coordinator. Any significant deviation will require the student to resubmit the Application for Ethical Approval before continuing with the research.

3.1.15 A significant deviation would include (but is not limited to) the following:

- revised aims and objectives of the research
- change of method (e.g. the use of interviews instead of focus groups)
- recruitment of participant group(s) not identified in the initial application for ethical approval
- fundamental change in how participants are recruited
- fundamental change in a data collection instrument (e.g. using a different questionnaire than that indicated in the initial application for ethical approval)
- significant revision of information sheets, consent forms or any other supporting documentation

3.1.16 On an annual basis, each Institute Ethics Committee will audit 10% or 20 (whichever is fewer) of Applications for Ethical Approval approved by the supervisor/tutor/module leader. The purpose of this audit is to identify training needs for supervisors/tutors/module leaders as appropriate.

3.2 Failure to comply with ethical review procedures

3.2.1 Any student who does not gain ethical approval before undertaking research will be subject to a penalty proportionate to the level of the offence. Where a student is subject to an externally imposed professional code of conduct, action may also be required under the code concerned.

3.2.2 An offence will be deemed as:

- a. Minor
- b. Major

3.2.3 An offence is normally deemed minor if:
a. the student did not gain ethical approval before undertaking research and  
b. the research did not involve primary data collection

3.2.4 For a minor offence:
  • an undergraduate student’s work will normally be downgraded by 2 grade points, e.g. a B+ will become a B-, a C- will become a D  
  • a postgraduate taught student’s work will normally be downgraded by 10%  
  • a postgraduate research student will not be permitted to progress, i.e. their research proposal (RDB1) will not be approved, until he/she has attained ethical approval

3.2.5 An offence is normally deemed major if:
  a. the student/s did not gain ethical approval before undertaking research and  
  b. the research involved primary data collection from humans or animals

3.2.6 For a major offence:
  • an undergraduate or taught postgraduate student will normally be awarded a mark of zero fail for the assessment  
  • a postgraduate research student will not be permitted to progress, i.e. their research proposal (RDB1) will not be approved, until he/she has attained ethical approval and the student will also be required to undertake Ethics training

3.2.7 If the offence is deemed particularly serious, e.g. if research of a sensitive nature has been undertaken with a vulnerable group, the matter may be referred to the University’s Ethics and Research Governance Committee which will consider whether additional penalties are appropriate.

3.2.8 Any student who makes a significant deviation from the approved research without being granted ethical approval for this deviation will be subject to a penalty proportionate to the offence to be decided in discussion between the supervisor/tutor/module leader and the Institute Ethics Coordinator.

4. Ethical Review Procedures (Staff and Associate Researchers)

4.1 Application for Ethical Approval

4.1.1 All staff and associate researchers are required to complete an Application for Ethical Approval before commencement of any research.

4.1.2 The application requires the researcher initially to complete a checklist designed to highlight any potential ethical issues with the
research. The researcher should always answer the questions honestly, taking into account the ethical principles outlined in Section 2 of this document.

4.1.3 When a researcher answers ‘no’ to all questions, he/she submits the signed form to the relevant Institute Ethics Coordinator. The research is not normally subject to any further review.

4.1.4 It is important to note that researchers should keep their answers to the checklist questions under review. If the researcher believes at any point during the research that he/she would now answer ‘yes’ to a question where he/she had formerly answered ‘no’, the researcher should immediately inform their Institute Ethics Coordinator who will advise the next course of action.

4.1.5 When a researcher answers ‘yes’ to one or more questions in the checklist he/she must progress to complete a full application for ethical approval and submit this to the relevant Institute Ethics Committee via the relevant Institute Ethics Coordinator.

4.1.6 If the research is externally funded or external funding is being sought the Institute Ethics Coordinator may be required to refer the application to the Ethics and Research Governance Committee automatically.

4.1.7 If the researcher has answered yes to question 20 of the checklist, he/she should liaise with Dr John-Paul Wilson (ethics@worc.ac.uk) before completing a full application to establish if NHS approval is required for the research.

4.1.8 The Institute Ethics Committee will review applications and contact the researcher with the outcome normally within 4 weeks. There are five possible outcomes:

- the application is approved without any changes needed
- the application is approved subject to revisions being made to the satisfaction of the committee
- the committee seeks additional information/documentation before making a decision
- the application is not approved
- the application is referred to the Ethics and Research Governance Committee

4.1.9 The Ethics and Research Governance Committee will review applications and contact the researcher with the outcome normally within 4 weeks. There are four possible outcomes:

- the application is approved without any changes needed
- the application is approved subject to revisions being made to the satisfaction of the committee
- the committee seeks additional information/documentation before making a decision
• the application is not approved

4.1.10 If a researcher wishes to deviate from the approved research at any time, he/she should discuss this with the Institute Ethics Coordinator. Any significant deviation will require the researcher to resubmit the Application for Ethical Approval before continuing with the research.

4.1.11 A significant deviation would include (but is not limited to) the following:
• revised aims and objectives of the research
• change of method (e.g. the use of interviews instead of focus groups)
• recruitment of participant group(s) not identified in the initial application for ethical approval
• fundamental change in how participants are recruited
• fundamental change in a data collection instrument (e.g. using a different questionnaire than that indicated in the initial application for ethical approval)
• significant revision of information sheets, consent forms or any other supporting documentation

4.2 Failure to comply with ethical review procedures

Any member of staff or associate researcher who does not gain ethical approval before undertaking research with humans or animals or who makes a significant deviation from the approved research without being granted ethical approval for this deviation will be subject to investigation under the Procedures for Dealing with Research Misconduct as set out in the University’s Guidelines and Procedures for Good Research Practice.

5. Appeals against a decision of an Ethics Committee

5.1 A researcher may not appeal against the decision of an Ethics Committee purely on the grounds he/she disagrees with the decision. The following constitute grounds for appeal:
• there were material errors in procedure which impacted on the decision of the Committee
• the decision demonstrates factual error on the part of the Committee
• there is evidence of bias or prejudice on the part of the Committee or of one or more of its members

5.2 If a researcher intends to make an appeal against a decision of an Ethics Committee, he/she is encouraged to engage in a dialogue with the Chair of that committee before doing so. It may be possible to reach a mutually satisfactory decision without recourse to appeal.

That is an Institute Ethics Committee or the University’s Ethics and Research Governance Committee.
5.3 If a researcher wishes to appeal against a decision of an Institute Ethics Committee, he/she is required to submit a written statement setting out the grounds for the appeal with any supporting evidence to the Chair of the Ethics & Research Governance Committee within 20 working days of receiving the Institute Ethics Committee’s decision.

5.4 He/she will normally consider the appeal within 10 working days of receiving the appeal paperwork and relay the decision to the researcher and to the relevant Institute Ethics Coordinator.

5.5 He/she may reach the following decisions:
   - the appeal is rejected and the original decision of the Institute Ethics Committee stands
   - the appeal is upheld and the Application for Ethical Approval is referred to the Ethics and Research Governance Committee for review

5.6 There is no further right of appeal if it is rejected.

5.7 If a researcher wishes to appeal against a decision of the Ethics and Research Governance Committee, he/she is required to submit a written statement setting out the grounds for the appeal with any supporting evidence to the Chair of the Research and Knowledge Transfer Committee within 20 working days of receiving the Ethics and Research Governance Committee’s decision.

5.8 He/she will normally consider the appeal within 10 working days of receiving the appeal paperwork and relay the decision to the researcher and to the Chair of the Ethics and Research Governance Committee.

5.9 He/she may reach the following decisions:
   - the appeal is rejected and the original decision of the Ethics and Research Governance Committee stands
   - the appeal is upheld and the Application for Ethical Approval is referred to an expert panel convened by the Chair of the Research and Knowledge Transfer Committee

5.10 There is no further right of appeal against this decision.

6. Complaints relating to the conduct of an Ethics Committee

6.1 A researcher may make a complaint relating to the conduct of an Ethics Committee in the following circumstances:
   - procedures were not followed as set out in this policy and this had a material impact on the delivery of the research
   - the researcher feels he/she was discriminated against on the grounds of age, disability, gender, race, faith or sexual orientation
- the researcher feels he/she was treated unfairly or unreasonably by the Committee during the process of ethical review

6.2 If a researcher intends to make a complaint relating to the conduct of an Ethics Committee, he/she is encouraged to engage in a dialogue with the Chair of that committee before doing so. It may be possible to reach a mutually satisfactory decision without recourse to complaint.

6.3 If a researcher wishes to make a complaint relating to the conduct of an Institute Ethics Committee, he/she is required to submit a written statement setting out the grounds for the complaint with any supporting evidence to the Chair of the Ethics and Research Governance Committee.

6.4 Complaints should be made within a reasonable timescale. A complaint may be summarily rejected where it is felt the researcher has not acted within a reasonable timescale.

6.5 Complaints should not be made at the same time that a researcher is in the process of making an appeal against a decision of the same Ethics Committee.

6.6 If the Chair upholds the complaint he/she will decide on a course of action to resolve or redress the complaint.

6.7 The decision to uphold or reject the complaint and any actions will be communicated to the researcher and the relevant Institute Ethics Coordinator within 10 working days.

6.8 There is no further right of complaint.

6.9 If a researcher wishes to make a complaint relating to the conduct of the Ethics and Research Governance Committee, he/she is required to submit a written statement setting out the grounds for the complaint with any supporting evidence to the Chair of the Research and Knowledge Transfer Committee.

6.10 Complaints should be made within a reasonable timescale. A complaint may be summarily rejected where it is felt the researcher has not acted within a reasonable timescale.

6.11 Complaints should not be made at the same time that a researcher is in the process of making an appeal against a decision of the Ethics and Research Governance Committee.

6.12 If the Chair upholds the complaint he/she will decide on a course of action to resolve or redress the complaint.
6.13 The decision to uphold or reject the complaint and any actions will be communicated to the researcher and the Chair of the Ethics and Research Governance Committee within 10 working days.

6.14 There is no further right of complaint.

7. Continuing Ethical Review

7.1 The University does not undertake a systematic continuing ethical review of research undertaken. As noted above, however, it encourages all researchers to review their answers to the checklist on an ongoing basis and to resubmit for approval where there are deviations from the approved research.

7.2 It is also common practice for Institutes to approve research in stages or phases rather than as a whole, recognizing that later phases of data collection may change substantively in light of earlier stages.

7.3 The University also undertakes an audit of a random sample of approved research. Some researchers will be approached to complete a questionnaire, in the case of a student in conjunction with their supervisor or tutor.

8. Roles and Responsibilities of Staff and of Committees in Ethical Review Procedures

8.1 It is the responsibility of the supervisor/tutor/module leader:
   - To support their students towards a greater understanding and engagement with ethical issues in research
   - To ensure their students are fully aware of the University’s Ethics Policy
   - To attend appropriate staff development and training on ethics

8.2 It is the responsibility of the Institute Ethics Coordinator:
   - To chair the Institute Ethics Committee
   - To represent the Institute on the University’s Ethics and Research Governance Committee
   - To facilitate ethical review procedures at Institute level
   - To maintain accurate records of all Applications for Ethical Approval submitted within the institute
   - To provide an annual written report to the University’s Ethics and Research Governance Committee through completion of the report template
   - To coordinate the training of staff and students within the Institute on ethical issues

8.3 It is the responsibility of the Institute Ethics Committees:
   - To promulgate good conduct in research and professional practice across the Institute
• To ensure mechanisms are in place to monitor the conduct of research that has been granted approval within the Institute
• To undertake review of all Applications for Ethical Approval referred to the Committee

8.4 It is the responsibility of the University’s Ethics and Research Governance Committee:
• To promulgate good conduct in research and professional practice across the institution
• To act in an advisory capacity to University Committees, Institute Committees, Research Centres and individuals (staff or student) on ethical and research governance matters
• To keep the University’s policies and guidelines on ethics and research governance under review, responding in particular to Research Council and Government Frameworks/Guidelines, and to make recommendations to Academic Board for their development
• To keep the University’s ethics policy and ethical review procedures under review, responding in particular to Research Council and Government Framework/Guidelines, and to make recommendations to Academic Board for their development
• To ensure mechanisms are in place to monitor the conduct of research that has been granted approval
• To monitor the operation of Institute Ethics Committees and to receive reports from these groups
• To undertake reviews of research projects (staff and student) when such projects are referred to the Committee by Institutes
• To formulate institutional responses to national and international developments relating to ethical and research governance issues

9. Collaborative Research

9.1 Where research is undertaken with another HEI, it is best practice that only the ethics committee of the lead researcher’s/principal investigator’s HEI will undertake a full ethical review of the research, with the HEI(s) of any co-investigator(s) being kept fully informed of the process and outcome. This is in line with the ESRC Research Ethics Framework which recommends that organisations should avoid duplication of full ethical review.

9.2 Where research is undertaken with an organisation outside the Higher Education sector that has its own ethical approval system, the same principle of avoiding duplication of full ethical review should be maintained. As noted at 3.2.3 and 4.2.2, in the case of research involving NHS patients or premises, full approval should be sought through an NHS Research Ethics Committee. The University will not undertake a full ethical review but will expect the researcher to submit a copy of all NHS review and approval paperwork to the relevant
Institute Ethics Coordinator. In the case of other organisations, for example the NCT, judgment should be made on a case-by-case basis as to whether the research should be subject to full review by Worcester and/or the collaborating organisation.