

## Quality Management System

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Higher Education Research Ethics Policy

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**Contents**

<b>Section and Title</b>	<b>Page Number</b>
Alternative Format Statement	2
1.0 Introduction	4
2.0 Definitions	4
3.0 Research on Human/Other Living Participants (or related biological materials)	5
4.0 Ethics Principles for Research involving Human Participants	6
5.0 Procedure	9
6.0 Research Ethics Committee (REC)	11
7.0 Considerations	14
8.0 Summary of Potential Liabilities of Researchers	16
Contact Information	17
Summary of significant changes	17

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# Higher Education Research Ethics Policy

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## 1.0 Introduction

**1.1** Bishop Auckland College is committed to maintain standards of professional conduct in all research activities. Central to the principles that guide research is that research must be conducted in accordance with the highest contemporary ethics standards.

**1.2** This policy provides information on Research Ethics at Bishop Auckland College. The policy covers research involving the collection of data and/or biological samples from human or other living participants. It also provides links to internal and external advice and full details of the Bishop Auckland College Research Ethics Committee (REC).

**1.3** The research ethics review process is part of the REC remit to scrutinise and advise on ethical considerations relating to any research carried out by, and for, Bishop Auckland College, which involves investigations involving the collection of data and/or biological samples from human or other living participants.

**1.4** This policy also contains processes staff and/or students must follow when completing research at Bishop Auckland College.

## 2.0 Definitions

**2.1** Definition of Research:

'Research' for the purposes of this policy is to be understood as:

- Original investigation undertaken in order to gain knowledge and understanding
- Work of direct relevance to the needs of commerce, industry and to the public and voluntary sectors
- Scholarship
- The invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights
- The use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

## **2.2** Definition of Research Activity:

Research activity is defined as Bishop Auckland College research activity where:

- Bishop Auckland College takes on ultimate responsibility for the research, and/or, the activity is being undertaken in fulfilment (or part-fulfilment) of a Bishop Auckland College programme of study/academic award

And/or

- A member of Bishop Auckland College staff, or a student enrolled at the College is:
  - An Academic Supervisor And/or
  - Holds the research funding

## **3.0 Research on Human/Other Living Participants (or related biological materials)**

It is essential that Bishop Auckland College research involving collection of data or biological samples from human/other living participants (including biological samples) is assessed or reviewed for ethical issues before any potential participants are contacted.

To do this, the REC Project Registration and Risk Checklist (HE-RR-01), should be completed and returned to [HE@bacoll.ac.uk](mailto:HE@bacoll.ac.uk). Research Supervisors will recommend to the REC Chair whether an ethical application is required. Research that has been deemed to contain ethics-related implications should go through the full research ethics review process, achieved by fully completing the REC Proforma (HE-RR-02) and returning it to [HE@bacoll.ac.uk](mailto:HE@bacoll.ac.uk). This form can be found at <https://bacoll.ac.uk/HE>.

Any research involving Bishop Auckland College students may require agreement from the Safeguarding Team. Any research involving Bishop Auckland College staff may require agreement from Human Resources. Research consisting entirely of literature review, desk or library-based research may not require ethical approval. However, Research Supervisors are responsible for recommending to both student/staff researchers and the Research Ethics Committee, whether or not a proposed project has ethical implications (even in cases where the potential ethical implication/risk is to the researcher only). The Human Research Authority (HRA) decision tool can be used additionally as guidance in determining if the proposed study would be categorised as research.

#### **4.0 Ethics Principles for Research involving Human Participants**

There are six principles<sup>1</sup> that must be adhered to when conducting Bishop Auckland College research:

##### **Principle 1: Compliance with protocol**

Research with humans conducted by Bishop Auckland College employees and their students should be aware of the range of research ethics, and in particular comply with an explicit protocol\*, defining how valid consent to participate is sought, gained and recorded, how data are collected, stored and accessed, and how participants are informed of their rights within the study.

A favourable opinion on the protocol should be gained from the REC before data collection commences, and from other bodies such as the Safeguarding Team, Human Resources and the UK National Health Service Research Ethics Committee(s), as appropriate. The only exception to this requirement shall be where any reasonable judgement would suggest that no harm could possibly arise to any person, living or dead, in connection with the proposed research.

##### **Principle 2: Valid consent**

Potential participants should always be informed in advance, and in understandable terms, of any potential benefits, risks, inconvenience or obligations associated with the research that might reasonably be expected to influence their willingness to participate.

Consent should always be gained in a consistent manner, as specified in the research project's ethics protocol. This should normally involve the use of an information sheet about the research and what participation will involve and a signed consent form. Sufficient time shall be allowed for a potential participant to consider their decision between the giving of the information sheet and the gaining of consent.

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<sup>1</sup> In these Principles, the term 'protocol' refers to a filed document which specifies the procedures for recruiting participants and gathering and managing data, with which all research staff agree to comply

Except in exceptional circumstances, where the nature of the research design requires it, no research shall be conducted without the opt-in valid consent of participants. In the case of children (individuals under 16 years of age) no research shall be conducted without a specified means of gaining their valid consent (or, in the case of young children, their assent) and the valid consent of their guardians, or persons who are legally responsible or appointed to give consent on their behalf.

Where participants are involved in longer-term data collection, the use of procedures for the renewal of consent at appropriate times should be considered. No inducement to participate should be offered prior to seeking consent, either in the form of payments or of gifts. Reasonable recompense for inconvenience and time contributed to the research and reimbursement of travelling expenses can be offered (subject to approved financial support being available).

Participants should be informed clearly that they have a right to withdraw their consent at any time up to a specified date, that any data that they have provided will be destroyed if they so request up to a specified date, and that there will be no adverse consequences for participants if they choose to withdraw or request data destruction. However, it must be clear that withdrawal after a specified date may not be possible as it would unduly affect the study.

### **Principle 3: Openness and integrity**

Researchers should be open and honest about the purpose and content of their research and behave in a professional manner at all times.

Researchers should comply with the College's principles for integrity in the general conduct of research. Where an essential element of research design would be compromised by full disclosure to participants prior to their involvement, such withholding of information should be specified in the project protocol and explicit procedures stated to obviate any potential harm arising from such withholding.

Deception or covert collection of data should only take place where it is essential to achieve the research results required, where the research objective has strong scientific merit and where there is an appropriate risk management and harm alleviation strategy.

Participants should be given opportunities to access the outcomes of research in which they have participated and debriefed if appropriate after they have provided data.

**Principle 4: Maximising benefit and protection from harm**

Researchers should make every effort to maximise the benefits of research while minimising the risks of any harm, either physical or psychological, arising for any participant, researcher, institution, funding body or other person or community.

Every project should include a risk analysis and, where significant risks are identified, should specify a risk management and harm alleviation strategy in the protocol.

Researchers should comply with the requirements of the UK Data Protection Act 2018, the Freedom of Information Act 2000 and any other relevant legal frameworks governing the management of personal information in the UK or in any other country where the research may be conducted.

Where research involves children or other vulnerable groups, an appropriate level of disclosure should be obtained from the Disclosure and Barring Service (DBS) for all researchers in contact with participants.

Where harm does nevertheless arise in the course of research, researchers should take remedial steps. For further support in this regard, researchers should speak to their research supervisor for further and immediate guidance.

Participants should be given information as to whom they may contact in the event of any issues arising in the course of the research that cannot be resolved with members of the project team.

**Principle 5: Confidentiality**

Except where explicit written consent is given to reveal identities, researchers should respect and preserve the confidentiality<sup>2</sup> of participants' identities and data. The procedure by which this is to be achieved should be specified in the protocol.

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<sup>2</sup> Note that the duty of confidentiality is not absolute in law and may be overridden by more compelling duties such as the duty to protect individuals from harm or in the public interest – such as in research involving public officials. Where a significant risk of such issues arising is identified in the risk assessment, specific procedures to be followed should be specified in the protocol.

**Principle 6: Professional codes of practice and ethics**

Where the subject of a research project falls within the domain of a professional body with a published code of practice and ethical guidelines, researchers should explicitly state their intention to comply with the code and guidelines in the project protocol.

Research within the UK NHS should always be conducted in compliance with an ethical protocol approved by an appropriate NHS Research Ethics Committee.

**5.0 Procedure****5.1 Ethical Clearance**

Ethical clearance is required for all Bishop Auckland College research activity, except those projects which consist entirely of literature review, desk or library-based research, which does not pose an ethical risk to the student researcher. Students, in particular, should also be made aware that some areas of literature and library-based research may nevertheless involve sensitive or controversial material which will require a degree of care when accessing and handling. Literature or library-based work which is primarily carried out external to the College, for instance in an off-site archive, requires ethical clearance.

Ethical clearance is obtained by application to the REC before research commences:

A research ethics application should be made as follows:

- Research Proposal Proforma (HE-RR-02) – this form is completed and submitted to the research supervisor by the student researcher. Research supervisors must provide supporting comments and signature sign-off of the HE-RR-02 document in order for the research ethics application to progress any further.
- Project Registration and Risk Assessment (HE-RR-01) – this form is completed and submitted to the research supervisor by the student researcher. Research supervisors must provide supporting comments and signature sign-off of the HE-RR-01 document. This will occur following final discussions regarding risk between the student researcher and the research supervisor. The research supervisor should return the OU-RR-01 form to the student researcher following sign-off. The student researcher should then submit their HE-RR-01 form to [HE@bacoll.ac.uk](mailto:HE@bacoll.ac.uk)

## **5.2** Dissertations and Research Projects

There are two distinct categories of dissertations/research projects:

1. Those not involving human/other living participants and/or not involving potential physical or psychological risk to the researcher(s) themselves. These projects will usually be entirely desk and/or library-based and the same kind of research will be done by an entire group of students. These projects DO NOT require ethical clearance. However, the member of staff responsible for the module in which such work is occurring must keep a record that confirms that these projects meet the criteria of “entirely desk and/or library-based” and such a record must be available for audit by REC if requested.
2. Those which do involve human/other living participants, and/or involving potential or psychological risk to the researcher(S) themselves. In these cases, ethical clearance WILL be required.

## **5.3** Case of doubt

If a member of staff, a supervisor or student, has concerns about the ethical propriety of a piece of research they should approach the Chair of the REC for advice as early in the project planning stage as is possible, and certainly well before preparing and applying for clearance.

## **5.4** Supplementary Documentation

If the research involves data collection from or about human/other living participants, normally the following documentation will be attached to the application for clearance by the approval route:

- Consent form
- Participant information sheet
- Data collection tools e.g., questionnaire, topic guides for focus groups, semi-structured interview questions (as appropriate)

As stated in the Ethics Principles for Research on Human Participants (section 3), the expectation is that research with human participants will be conducted on the basis of valid informed consent.

Projects seeking clearance for methods involving variation from this may be approved by the REC, but only in very specific contexts in which the lack of proper information is justified by the value of the research proposed and the College is not exposed to undue risk nor would insurance cover be compromised. The Chair of the REC may need to seek confirmation regarding Bishop Auckland College's insurance status as part of the review process in such projects.

### **5.5 Contact Details**

The personal contact details of researchers should not be used in study documentation – in all cases only College contact details should be used. For any staff or student research the Academic Supervisor's College contact details should be used. If telephone contact details are required this should either be the supervisor's college number, the student's business number, or a dedicated number for that study only.

### **5.6 External (Non-Bishop Auckland College) Approvals and Permissions**

It is the responsibility of the applicant for clearance to determine which external approvals and permissions are required for the project they propose and to detail that data in their application. It is the responsibility of the applicant to ensure that the governance standards and requirements of all relevant external bodies or agencies are adhered to in the planning and conduct of the research.

DBS checks are commonly needed for researchers working in certain areas. The REC will not accept an applicant's self-verification of such checks. As a result, documentary proof in some form must be included with any applications for clearance.

## **6.0 Research Ethics Committee (REC)**

### **6.1 Arrangements**

The REC member is as follows:

- I. Director of Quality and Higher Education (Chair)
- II. Higher Education Development Coordinator (Deputy Chair)
- III. Programme Leaders (appropriate to programmes being considered)
- IV. Module Leaders for the relevant research modules
- V. Higher Education Administrator

Proposing and determining that the Committee is quorate. The Committee will be deemed as quorate by the Chair, if attended by the Director of Quality and HE or HE Development Coordinator, the at least two programme leaders – including the one whose students' research proposal is being considered, plus one other. Each module leader for which research proposals are being presented, and a suitable administrator.

The REC will convene at appropriate points across the academic year. Dates will be set at the commencement of each academic year in conjunction with programme leaders' assessment plans.

Once an application has been received by the REC it will be presented during a meeting by a representative of the student researchers programme team. Other members of the REC will be responsible for assessing the ethical approval. The representative of the student's programme team will only be involved in the discussion to provide information relating to the application. They will not be involved in the decision-making process. A formal response of the outcome of all research ethics applications will be sent via email, within 7 working days of the date of the REC meeting however, some applications can take longer.

## **6.2** Cases of REC Concern

Where the REC has concerns about the ethical propriety of the proposed research project these concerns will be sent in writing to the applicant and a response invited. In addition, a member of the REC may be nominated to work with the researcher(s), to assist them in addressing the issues identified during review.

## **6.3** Opportunity for Resubmission of a REC Application

The REC will allow resubmission of a previous ethical application provided the researcher follows the feedback provided by the REC and gains their research supervisor's permission to resubmit their application.

## **6.4** Appealing REC Decisions

Applicants may appeal a final decision made by the REC, but only after first attempting to resolve any issue by dialogue. Appeals may be made only with regards to procedural error by the REC and not on the basis of ethical judgement and/or disagreement.

Students who consider that the College has failed to carry out its duty to act fairly in the application of this Research Ethics Policy, and would like to appeal this decision, they should consult the Academic Appeals Procedure for further guidance outside of this Policy.

#### **6.5** Submission of Project Registration and Risk Assessment Research Proposal Proforma

A single copy of the Project Registration and Risk Assessment and Research Proposal Proforma must be filed in the Programme Course File on completion and signature by the Chair of the REC.

As part of post-clearance audit procedures, the HE Office may request copies of specific ethical release or ethical approval forms at any time whilst a project is ongoing or afterwards.

#### **6.6** Post clearance audit of projects

It is a condition of ethical clearance that a small number of projects will be audited each year to ensure that:

- Applicants are following this policy correctly in order to gain ethical clearance
- Project protocols are being followed, particularly after ethical approval
- Any research design changes that may affect the ethical propriety of the research are being resubmitted to the REC for further ethical clearance
- Proper checks and balances are being made across the College to ensure legal compliance

The audit should have taken place by the last meeting of the REC for the academic year in question and will be overseen by HE Office and the Chair of Academic Board. Projects selected for audit and the results should be reported on as part of the REC's Annual Report. It is expected that the projects audited will be selected from the full diversity of levels, including staff projects.

## **7.0 Considerations**

### **7.1 Implications for the Assessment Process**

If a criterion for submission for any staff or student dissertations/research projects is the obtaining of ethical clearance, failure to complete such procedures will invalidate submission for assessment. Any staff or student dissertations/research projects which commenced with ethical clearance, but for which contact between supervisor and student ceased during preparation, cease to be ethical and will invalidate submission for assessment. Assessment Board regulations must reflect the above.

### **7.2 Recruitment of participants for research projects**

Recruitment of human participants must be completed carefully and with respect, normally ensuring proper and valid consent is obtained from participants.

Inducements of any kind are not permitted to be used to encourage participation due to of the risk of manipulation and/or coercion, however where expenses are to be incurred, this must be discussed in advance with the relevant Director of Curriculum who has budgetary responsibility for the relevant curriculum area.

It is expected that members of staff will not normally be approached to be recruited as participants in student dissertations or research work.

Students who make use of the Bishop Auckland College logo for materials designed to recruit participants for research projects must request the use of this logo via their supervisors.

Staff are free to use the Bishop Auckland College logo on their recruitment materials as is.

### **7.3 Research Ethics Training**

In accordance with college policy, members of staff involved in research may be required to attend Research Ethics Training, which is offered when required throughout the academic year. Staff who are unfamiliar with the concepts set-out in the Ethics Principles for Research Involving Human Participants (conformity with which is attested to in certifying via ethical release), they are strongly encouraged to attend training.

**7.4** Use of the internet in research

In any project using the internet as a search or research tool, the applicant must ensure that the researchers concerned are aware of, and have discussed, the 'Good Conduct in the use of the internet for Research' (Appendix 1).

**7.5** Use of Freedom of Information or Other Legislation to Obtain Data

Researchers may not compel individuals or organisations to supply research data through the use of legislative provisions, for example by using the Freedom of Information Act or the Environmental Information Regulations. Applications for specific exceptions to this requirement can be submitted through the usual process (i.e., FOI requests to be made through the Quality Office) which will in turn can be submitted to Academic Board for consideration on a case-by-case basis.

**7.6** External researchers' access, staff and/or students, premises, equipment and/or expertise

Bishop Auckland College encourages and assists external researchers wherever possible. Any external researcher who wishes to conduct research by employing Bishop Auckland College staff and/or enrolled students as participants and/or using Bishop Auckland College premises, equipment or expertise in any way, must seek and receive formal approval for that from the relevant Director of Curriculum– for single subject group domain research – or from the Director responsible for Higher Education for multiple or cross subject domain research, prior to commencement of the research.

To enable accurate record keeping, the person granting approval should notify the Chair of the REC and the Director responsible for Higher Education in writing, both when approval is granted, and when the project is completed.

In all cases, prior to giving a decision to any external researcher, the Director responsible for Higher Education and/or the relevant Director of Curriculum (s) must consider how the proposed research activity may impact upon students, student activities, course management and any academic, technical and/or support staff that may be involved/affected.

## **8.0 Summary of Potential Liabilities of Researchers**

**8.1** Harm occurs to participants, property, resulting in claim of negligence:

- Negligence involves a lack of proper process of risk assessment and can be intentional or reckless
- Going via institution's REC procedures constitutes protection
- Research conducted without proper procedural accountability severs the protection of the institution's indemnity arrangements and leaves the researcher open to personal liability for negligence. In practice, this means that if a researcher chooses not to apply for ethical clearance, and a claim is made against them by a participant for any reason, then the researcher may be personally liable. This may also apply in cases where a researcher may be personally liable. This may also apply in cases where a researcher has applied for ethical clearance but who chooses to ignore requirements placed upon the research protocol by the REC in order for it to proceed, or who subsequently changes the research protocol by the REC in order for it to proceed, or who subsequently changes the research design previously approved in the protocol submitted to the REC without notification.
- Lack of valid consent – research may be exposed for criminal and/or civil assault or battery which may attract a criminal punishment of a fine and/or imprisonment and a civil claim for damages.
- Breach of confidentiality – criminal liability for the institution under Data Protection Act 2018 for serious breaches of the Act which attracts a maximum fine of £500,000 and financial claim for damages by participants for breach of common law duty of confidentiality against the institution or individual researchers. In addition, potential criminal sanctions exist for failure to disclose criminal activity where discovered.

### **Contact Information**

For questions or feedback regarding this policy, please contact:

Vicky Nelson

Data Protection Officer

**Email:** [Quality@bacoll.ac.uk](mailto:Quality@bacoll.ac.uk)

**Phone:** 01388 443069

### **Summary of significant changes**

For information about changes made to this Procedure see the [Change log](#) found on our website.