Ethics Policy

Contact Officer
Deputy Pro Vice Chancellor Research

Purpose
This policy sets out the principles for ethical research and the processes by which researchers should seek ethical approval for their research. 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.

Overview
This policy is organised into sections:
1. Scope of Policy
2. Ethical Principles
3. Roles and Responsibilities of Staff and of Ethical Review Bodies in Ethical Review Procedures
4. Ethical Review Procedures (taught degree students)
5. Ethical Review Procedures (research degree students)
6. Ethical Review Procedures (Staff and Associate Researchers)
7. Deviation from approved research
8. Failure to comply with ethical review procedures
9. Review of a decision of an Ethical Review Body
10. Complaints relating to the conduct of an Ethical Review Body
11. Continuing Ethical Review
12. Collaborative Research

Scope
The policy applies to all staff and research students at the University engaged in research, and any individual who is not a member of staff or student at the University but is undertaking research using University premises and facilities, and/or in the University’s name. For the purpose of the policy, these groups are referred to collectively as “researchers”.

The Policy

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 Research Committee on a bi-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
   - Any risk of harm to participants, animal subjects or the researcher(s) should be appropriately mitigated

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. their political opinions
   c. their religious beliefs or other beliefs of a similar nature
   d. whether they are a member of a trade union
   e. their physical or mental health or condition
   f. their sexual life
   g. the commission or alleged commission by them of any offence
   h. proceedings for any offence committed or alleged to have been committed by them, 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 they lack capacity
- not treat a person as unable to make a decision unless all practicable steps to help them 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 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

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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’. 
(or representative of the researcher, e.g. a gatekeeper) and the participant - such as between a lecturer and their students or a doctor and their 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.

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 **Risk 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 make adjustments to the project design accordingly 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.

2.6.5 For research with animals, high standards should be set for their care and welfare and experimental techniques should be designed to minimise distress to the animals.
3. Roles and Responsibilities of Staff and of Ethical Review Bodies in Ethical Review Procedures

Staff

3.1 A great many staff are engaged in the supervision of student research (hereafter referred to as “supervisors”) whether in the context of Doctoral or Masters supervision, as tutor for an undergraduate independent study or as a module leader where research is a significant element of the module content and/or assessment. It is the responsibility of these staff:
- To support their students towards a greater understanding and engagement with ethical issues in research
- To ensure their students are fully aware of this policy
- To approve Applications for Ethical Approval as set out in this policy
- To attend appropriate staff development events on ethics to ensure their knowledge is up-to-date and relevant

3.2 More broadly it is the expectation that staff with experience of research and/or of ethics advise and support less experienced staff in developing Applications for Ethical Approval and in engaging in ethical research.

3.3 Each institute will have an identified Ethics Coordinator. It is the responsibility of the Institute Ethics Coordinator:
- To chair the Institute Ethics Panel
- To facilitate ethical review procedures for students (excluding PGR students) at Institute level
- To maintain accurate records of all Applications for Ethical Approval for students (excluding PGR students) submitted within the institute
- To provide an annual written report to the relevant Research Ethics Committee through completion of the annual report template
- To coordinate the training of staff and students within the Institute on ethics, research integrity and research data management
- To act in an advisory capacity to staff and students within the Institute

Ethical Review Bodies

3.4 Each Institute will have an Ethics Panel. It is the responsibility of the Institute Ethics Panel:
- 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 oversee ethical review procedures for students (excluding PGR students) at Institute level
- To undertake review of all Applications for Ethical Approval referred to the Panel
- To audit 10% or 20 (whichever is fewer) of Applications for Ethical Approval approved by the supervisor
- To report to the relevant Research Ethics Committee

3.5 The University will have two Research Ethics Committees which will have responsibilities for
defined subject areas as follows:
- Health and Sciences
- Humanities, Arts and Social Sciences

3.6 It is the responsibility of the University’s Research Ethics Committees, within their defined subject area:
- To promulgate good conduct in research in relevant subject areas.
- To keep the University’s policies and procedures for ethical approval of research projects under review, responding in particular to Research Council and Government Framework/ Guidelines, and to make recommendations to Research Committee for their development.
- To review all applications for ethical approval from staff and PGR students
- To review all applications for ethical approval from UG and PGT students referred by Institute Ethics Panels and to hear appeals against decisions of Institute Ethics Panels.
- To monitor the operation of relevant Institute Ethics Panels and to receive annual reports from these Panels.
- To report to Research Committee
- To act in an advisory capacity to Research Committee and other committees as required.
- To act in an advisory capacity to researchers applying for external ethical approval in particular through the HRA.

4. Ethical Review Procedures (taught degree students)²

4.1 Any student intending to undertake research involving humans or animals (as specified at 1.4 of this policy) is required to complete an Application for Ethical Approval before commencement of the research.

4.2 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.

4.3 When a student answers ‘no’ to all questions, they submit the form to the supervisor. If the supervisor is satisfied with the answers in the checklist, they submit the approved form to the relevant Institute Ethics Coordinator. The research is not normally subject to any further review.

4.4 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 they would now answer ‘yes’ to a question where they had formerly answered ‘no’, the student should immediately inform their supervisor who will advise the next course of action.

4.5 When a student answers ‘yes’ to one or more questions in the checklist normally they must progress to complete a full application for ethical approval; however, where the research involves work with the NHS they should seek advice from Ethics Help as they may need to seek relevant approvals through the Health Research Authority in place of or in addition to UW

² Any student on a Foundation degree, Undergraduate (UG) degree or Postgraduate Taught (PGT) degree.
The completed application, and supporting documents, should be submitted to the student’s supervisor for consideration. The supervisor should work with the student to ensure that all ethical issues have been identified and addressed and that all the required supporting documentation has been provided.

If the ethical risk is deemed low, they may approve the Application and submit it (and the associated documentation) to the relevant Institute Ethics Coordinator.

If the ethical risk is deemed more significant, the student should submit the Application for Ethical Approval and associated paperwork to the relevant Institute Ethics Coordinator.

What constitutes low ethical risk will be determined by the Institute Ethics Panel (as appropriate to the disciplines under its remit) but would normally describe research focused on topics of limited sensitivity; involving limited intrusion or disruption to others; and involving participants who would not be considered vulnerable in the context of the research.

The Institute Ethics Panel will review applications in line with the Standard Operating Procedures for Institute Ethics Panels.

The outcome of the review will be communicated to the student and supervisor. Possible outcomes are as follows:

- Approved
- Approved subject to amendments being made to the satisfaction of the Chair
- Resubmission taking into account amendments set out by the committee
- Referral to another ethical review body
- Application incomplete
- Rejection

Where a researcher is asked to complete amendments for the approval by the Chair a timescale will be specified. Failure to meet this timescale may lead to the researcher having to make a new application.

5. Ethical Review Procedures (research degree students)

Any PGR students intending to undertake research involving humans or animals (as specified at 1.4 of this policy) is required to complete an Application for Ethical Approval before commencement of the research.

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.

When a student answers ‘no’ to all questions, they submit the form to the supervisor, normally

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3 Any student on a Professional Doctorate programme, PhD programme, MPhil programme or MRes programme.
the Director of Studies. If the supervisor is satisfied with the answers in the checklist, they submit the approved form to the Secretary of the relevant Research Ethics Committee. The research is not normally subject to any further review.

5.4 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 they would now answer ‘yes’ to a question where they had formerly answered ‘no’, the student should immediately inform their supervisor who will advise the next course of action.

5.5 When a student answers ‘yes’ to one or more questions in the checklist normally they must progress to complete a full application for ethical approval; however, where the research involves work with the NHS they should seek advice from Ethics Help as they may need to seek relevant approvals through the Health Research Authority in place of or in addition to UW approval.

5.6 The completed application, and supporting documents, should be submitted to the student’s supervisor for consideration. The supervisor should work with the student to ensure that all ethical issues have been identified and addressed and that all the required supporting documentation has been provided.

5.7 The supervisor should also agree with the student whether the application is to be submitted for Full Review or Proportionate Review.

5.8 Researchers should only submit for Proportionate review where the proposed research is of low ethical risk. Such research would normally focus on topics of limited sensitivity; involve limited intrusion or disruption to others; and involve participants who would not be considered vulnerable in the context of the research.

5.9 The student should submit the agreed Application for Ethical Approval and associated documents to ethics@worc.ac.uk identifying in the subject line the specific Research Ethics Committee to which they are submitting.

5.10 Research Ethics Committees will review applications in line with the Standard Operating Procedures for Research Ethics Committees.

5.11 The outcome of the review will be communicated to the student and supervisor. Possible outcomes are as follows:

- Approved
- Approved subject to amendments being made to the satisfaction of the Chair
- Resubmission taking into account amendments set out by the committee
- Referral to another ethical review body
- Application incomplete
- Rejection

5.12 Where a researcher is asked to complete amendments for the approval by the Chair a timescale will be specified. Failure to meet this timescale may lead to the researcher having to make a
new application.

6 Ethical Review Procedures (Staff and Associate Researchers)

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

6.2 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.

6.3 When a researcher answers ‘no’ to all questions, they submit the signed form to ethics@worc.ac.uk identifying in the subject line the specific Research Ethics Committee to which they are submitting. The research is not normally subject to any further review.

6.4 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 they would now answer ‘yes’ to a question where they had formerly answered ‘no’, the researcher should immediately inform the Secretary of the relevant Research Ethics Committee who will advise the next course of action.

6.5 When a researcher answers ‘yes’ to one or more questions in the checklist normally they must progress to complete a full application for ethical approval; however, where the research involves work with the NHS they should seek advice from Ethics Help as they may need to seek relevant approvals through the Health Research Authority in place of or in addition to UW approval.

6.6 The researcher should identify whether the application is submitted for Full Review or Proportionate Review.

6.7 Researchers should only submit for Proportionate review where the proposed research is of low ethical risk. Such research would normally focus on topics of limited sensitivity; involve limited intrusion or disruption to others; and involve participants who would not be considered vulnerable in the context of the research.

6.8 The researcher should submit the agreed Application for Ethical Approval and associated documents to ethics@worc.ac.uk identifying in the subject line the specific Research Ethics Committee to which they are submitting.

6.9 Research Ethics Committees will review applications in line with the Standard Operating Procedures for Research Ethics Committees.

6.10 The outcome of the review will be communicated to the researcher. Possible outcomes are as follows:

- Approved

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4 For the purposes of this policy, staff undertaking a UG or PGT degree will be dealt with under the student procedures set out in section 3.
6.11 Where a researcher is asked to complete amendments for the approval by the Chair a timescale will be specified. Failure to meet this timescale may lead to the researcher having to make a new application.

7 Deviation from approved research

7.1 Deviations from approved research are defined as major or minor.

7.2 A major deviation would include (but is not limited to) the following:
- 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 changes in how participants are recruited
- fundamental changes 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

7.3 A minor deviation would include (but is not limited to) the following:
- minor changes in how participants are recruited
- minor changes in a data collection instrument (e.g. non-material revisions to the wordings of a questionnaire included in the initial application for ethical approval)
- minor revision of information sheets, consent forms or any other supporting documentation

7.4 Researchers should seek guidance in assessing whether a deviation is minor or major from their supervisor, Institute Ethics Coordinator or the Secretary of the relevant Research Ethics Committee as appropriate.

7.5 For minor deviations, researchers should retain a record but no further action is necessary.

7.6 For major deviations, researchers should complete a new Application for Ethical Approval and submit to the appropriate process.

8. Failure to comply with ethical review procedures

Student

8.1 Any student who does not gain ethical approval before undertaking research will be subject to a penalty as set out in the Procedures for Investigations of Cases of Alleged Academic Misconduct, which will normally be proportionate to the ethical risk associated with the
research.

8.2 If a student makes a significant deviation from the approved research without being granted ethical approval for this deviation this will also be treated under the Procedures for Investigations of Cases of Alleged Academic Misconduct.

**Staff**

8.3 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 the Procedures for Dealing with Research Misconduct.

9. **Review of a decision of an Ethical Review Body**

9.1 A researcher may *not* ask for a review of the decision of an ethical review body\(^5\) purely on the grounds they disagree with the decision. The following constitute grounds for review:

- there were material errors in procedure which impacted on the decision of the body
- the decision demonstrates factual error on the part of the body
- there is evidence of bias or prejudice on the part of the body or of one or more of its members

9.2 If a researcher intends to request a review of the decision of an ethical review body, they are encouraged to engage in a dialogue with the Chair of that body before doing so. It may be possible to reach a mutually satisfactory decision without recourse to review.

9.3 If a student wishes to request a review of a decision of an Institute Ethics Panel, they are required to submit a written statement setting out the grounds for the review with any supporting evidence to the Chair of the relevant Research Ethics Committee within 20 working days of receiving the Institute Ethics Panel’s decision.

9.4 They will normally consider the request within 10 working days of receiving the paperwork and relay the decision to the student and their supervisor and to the relevant Institute Ethics Coordinator.

9.5 They may reach the following decisions:

- the case is rejected and the original decision of the Institute Ethics Panel stands
- the case is upheld and the Application for Ethical Approval is referred to the relevant Research Ethics Committee for review

9.6 There is no further right of review if it is rejected.

9.7 If a researcher wishes to request a review of a decision of a Research Ethics Committee, they are required to submit a written statement setting out the grounds for the request with any supporting evidence to the Chair of the Research Committee within 20 working days of receiving

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\(^5\) That is an Institute Ethics Panel or a University Research Ethics Committee.
They will normally consider the request within 10 working days of receiving the paperwork and relay the decision to the researcher (and supervisor in the case of a student) and to the Chair of the Research Ethics Committee.

They may reach the following decisions:
- the case is rejected and the original decision of the Research Ethics Committee stands
- the case is upheld and the Application for Ethical Approval is referred to an expert panel convened by the Chair of the Research Committee

There is no further right of review of this decision or any subsequent decision of the expert panel.

10. Complaints relating to the conduct of an Ethical Review Body

A researcher may make a complaint relating to the conduct of an ethical review body 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 they were discriminated against on the grounds of age, disability, gender, race, faith or sexual orientation
- the researcher feels they were treated unfairly or unreasonably by the body during the process of ethical review

If a researcher intends to make a complaint relating to the conduct of an ethical review body, they are encouraged to engage in a dialogue with the Chair of that body before doing so. It may be possible to reach a mutually satisfactory decision without recourse to complaint.

If a researcher wishes to make a complaint relating to the conduct of an ethical review body, they are required to submit a written statement setting out the grounds for the complaint with any supporting evidence to the Chair of the Research Committee.

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.

If the Chair of the Research Committee upholds the complaint they will decide on a course of action to resolve or redress the complaint.

The decision to uphold or reject the complaint and any actions will be communicated to the researcher and the Chair of the ethical review body within 10 working days.

There is no further right of complaint.

11. Continuing Ethical Review

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.

11.2 It is also common practice for ethical review bodies 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.

11.3 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.

12. Collaborative Research

12.1 Where research is undertaken with another HEI, it is best practice that only the relevant 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.

12.2 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. In the case of research involving NHS patients or premises as noted above, approval should be sought through relevant NHS ethical review processes with the outcome and approval paperwork being forwarded to the relevant ethical review body. In the case of other organisations, 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, with advice being sought from the relevant Institute Ethics Coordinator or Secretary of a Research Ethics Committee.

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<td>Academic Board</td>
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