

Quality System

Policy Number

POL-OU-04

Policy Title

Higher Education Research Ethics Policy for
The Open University

Written by:	Equality Impact Assessment	Date of Policy	Date of next review
Author: Kevin Hodgson	Date:	September 2019	September 2020

Higher Education Research Ethics Policy for The Open University

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 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 with humans or human materials.
- 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 Participants

It is essential that Bishop Auckland College research involving collect data or biological samples from human participants is assessed or reviewed for ethical issues **before** any potential participants are contacted To do this the REC Project Registration and Risk Checklist, should be completed and returned to researchethics@bacoll.ac.uk. The REC Chair will then access whether an ethics review will be required (a response will be received within 7 working days). 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 and returning it to researchethics@bacoll.ac.uk.

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 ethics review and, if unsure, the Human Research Authority (HRA) decision tool should be used to determine if the proposed study would be categorised as research.

3.1 Ethics Principles for Research involving Human Participants

There are six principles¹ 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 agents and assignees, 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.

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).

¹ 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

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.

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 confidentiality² of participants' identities and data. The procedure by which this is to be achieved should be specified in the protocol.

² 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.

Principle6: 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.

4.0 Procedures

A simplified flowchart of the Ethical Clearance procedure is included here in Appendix 2.

4.1 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. Projects which are entirely literature or desk and/or library-based do not need to receive Ethical Clearance but staff and students undertaking such research should be familiar with the College's policies on use of the internet in research (see Considerations section). 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:

Application can be made via two routes:

- **REC Project Registration and Risk Checklist** – this form is completed if the staff member and/or student is unsure if ethics related implications exist within the proposed research. The checklist should then be submitted to researchethics@bacoll.ac.uk for consideration by the REC chair. The REC chair will review the form within 7 days and state via return email if there are ethics related implications within the proposed research. The weekly submission deadline for fully completed REC Project Registration and Risk Checklist forms is **Thursday at 5:00pm**.
- **REC Proforma** – this form is completed once the REC chair has reviewed the REC Project Registration and Risk Checklist form and deemed there to be ethics related implications. If staff and/or student believe their proposed research has ethics related implications, they can complete the REC Proforma without completing the REC Project Registration and Risk Checklist form. The weekly submission deadline for fully completed REC Proforma forms is **Thursday at 5:00pm**, via researchethics@bacoll.ac.uk.

4.2 Final Year Undergraduate Dissertations and Projects

There are two distinct categories of undergraduate projects:

1. Those not involving human 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 participants, and/or involving potential or psychological risk to the researcher(S) themselves. In these cases, ethical clearance **WILL** be required.

In some cases, supervisors may choose to certify the propriety of their *undergraduate* students' work. In those cases, it is vital that both the member of staff and the student have considered how their proposed work accords with this policy and can verify the statements which staff certify by signing the form. Staff are advised to consider that by certifying their students' work they are

indicating their agreement to accept full responsibility for the ethical propriety of that work. Staff who work in areas in which ethical issues tend to be more prominent and sensitive will need to be very careful in undertaking such certification.

4.3 Chair's action of full REC referral

Upon review of the REC Project Registration and Risk Checklist form, the Chair of the REC will decide if the proposed research can be approved. If the Chair decides they cannot approve the research, it would be referred to the REC. This decision will be made within 7 days, with the researcher notified via email.

4.4 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.

4.5 Supplementary Documentation

If the research involves data collection from or about human 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.

4.6 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 undergraduate 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.

4.7 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.

5.0 Research Ethics Committee (REC)

The REC will consist of a chair, internal members and external consultants.

The REC will review fully completed REC Proformas and decide if the proposed research project contains ethical concerns

Once an application has been passed for review, a decision will be made, and a formal response sent via email, within 21 working days, however, some applications can take longer.

5.1 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.

5.2 Referral to Academic Board

When a REC is unable, after dialogue with the researcher(s) concerned, to resolve concerns and assure itself of the ethical propriety of research, it shall refer the matter to the Director responsible for Higher Education for information and the Academic Board for action.

5.3 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*. Appeals will be made to Academic Board, whose decision on appeal matters is final. Any appeal will be overseen by the Chair of Academic Board.

5.4 Filing of REC Project Registration and Risk Checklist/REC Proforma Forms

A single copy of the REC Project Registration and Risk Checklist Form and REC Proforma must be filed in the Programme Course File on completion and signature by the Chair of the REC (or following approval upon referral to Academic Board).

As part of post-clearance audit procedures, the Chair of the Academic Board and/or the Associate Director – HE (Teaching & Learning) may request copies of specific ethical release or ethical approval forms at any time whilst a project is ongoing.

5.5 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 using appropriate route for 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 reported on
- 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 the Chair of the REC 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.

6.0 Considerations

6.1 Implications for the Assessment Process

A criterion for submission for final year undergraduate dissertations/projects is obtaining of ethical clearance. *Failure to complete such procedures will invalidate submission for assessment.*

Final year undergraduate dissertations/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.

6.2 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.

If inducements of any kind are used, not exclusively but particularly monetary incentives (beyond expenses) to encourage participation, this must be completed with careful considerations of the risk of manipulation and/or coercion.

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 use 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.

6.3 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 regularly 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.

6.4 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).

6.5 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 to Academic Board for consideration on a case-by-case basis.

6.6 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 form the relevant Subject Lead – 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 Subject Leader(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.

7.0 Summary of Potential Liabilities of Researchers

7.1 Harm occurs to participants, property, resulting in claim of negligence

- a) Negligence involves lack of proper process of risk assessment and can be intentional or reckless
- b) Going via institution's REC procedures constitutes protection

Higher Education Research Ethics Policy for The Open University



- c) 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.
- d) 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.
- e) 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.

For further information contact:

Kevin Hodgson
HE Development Manager

September 2019

Appendix 1 – Good Conduct in the use of the internet for Research

Purpose

This section provides guidance specifically on the use of the internet for general research purposes in order to minimise risks posed by the internet environment and ensure best practice is observed.

Because of the nature of the internet it is possible that uncontrolled experimentation may result in exposure to and/or encouragement of criminal activities such as:

- Breaches of Computer Misuse Act
- Breaches of the Data Protection Acts
- IPR violations (e.g. Copyright)
- Disturbing or illegal images (e.g. Paedophile materials, terrorist images)
- Grooming activities
- Fraud (phishing, 419 scams, auctions, etc)

Departments may wish to consider the development of additional guidance that addresses specific discipline-based risks not addressed in these notes of guidance.

This guidance applies to all members of the institution involved in research. This will include staff and undergraduate students. It also applies to those who are not members of the institution, but who are conducting research on the institution's premises or using the institution's research facilities.

Risk to the College's Computer Network

Any activity which may expose parts of the College computer network to risk of infection or attack must be approved by IT Services.

Solicited Data

Collection of data through the internet needs to be carefully managed to avoid unnecessary risks to the reputations of the researcher and/or the College or to the quality of the research results.

Bulk Email

Generally, mass emailing should be discouraged as it can be perceived as activity akin to "spamming". Where questionnaires are to be distributed by email, researchers should carefully target their subjects and requests permission from the subjects before the questionnaires are distributed. The precise nature of the study should be clearly explained in the initial contact and parameters such as expected time to complete the questionnaire/interview should be given. Where research supervisors are aware that several such exercises may be conducted, a register of participants should be maintained and used to ensure that no participants are being targeted too regularly or asked to participate to such an extent that they may consider the researchers to be a nuisance.

Newsgroups and Chatrooms

Newsgroups and chatrooms should be considered a form of "bulk email" with the added complication that it is not possible to identify all recipients, or the originators of the messages posted in them. Furthermore, newsgroup users tend to form self-selecting group with a bias toward particular interests or opinions. Data collected as a result of newsgroup usage is likely to be strongly biased as a result.

Web-Based Questionnaires

Broadcast invitations to participate in an unsecured web-based questionnaire can result in skewed results, as for newsgroup participation. Furthermore, it is difficult to ensure that each respondent is only completing the questionnaire once. If web-based questionnaires are to be used, they should be constructed in such a way that participants can only access the questionnaire after an appropriate invitation and can only complete it once. Provision of such a mechanism introduces issue of Data Protection in that the respondents may become individually identifiable. Care should be taken to dissociate identity verification mechanisms from gathered data unless it is essential to the study.

Higher Education Research Ethics Policy for The Open University



Observation

In order to monitor illicit activity using electronic communications, the observer must be, albeit to a limited extent, a participant in the activity. That is to say that, at the very least they are likely to be required to create a user identity which can be used to log in to the communications system under observation.

Use of a 'User Identity'

Because a user identity can be traceable, it is inappropriate for an observer's "main", "personal" or "Official" user identity (e.g. College used email address) to be used for this activity. Instead, a disposable identity should be created for the duration of the research.

Use of Computer Equipment

Any computer equipment to be used for observation purposes should be dedicated to this task only, and be accessible by the observer(s) in question. This avoids issues of accidental deposition of unwanted material on publicly accessible machines. Where the observer believes there is a possibility, no matter how slight, that they may encounter material which others would consider objectionable, steps must be taken to ensure that such material cannot be viewed by those not involved in the research.

Use of Servers

Any servers connected to the College network, and visible to users outside the research team, must be carefully managed and constructed to avoid enticement and/or encouragement to commit criminal acts or acts in violation of acceptable use policies and agreements. Information presented on web pages/file servers etc. must comply with appropriate legislation and be factually correct. It may be necessary to include information about the purposes for which the server is operating and provide further details of the research.

Observation of Criminal Activity

Where the research may require observation of obvious criminal activity (e.g. Paedophile grooming, fraudulent auction sales etc.), risk assessment is essential. Participation and/or authorisation by appropriate law-enforcement bodies may be required, as may psychological assessment of the observer. Observed activities which will cause termination of the study must be clearly defined and adhered to. Observers must not participate in or encourage subjects to develop criminal activity in any way.

Throughout the observation, an accurate contemporaneous log must be maintained. Appropriate rest periods should be scheduled. The observer must cease observation if they become concerned by any activity which has been observed.

Internet-Originated References

Use of internet-originated references should be treated very carefully. It must be remembered that the internet is a public medium and that anyone with access to the appropriate technology can publish anything they wish without it being subjected to independent verification. Before a reference is accepted as being appropriate for citation, the researcher should take steps to ascertain the reliability of the source material. For example, an online journal or online version of a print journal can usually be considered to be as good as a print journal only when its editorial and review policies are compatible with the usual standards expected of a reliable academic publication. Some community-built information sources may be considered unreliable because of the way in which any user of the service can amend any existing data or contribute new data without independent review or verification.

Higher Education Research Ethics Policy for The Open University



Appendix 2 – Ethical Clearance Flowchart

