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8B – Research Ethics Code of Practice: Policy and Procedure

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INTRODUCTION

1. SCOPE AND PURPOSE

- 1.1 The Research Ethics Code of Practice (henceforth referred to as RECP) applies to all staff (those undertaking research and those involved in the supervision of student research) and all undergraduate, postgraduate taught and postgraduate research (PGR) students undertaking research under the auspices of Bournemouth University (BU).
- 1.2 BU recognises the importance of maintaining public confidence in the ethical quality of research conducted by staff and students of the University. The purpose of ethical approval within BU is threefold:

- This reflects BU's commitment to good ethical practice, as a principle in itself and as a means of maintaining public confidence in the work undertaken by staff and students of the University;
- The provisions for ethical approval assists researchers and supervisors undertaking research to identify appropriate issues and address these in the development of research proposals;
- The approval process itself acts as a safeguard to researchers and supervisors who can be confident of the ethical propriety of their project once it has been approved.
- 1.3 The RECP is designed to provide guidance about conducting ethical research and to provide details of the University process for ensuring appropriate consideration, approval and documentation by staff and students.
- 1.4 The aims of the RECP are:
 - To ensure that all staff and students undertaking research at BU are made aware of the University's policies and procedures regarding research ethics;
 - To ensure that all staff and students undertaking research at BU have a common understanding of their respective roles and responsibilities;
 - To promote policies and procedures which protect the University's reputation as a research institute.
- 1.5 All researchers and research supervisors must read the RECP prior to commencement of research. If further clarification or guidance is needed, members of the Research Ethics Committee Panels (henceforth referred to as Ethics Panels) should be consulted. The list of members of the Ethics Panels is available on the <u>Research Ethics</u> web page.
- 1.6 BU requires that all research (as defined in Section 5) receives ethical approval prior to the commencement of research. This includes internal ethical approval as well as external approval where necessary (e.g. external approval from the NHS National Research Ethics Service (NRES), Social Care Research Ethics Committee). Sections 10.5 and 10.6 provide detailed guidance on external approval.
- 1.7 Failure to conduct research in accordance with the RECP may result in the loss of funding support, withdrawal or failure of degree awards, personal disciplinary or legal action taken against the researcher, supervisors or the University. Section 12 provides detailed guidance on non-compliance and misconduct.
- 1.8 The RECP is revised annually by the Research and Knowledge Exchange Office (R&KEO) to reflect changes in BU policy and national guidelines (as per Section 2.1).
- 1.9 More information on research ethics can be found on the <u>Research Ethics</u> web page.

2. KEY RESPONSIBILITIES

- 2.1 Responsibility for drafting and reviewing research ethics policies and procedures as set out in this document lies with R&KEO, in consultation with the University Research Ethics Committee (UREC). Implementation of these policies and procedures is the responsibility of Ethics Panels and is monitored by R&KEO and UREC.
- 2.2 The key responsibilities for those involved in conducting research and supervising research are set out in the following Sections, in particular:

- University Responsibilities, Section 6;
- Researcher Responsibilities, Section 7;
- Ethics Panel and Supervisor Responsibilities, Section 8.

3. LINKS TO OTHER BU DOCUMENTS

- 3.1 This document is part of BU's Academic Regulations, Policies and Procedures which govern the University's academic provision. Each document has a unique section of the series it belongs to. Other documents which may have relevance to this one include:
 - <u>6M Misconduct in Academic Research: Policy and Procedure</u>
 - <u>8A Code of Practice for Research Degrees</u>

POLICY

4. RESEARCH ETHICS PRINCIPLES

- 4.1 Research should be designed, reviewed and undertaken to ensure integrity, value and quality.
- 4.2 The results of research should benefit society either directly or by generally improving human knowledge and understanding.
- 4.3 Researchers must ensure their proposed research projects follow the ethical guidelines of an appropriate professional practice recognised by their Academic School where applicable.
 Schools will be responsible for identifying appropriate professional practices with ethical guidelines. Section 10.10 provides detailed guidance on journalism and broadcast research.
- 4.4 Research should be undertaken in accordance with commonly agreed standards of good practice which include the concept of 'beneficence' (do positive good) and 'non-maleficence' (do no harm).
- 4.5 Participants should be fully informed about the purpose, methods and intended possible use of the research. Where there are exceptions to this, the purpose and rationale of such research projects will be fully considered, as appropriate, before approval is given. Section 9 provides detailed guidance on informed consent.
- 4.6 Researchers should respect the human participants involved in their research as persons of worth whose participation is a matter of their autonomous choice (Section 9.4 provides further guidance on research on participants who lack the capacity to consent). The process of securing informed consent upholds the principle of respecting autonomy. Special consideration needs to be given in circumstances where a participant is unable to appreciate the implications of participating in research.
- 4.7 Research participants must normally participate voluntarily, free from coercion (Section 9.7 provides further guidance on covert research). In this regard, incentive payments could be seen as coercive, or as exerting undue influence on potential participants' decisions about whether to take part in research. Section 9.4 provides further guidance on reimbursement of research participants.

- 4.8 Researchers must consider the physiological, psychological, social, political and economic impact of their research on participants. Efforts must be made to protect participants against physical, mental, emotional, economic or social injury in order to ensure, as far as possible, that no harm comes to them as a result of being involved in the study.
- 4.9 The confidentiality of information supplied by participants must be respected, except where the requirements of professional practice determine. Any limits to confidentiality must be explained to participants.
- 4.10 Issues of anonymity and anonymisation of results should be fully considered, and where personal disclosure or identification is likely, this must be discussed with the participants and their specific consent to this obtained. Pseudonyms do not always protect anonymity and researchers need to ensure other personal information is not given that could make the participant identifiable.
- 4.11 All research must comply with the <u>Data Protection Act 1998</u> and the eight <u>Data Protection</u> <u>Principles</u>. All funded, contractual or collaborative research must comply with the specified requirements for data storage and retention. *Appendix 1: Research Data Storage and Retention* provides detailed guidance on data storage and retention.
- 4.12 The health and safety of researchers and participants should be considered in the design and execution of research projects.
- 4.13 Research outcomes should be disseminated in a manner which makes them accessible to participants.
- 4.14 The independence of the research outcomes must be ensured. External sources of funding and any potential conflict of interest must be declared during the ethical approval process.
- 4.15 Researchers should comply with the University's guidelines on authorship of publications, which is clearly outlined in the Graduate School's <u>Guidelines on Authorship of Publications for</u> <u>PGRs and Supervisors</u>. While this document is primarily aimed at the publication of research outputs from PGR research projects, the guidance is applicable to all researchers at BU.
- 4.16 Failure to comply with the terms of ethical approval for a research project, or failure to seek further approval if required, may lead to action under the University's <u>Misconduct in Academic</u> <u>Research: Policy and Procedure</u>.

5. RESEARCH ETHICS DEFINITIONS

- 5.1 Research is a form of disciplined enquiry which aims to contribute to a body of knowledge or theory. This does not normally extend to teaching only activities, demonstrations and general coursework assignments, but does apply to undergraduate and postgraduate taught research dissertations, or projects made publically available outside the University.
- 5.2 Research ethics are the moral principles guiding the planning and conduct of research, the publication of outcomes and post-project care and/or disposal of records or materials.
- 5.3 Research with human participants should be taken in its broadest possible sense and includes questionnaires, observations and the use of materials derived from human participants as well as invasive or intrusive procedures.

- 5.4 Types of research or activities requiring ethical approval include, but are not limited to, those listed below:
 - Funded Research: research that is funded in whole or in part by an organisation (both internal and external funding);
 - Staff Research: an agreed programme of research undertaken by a member of staff under the auspices of Bournemouth University that is not 'Funded Research';
 - Postgraduate Research Degrees: a research degree involving a programme of research undertaken by a postgraduate student registered at Bournemouth University;
 - Undergraduate and Postgraduate Taught Dissertations or Projects: a research programme for a dissertation undertaken by an undergraduate or postgraduate student registered at Bournemouth University;
 - Institutional Research: any research conducted or commissioned by Bournemouth University;
 - Basic Research: experimental and theoretical work undertaken to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view;
 - Strategic Research: applied research that is in a subject area which has not yet advanced to the stage where eventual applications can be clearly specified;
 - Applied Research: work undertaken in order to acquire new knowledge.
- 5.5 If you are unsure if your project is considered research, consult with a member of an Ethics Panel or your supervisor for guidance and clarification. For the purposes of best practice, or where there is any doubt as to whether ethical approval should be sought, it is recommended that BU's standard ethical procedures are followed. This is especially pertinent for projects where any data of any type is collected, which researchers may wish to re-use or represent in another format at a later date.

6. UNIVERSITY RESPONSIBILITIES

- 6.1 Bournemouth University will ensure that staff and students have been informed of the research ethics requirements of the University.
- 6.2 BU will promote and facilitate staff and student development in research ethics.
- 6.3 BU will ensure all academic staff, those staff who supervise students and post graduate researchers are made aware of their obligations to complete research ethics e-module training every two years.
- 6.4 BU may undertake monitoring of approved research projects to ensure compliance. An Ethics Panel may monitor the progress of the research project to ensure compliance with the terms of approval.
- 6.5 UREC is responsible for guiding ethics policies and processes and reviewing applications which cannot be adequately dealt with, or recommended to it, by an Ethics Panel.
- 6.6 BU will ensure UREC has external membership in accordance with the terms of reference, reflecting the importance of independent (including lay) contributions to decisions on ethical approval and ethical policy.
- 6.7 Ethical review is the responsibility of each Ethics Panel; however, UREC has overall responsibility for ethical review and may intervene at any stage.

- 6.8 The composition and responsibilities of UREC and Ethics Panels are set out in detail on the <u>Research Ethics</u> web page along with their terms of reference. The chief responsibilities of these committees for research ethics are:
 - Policy development;
 - Development and communication of good practice;
 - Debate and developmental work relating to research ethics issues;
 - Determination of specific ethical issues;
 - Developmental opportunities for UREC and Ethics Panel members, including lay and/or external members;
 - Approval of research proposals;
 - Oversight of research ethics processes;
 - Guidance and recommendation on misconduct related to research ethics;
 - Audit of compliance with the RECP.

7. RESEARCHER RESPONSIBILITIES

7.1 Responsibility for ethical conduct primarily rests with the researcher. The researcher (staff or student) is responsible for the following:

Prior to commencing the research project, the researcher must:

- In the case of students, ensure you discuss the project with your supervisor prior to seeking ethical approval;
- Complete the Online Ethics Checklist;
- Ensure compliance with any other additional requirements (such as those defined by the NHS, the law of the country within which the research is taking place, research collaborator(s) or any other relevant organisation or body);
- Obtain ethical approval before any data collection commences for the project.

Throughout the research project, the researcher must:

- Operate in an ethical manner with due regard to the ethical considerations and challenges relevant to the research project;
- Operate within the provisions of the ethical approval granted;
- Ensure that where the scope of the research project changes, that such changes are discussed with a member of an Ethics Panel or your supervisor to ensure the ethical approval you have been granted remains appropriate (you must re-submit for ethical approval if changes to the research project mean that your previous ethical approval is no longer valid).

Following completion of the research project, the researcher must:

- Ensure data is stored securely and retained/destroyed in accordance with the <u>Data</u> <u>Protection Act 1998</u>. Appendix 1: Research Data Storage and Retention provides detailed guidance on data storage and retention;
- Ensure dissemination of the findings is appropriate in terms of anonymity and confidentiality.
- Ensure authorship of publications is in accordance with the Graduate School's <u>Guidelines on Authorship of Publications for PGRs and Supervisors</u>. While this document is primarily aimed at the publication of research outputs from PGR research projects, the guidance is applicable to all researchers at BU.

- 7.2 It is the researcher's responsibility to abide by the terms of the ethical approval given. If the need for further ethical approval becomes apparent as the project develops, it is the responsibility of the researcher to apply for that further approval.
- 7.3 All researchers must take full responsibility for ensuring appropriate storage and security for all study information, including research data and consent forms. All stored data must comply with the <u>Data Protection Act 1998</u>. *Appendix 1: Research Data Storage and Retention* provides detailed guidance on data storage and retention.
- 7.4 All research undertaken by staff or students must comply with the legal requirements of the UK, and/or the country of location of the research project.

8. ETHICS PANEL AND SUPERVISOR RESPONSIBILITIES

- 8.1 It is the responsibility of Ethics Panels and supervisors to determine whether a research project is ethically sound and grant approval for the research to commence. As recommended by the <u>ESRC Framework for Research Ethics</u>, Ethics Panels and supervisors should regard the following aspects of research to be considered as involving above minimal risk and therefore likely to require a more thorough ethical review prior to approval.
 - Research involving potentially vulnerable groups, for example, children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Dependent or unequal relationships can be defined as pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other. Examples may include relationships between:

-Carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients or people in residential care or supported accommodation;

- -Health care professionals and their patients or clients;
- -Teachers and their students;
- -Prison authorities and prisoners;
- -Governmental authorities and refugees;
- -Employers or supervisors and their employees;
- -Service-providers (government or private) and especially vulnerable communities to whom the service is provided (e.g. homeless, rough sleeping).
- Research involving those who lack capacity. All research involving those who lack capacity, or who during the research project come to lack capacity, must be approved by an 'appropriate body' operating under the <u>Mental Capacity Act 2005</u>. It is illegal to conduct such research without approval of an 'appropriate body'. An 'appropriate body' is a REC recognised by the Secretary of State or Welsh Ministers. All NHS Research Ethics Committees (RECs) in England and Wales are recognised. RECs in Scotland and Northern Ireland are not recognised for the purposes of the Mental Capacity Act. In addition, there is a national <u>Social Care REC</u> (SCREC) established in 2009 under the aegis of the Social Care Institute of Excellence (SCIE), which is recognised as an 'appropriate body' under the Mental Capacity Act.
- Research involving sensitive topics, for example participants' sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health or their gender or ethnic status.

- Research involving deceased persons, body parts or other human tissues including bodily fluids (e.g. blood, saliva).
- Research using administrative data or secure data. Researchers using these data sets will need to be approved by the body supplying the data and keep data in secure areas. In most cases a light touch review confirming that researchers have met these requirements will be sufficient. Issues however may arise when data are linked and where it may be possible to identify participants.
- Research involving groups where permission of a gatekeeper is normally required for initial access to members. This includes research involving gatekeepers such as adult professionals (e.g. those working with children or the elderly), or research in communities (in the UK or overseas) where access to research participants is not possible without the permission of another adult, such as another family member (e.g. the parent or husband of the participant) or a community leader.
- Research involving deception, covert research or which is conducted without participants' full and informed consent at the time the study is carried out. It is recognised that there are occasions when the use of covert research methods is necessary and justifiable and consent may need to be managed at a point beyond the completion of research fieldwork. Section 9.7 provides detailed guidance on conducting covert research.
- Research involving access to records of personal or sensitive confidential information, including genetic or other biological information, concerning identifiable individuals.
- Research which may induce psychological stress, anxiety or humiliation, or cause more than minimal pain. Minimal can be defined as negligible or of a minimum amount, quantity or degree.
- Research involving intrusive interventions or data collection methods for example, the administration of substances, vigorous physical exercise or techniques such as hypnosis. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life.
- Research where the safety of the researcher may be in question, in particular those conducting field research and locally employed research assistants working outside the UK.
- Research involving members of the public in a research capacity in research data collection (e.g. community-based participatory research). Further guidance can be found on the National Co-ordinating Centre for Public Engagement web page regarding <u>ethics</u> in community-based participatory research.
- Research undertaken outside of the UK where there may be issues of local practice and political sensitivities. In some cases partnership with a research organisation in the area involved may prove helpful. It is also necessary to check the requirements for ethics review in the countries included in the research. BU requires that all research undertaken outside of the UK undergoes a risk assessment prior to commencement.
- Research involving respondents through the internet, in particular where visual images are used, and where sensitive issues are discussed. The British Psychological Society's Ethics Guidelines for Internet-mediated Research should be consulted prior to the commencement of research. The term 'internet-mediated research' (IMR), as used in this document' covers a wide range of quantitative and qualitative approaches to research involving human participants. IMR can be broadly defined as any research involving the remote acquisition of data from or about human participants using the internet and its associated technologies.
- **Other research involving visual/vocal methods** particularly where participants or other individuals may be identifiable in the visual images used or generated.

- Research which may involve data sharing of confidential information beyond the initial consent given for example where the research topic or data gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.
- Research involving procedures beyond those normally experienced in everyday life.
- 8.2 Ethics Panels are responsible for reviewing and approving staff and PGR ethics checklists indicating above minimal risk and are also available for guidance and clarification on all ethical matters. Members of Ethics Panels are academic staff who have experience and expertise in providing guidance on research ethics and reviewing submissions for ethical approval.
- 8.3 Supervisors overseeing the research projects of PGRs have a responsibility to discuss research ethics with their student(s) and ensure the student is prepared to submit an ethics checklist to an Ethics Panel if required. Supervisors overseeing the research projects of undergraduate and postgraduate taught students have a responsibility to discuss research ethics with their student(s), review the student's ethics checklist to ensure the research project is in line with basic research ethics principles and approve the research to commence if it involves minimal risk. Undergraduate and postgraduate taught student research involving above minimal risk will be reviewed and approved by a Programme Team. The University provides research ethics training to all supervisors to ensure they have the appropriate knowledge to inform their students regarding basic research ethics principles.

9. INFORMED CONSENT

- 9.1 Informed consent, also known as valid consent entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision on their possible involvement.
- 9.2 The quality of the consent obtained is critical to its validity. The onus is on the researcher to ensure that the consent is freely given and fully informed. The quality of the consent is affected by a number of factors, these being: the format of the record of consent, the competence and capacity of the participant to give consent and the clarity of the information provided to the participant.
- 9.3 Wherever possible a signed consent form should be obtained. If written consent is not possible, oral consent can be given after the researcher has read out the details of the consent form and information sheet. This should be witnessed by a second person unless consent is recorded on video or sound with time and date stamp.
- 9.4 There are a number of circumstances where the competence and/or capacity of participants is absent or compromised. These circumstances typically fall within the following categories, however this list is not exhaustive and researchers should consider the issues of competence and capacity for all participant groups.
 - Children and young people: If children are involved in a research study, they should be included in key aspects of the process of consent (e.g. have information on the study explained in terms they are able to understand). The child's parent/legal guardian must be informed and give their consent to participate in the study. *Appendix 2: Research with Children and Young People* provides detailed guidance on research with children and young people.

- Adults lacking capacity to consent to research: In the case of research with adults who lack capacity under the terms of the <u>Mental Capacity Act 2005</u> these projects must be reviewed by NRES. Guidance on the Act states that researchers should assume that a person has capacity, unless there is proof that they do not have capacity to make a specific decision, and those potential participants must receive support to try to help them make their own decision. The potential participant has the right to disagree with the decisions that others (such as relatives or carers) might make.
- Other vulnerable groups: There are many factors that may affect the ability of participants to freely give informed consent, for example institutional groups (e.g. employees, prisoners, patients) may feel coerced into taking part in research by the consent of the institutional authority to carry out research within their domain. Researchers should, therefore, ensure that members of an institutionalised group understand that the institutional consent places them under no greater obligation to participate in the research.
- Other factors which may affect voluntariness: Voluntariness can be called into question when other pressures may be an influence, for example, when a university teacher proposes to use students as participants in their research, or when researchers propose to pay participants more than their expenses and lost earnings. It is important that payment does not override the principles of freely given and fully informed consent. It is imperative that participants know, before they start the research, that they can withdraw from the study at any time without losing their payment. Please note Leeds University guidance on reimbursement of research participants as an example of best practice.
- In cases where significant cultural differences may affect understandings about the nature of informed consent the researcher should employ culturally appropriate methods to allow subjects to make decisions to participate or to withdraw from the research process.
- 9.5 The circumstances outlined in Section 9.4 may require the researcher to obtain a <u>Disclosure</u> and <u>Barring Service</u> (DBS) check (formally Criminal Records Bureau). BU's <u>DBS Guidance</u> document provides further information on the DBS. Additionally, Ethics Panels can provide guidance on this.
- 9.6 Where the nature of the research is such that informing participants of some details before the work is carried out might render the results invalid, for example within aspects of the social and cognitive sciences such as perception, there must be appropriate explanations following the study. In these circumstances, justification for this course of action is required to be submitted for approval to an Ethics Panel. Researchers must provide convincing reasons why such research should proceed without the necessary informed consent. Researchers should not mislead participants if it is thought that prior permission will not be obtained.
- 9.7 The primary objective of any researcher should be to conduct research openly and without deception. However, there may be times when it is necessary to fulfil the aims and objectives of a research study to engage in covert research or to use deliberate deception. Research involving deliberate deception or covert data collection, as opposed to in-community observational research in which it may not be possible to inform all those observed, should only be used as a last resort or when no other approach is possible to achieve the research aims and objectives. Any research involving deliberate deception must be submitted to an Ethics Panel for approval. For research projects where full information to the participant would invalidate the research or would be meaningless, the following principles should be adopted:

- Withholding of information from participants should only occur when the researcher is clear that the aims and objectives of the research cannot be achieved by any other means;
- Researchers must consider the ethical and moral implications of such work, and, as far as possible, ensure the welfare of the participants;
- Debriefing should normally follow participation where it is possible to identify those who participated;
- Where deception has been substantial, based on the principle of 'reasonableness', the participant should usually be offered the option of withholding the data in accordance with the principles underlying informed consent;
- Researchers should be mindful of the potential risks to themselves as well as participants when using covert methods;
- Undertaking covert research, or using deception, does not negate the necessity of ethical scrutiny; indeed, it emphasizes its importance, and demands reflection on the moral autonomy of the researcher.
- 9.8 Participants should be given an information sheet which outlines in layman's terms the purpose of the research, potential hazards, any discomfort participation may entail, emphasise the right to withdraw from the study, state their rights under the Freedom of Information Act 2000 and Data Protection Act 1998, provide researcher contact details and outline the complaints procedure. Participants should also sign a consent form. This does not apply to survey research however which by its return is accepted as an expression of consent to participate. Covert studies are exempt from providing information sheets and consent forms for participants; however, as outlined earlier, such studies must obtain the consent of an Ethics Panel. A document on how to prepare a participant information sheet and a sample consent form are available on the Research Ethics web page.
- 9.9 Participants should be given sufficient time to understand the information, to ask questions and to express any concerns that they may have.
- 9.10 In all cases of research, researchers should inform participants of their right to refuse to participate or withdraw from the investigation whenever and for whatever reason they wish.
- 9.11 Where a participant is interviewed as part of any research they should be informed of the nature and purpose of the project and given a clear explanation as to why they have been asked to contribute and be informed as to the areas of questioning. The participant should be made aware of any significant changes to the research as it develops which might reasonably affect their original consent to participate.
- 9.12 For recorded interviews, written consent should be obtained. However it is acknowledged there may be circumstances in which participants give their recorded verbal consent at the start of research and their continued consent is implicit through their on-going involvement in the research. For significant contributions to research, participants should always sign a consent form to formalise the terms of their participation. If the material is to be broadcasted, they should be informed as to when the first broadcast is likely to be. They should also be given an opportunity to preview the material wherever possible. It should be made clear to the participant that previewing this does not surrender editorial control and that changes made as a result will generally only relate to the correction of agreed factual inaccuracies or for reasonable concerns about welfare or security.

PROCEDURE

10. RESEARCH ETHICS REVIEW AND APPROVAL PROCESS

- 10.1 The Online Ethics Checklist is available at <u>https://ethics.bournemouth.ac.uk</u>. Researchers should login using their University credentials and click on 'Create' to begin the ethics checklist.
- 10.2 A document outlining the questions on the ethics checklist is available on the dashboard of the Online Ethics Checklist and on the <u>Research Ethics</u> web page.
- 10.3 *Appendix 3: Research Ethics Review and Approval Process* provides detail on the review and approval process for all researchers applying for ethical approval. Details of the ethical review and approval process is outlined below:
 - Undergraduate and Postgraduate Taught students submit their ethics checklist to their Supervisor and if minimal risk is identified, the Supervisor grants approval. If above minimal risk is identified, an Ethics Programme Team review the application. The Ethics Programme Team comprises of at least three people who will meet to review the submitted checklist and either approve this or return it to the applicant for further detail or amendments. The meeting is minuted by the relevant Programme Team administrators to document the decision and rationale. Minutes from these meetings will be submitted to the relevant Research Ethics Panel for auditing at appropriate intervals and members of the Ethics Programme Team may be required to attend the Panel meeting to discuss the decisions made.
 - **Postgraduate Research** students submit their ethics checklist to their Supervisor. The Supervisor is responsible for the review to ensure a good quality application and if minimal risk is identified, the Supervisor will forward to a Faculty Ethics Champion for approval. If above minimal risk is identified, the ethics checklist is submitted to the relevant Ethics Panel via the Ethics Filter, who ensures the relevant documentation and attachments are contained within the proposal. The Postgraduate Research student, together with the Supervisor attends the Ethics Panel meeting to respond and discuss the application further in order for approval to be given. If approval cannot be given in the meeting, Chair's Actions will be initiated and referral to UREC can be made in this process.
 - Staff members complete an ethics checklist and if minimal risk is identified, an Ethics Panel Member will conduct a light-touch review and grant approval. If the Ethics Panel member identifies above minimal risk during the light-touch review, the ethics checklist will be referred to an Ethics Panel for review. The Ethics Panel member will complete the light-touch review within one week upon receipt of the ethics checklist. If above minimal risk is identified, the ethics checklist is submitted to the relevant Ethics Panel via an Ethics Filter, and the Staff member attends the Ethics Panel meeting to respond and discuss the application further in order for approval to be given. If approval cannot be given in the meeting, Chair's Actions will be initiated and referral to UREC can be made in this process.
 - NHS/ external ethical approval: For projects which require NHS or another external ethical approval, the researcher submits their application to the relevant body and following approval, the approval document must be submitted to the relevant Ethics Panel via the Ethics Filter for auditing purposes. Section 10.5 and 10.6 provides further guidance on research involving the NHS.

- International research: The protocol for ethical review of research undertaken outside the UK where the researcher is collaborating with a third party and the third party is responsible for the ethics, BU approval is not necessary. Approval documents must be sent to the relevant Research Ethics Panel via the Ethics Filter as evidence for auditing purposes. If the researcher/ BU is the project lead and the country has established ethical guidelines that must be adhered to, the country's ethical approval must be gained and approval documents must be sent to the relevant Research Ethics Panel via the Ethics Panel via the Ethics Filter as evidence for auditing and approval documents must be sent to the relevant Research Ethics Panel via the Ethics Filter as evidence for auditing purposes. If the researcher/ BU is the project lead and the country does not have established ethical guidelines, the researcher must submit an ethics checklist.
- 10.4 Occasionally, research projects may be subject to external drivers which create a greater urgency for approval. Typically, research involving the public and private sector may be subject to time sensitive funding obligations and therefore make expedited review of ethics necessary. Such proposals require a detailed evidence based justification, such as:
 - The need to coordinate data gathering with researchers or organisations external to BU;
 - An unforeseen or unpredicted change in the accessibility of the participant group;
 - Additional demands or deadline requirements of funding organisations;
 - The need to complete the study within an accelerated time frame;
 - Contractual requirements;
 - The proposed research is critical to BU's strategic vision.

The Ethics Filter will determine when processing a proposal identified as above minimal risk, which has an attached case for expedited review, whether this is warranted. Processing applications for expedited ethical approval requires additional resource; therefore, the Ethics Panels will not accept requests where these factors are not clearly evident. Those cases for expedited review will be sent to the Chair and the proposal will be allocated to selected members of the Research Ethics Panel.

- 10.5 Research involving the NHS, including patients, carers or data must gain ethical approval from NRES. Further information on NHS ethical review requirements can be found on the <u>NRES website</u>, which includes a <u>decision tool</u> to determine if approval is required. The <u>Dorset</u> <u>Research Consortium</u> is available for support and guidance.
- 10.6 The Research Governance Framework for Health and Social Care (v2, 2005) states broad principles of good research governance in health and social care. Research which falls within the scope of the Research Governance Framework requires a research Sponsor. Formal confirmation of sponsorship must be obtained prior to an application for Host Organisation (e.g. NHS Trust, Social Care) or NHS REC approval. If the BU Researcher has an associated NHS contract, the NHS Trust or third party may be approached to take the role of Sponsor. In all other cases, BU will act as Sponsor; the <u>Standard Operating Procedures (SOP) for obtaining approval for BU Sponsorship</u> provides detail of this.
- 10.7 Projects that fall under the auspice of Public Engagement may require ethical approval. For the purposes of best practice, or where there is any doubt as to whether ethical approval should be sought, it is recommended that BU's standard ethical procedures are followed. This is especially pertinent for projects where any data of any type is collected, which researchers may wish to re-use or represent in another format at a later date. Consult with a member of an Ethics Panel or your supervisor prior to commencement of the project to determine if ethical approval is required. Further guidance can be found on the National Co-ordinating

Centre for Public Engagement website regarding <u>ethics in community-based participatory</u> research.

- 10.8 Studies involving further analysis of existing data (secondary analysis) will require ethical approval. Depending on whether or not the nature of the data is sensitive or if individuals can be identified from the research will determine if the data can be used in the research project. The re-use of existing data will be considered so long as:
 - The data is completely anonymous when provided to the researcher;
 - It is not possible to identify participants from any resulting report;
 - Use of the data will not cause damage and distress.
- 10.9 Research projects that require local research ethics committees (based on research-specific licences, such as the <u>Human Tissues Act 2004</u> and the <u>Animals (Scientific Procedures) Act 1986</u>) will require committee meeting minutes to be included in the UREC meeting minutes for oversight purposes. All UREC meeting minutes are included for review to Senate, which ensures University leadership are aware of research activity that falls within a research-specific licence. Where necessary, information may be redacted from UREC minutes at the discretion of the Chair in the interests of confidentiality, or where they pertain to sensitive research-specific licences.
- 10.10 Staff and students undertaking research largely informed by practices and approaches to inquiry and dissemination common in professional journalism and broadcasting must comply in full with the RECP. In addition, this permission (including any exception or variance) must be recorded and with reference to appropriate Professional Body guidance as a condition for ethical approval. The journalistic/broadcast researcher must have gained specific approval from an Ethics Panel or their supervisor to proceed with the research/inquiry. Detailed guidance is available as an appendix to the RECP entitled <u>Research Ethics Supplementary Guide: For Reference by Researchers Undertaking Journalism and Media Production Projects</u>. The document collates practice guidance from Press Complaints Commission's ethics guide, OFCOM's Broadcasting Code and the BBC's Editorial Guidelines with special attention paid to informed consent. This guide must be consulted by staff, students and supervisors in advance of undertaking any journalism or broadcast-based research. The Online Ethics Checklist includes the opportunity for researchers to declare that this document has been consulted and that declaration will be a condition of approval.

11. APPEALS

- 11.1 If at any stage the application for ethical approval is likely to be rejected, this will normally be referred back to the researcher with the deficiencies of the application identified, giving the researcher the opportunity of a further submission.
- 11.2 Where an application for ethical approval is not approved at Ethics Panel level, the researcher has the opportunity to appeal to UREC. The researcher and person(s) responsible for considering the application have the right to attend the meeting and speak to the issue. The decision of UREC is final and the matter is concluded at this point.

12. NON-COMPLIANCE AND MISCONDUCT

12.1 The University expects that all research carried out in its name complies with the requirements and expectations of the RECP. Where a research study or researcher is

suspected to be in breach of the RECP, action may be taken at School or University level to resolve this.

- 12.2 In the interests of openness, good practice and the reputation of the University, members of staff and students of the University, and members of the public, are entitled to raise concerns about the correct ethical practices in research, and particularly in relation to compliance with research ethics. Concerns or complaints should be directed to the Secretary of UREC; contact information is available on the <u>Research Ethics</u> web page.
- 12.3 BU considers that failure to gain ethical approval before starting a project, non-compliance with conditions specified by an approval body (e.g. funder, external ethical approver) or making significant changes to a research project without notifying an Ethics Panel or supervisor is classified as research misconduct. Further detail can be found in the University's <u>Misconduct in Academic Research: Policy and Procedure</u> document.
- 12.4 A serious breach of research ethics is considered research misconduct and will be dealt with according to the University's <u>Misconduct in Academic Research: Policy and Procedure</u> document. The following are **examples** of what constitutes a serious breach of research ethics:
 - Deliberately attempting to deceive when making a research proposal;
 - Failure to obtain appropriate permission to conduct research with ethical implications;
 - Failure to follow protocols contained in ethical consent and/or unethical behaviour in the conduct of research;
 - Failure to meet relevant legal requirements and/or to follow any protocols set out in the guidelines of appropriate recognised professional, academic, scientific and governmental bodies;
 - Unauthorised use of information acquired confidentially;
 - Failure to follow any procedures and health and safety protocols that avoid unreasonable risk or harm to humans, animals or the environment;
 - The misuse of research findings which may result in harm to individuals, populations, animals or the environment;
 - Failure to declare a conflict of interest which may significantly compromise, or appear to significantly compromise, the research integrity of the individual concerned and the accuracy of any research findings;
 - Inciting others to commit research misconduct¹;
 - Failure to declare (where known) that an external collaborative partner has been found to have committed research misconduct in the past or is currently being investigated following an allegation of research misconduct;
 - Facilitating misconduct in research by collusion in, or concealment of, such action²;
 - Submitting an accusation of research misconduct based on vexatious or malicious motives³.

13. ACKNOWLEDGEMENTS

13.1 The review of the policy and procedures for research ethics at Bournemouth University has drawn heavily on a number of publically available sources, with many contributions from these

¹ September 2016: This definition was moved to *6M* – *Research Misconduct:Policy and Procedure* (section 4.3) in August 2016 and will be removed from this document later in the autumn term.

² See footnote 1 above.

³ September 2016: This definition was moved to 6M – Research Misconduct:Policy and Procedure (section 5.5.1) in August 2016 and will be removed from this document later in the autumn term.

sources now incorporated with aspects of the previous policy and procedures to produce the University's Research Ethics Code of Practice: Policy and Procedure:

- Canterbury Christ Church University, Research Data Storage and Retention;
- Department of Health, Research Governance Framework for Health and Social Care: Second Edition;
- Economic and Social Research Council, *Framework for Research Ethics 2010: Updated September 2012;*
- Leeds Metropolitan University, Research Ethics Policy and Research Ethics Procedures;
- National Children's Bureau, Guidelines for Research with Children and Young People;
- National Health and Medical Research Council, Australian Government, *National Statement on Ethical Conduct in Human Research;*
- Research Council's UK, *RCUK Policy and Guidelines on Governance of Good Research Conduct;*
- UK Research Integrity Office, Code of Practice for Research: Promoting Good Practice and Preventing Misconduct;
- Universities UK, The Concordat to Support Research Integrity;
- University of the Arts London, *Guidance for Research Ethics Approval*
- University College London, Research Ethics Framework and Procedure for Investigating and Resolving Allegations of Misconduct in Academic Research;
- University of Leeds, Protocol for Reimbursement of Research Participants;
- University of Leicester, Research Ethics Code of Practice.

APPENDIX 1: RESEARCH DATA STORAGE AND RETENTION

The data collected during research projects falls into two categories:

- 1. Governance documentation: research protocols, recruitment literature, participant information sheets, consent forms and similar;
- 2. Project documentation: completed questionnaires, audio tapes, transcripts, video and still images and similar.

The use of space-efficient (e.g. electronic) storage methods should be maximised, except where external requirements specify retaining primary data sources in their original format. The biggest space saver would be to scan paper records and save them as 'pdf' files. This is increasingly routine practice in many organisations as a means of tracking and storing correspondence.

All data stored electronically should be securely backed-up in addition to the main storage. It is particularly important that research data stored on researchers' personal computers away from University premises is suitably backed up. The availability of access to the University network from home or other remote locations enables researchers to back up their data in a suitably secure fashion on their personal or shared network drives.

In keeping with Principle 5 of the <u>Data Protection Act 1998</u>, data retention periods should be kept to an absolute minimum. In cases where the University has full control, best practice indicates this should be as follows:

- Undergraduate and Postgraduate Taught: data to be retained for one full academic year after the award of the degree (to allow for inclusion in annual research audit). Projects reviewed by external ethics committees would be subject to their requirements.
- **Postgraduate Research**: data to be retained for 5 years after the award of the degree unless subject to conditions set by funders/external partners, or if part of a longitudinal study. Projects reviewed by external ethics committees would be subject to their requirements.
- Staff research: data to be retained for 5 years after final completion of the research (which would be taken to be the date of publication of the research or presentation to the sponsor) unless subject to conditions set by funders etc., or if part of a longitudinal study. Where there is no publication, the data should be kept for 5 years from the completion of the fieldwork. Projects reviewed by external ethics committees would be subject to their requirements.

Retention of Committee Papers. NHS Ethics Committees are required to retain their records for at least 10 years after completion of the project concerned. UREC and Ethics Panels should similarly retain their records for a period of 10 years.

Destruction of data. When no longer required, all personal data must be securely destroyed, and the data owner is responsible for the data up to the point of destruction. IT Services should be consulted regarding secure destruction of data held electronically on computer discs and other media such as DVD and audio/videotape. There must also be adequate safeguards to protect personal data whilst it is in storage, including periodic checks to ensure that the data is safe.

Data Protection Act 1998: Sensitive Personal Data and the Data Protection Principles

To ensure compliance with the <u>Data Protection Act 1998</u> participants must be informed about what information will be held about them and who will have access to personal, identifiable information.

The Act classifies sensitive personal data as consisting of information to the following:

- Data relating to a person's racial or ethnic origin;
- Political opinions;

- Physical or mental health condition;
- Sexual life;
- Religious beliefs or other beliefs of a similar nature;
- Membership of a trade union;
- Any proceeding for any offence committed or alleged to have been committed by the participant.

The Data Protection Act 1998 outlines eight <u>Data Protection Principles</u> which must be complied with when collecting and holding personal data. Bournemouth University is registered as a Data Controller with the Information Commissioner. The eight Data Protection Principles are:

- 1. Personal data shall be published fairly and lawfully;
- 2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be processed in any manner incompatible with that purpose or those purposes;
- 3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed;
- 4. Personal data shall be accurate and, where necessary, kept up to date;
- 5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes;
- 6. Personal data shall be processed in accordance with the rights of data subjects under the Data Protection Act 1998;
- Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and accidental loss or destruction of, or damage to, personal data;
- 8. Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedom of data subjects in relation to the processing of personal data.

The following points should be considered in research ethics applications:

Data security and records management

- The researcher needs to make reference to their duties under the Data Protection Act 1998. Has the processing of the data been considered and has the issue of the sensitivity of the data been considered in relation both to data protection and general lawfulness?
- What steps will be taken to ensure the confidentiality and/or anonymity of personal information? Give details of anonymisation procedures and of physical and technical security measures. Personal data held on mobile devices must be encrypted.
- Who will have access to personal information relating to the study? Confirm that any necessary wider disclosures of personal information (e.g. to the supervisor, translators, transcribers) have been properly explained to participants.
- The researcher must take responsibility for ensuring appropriate storage and security for project information including research data, consent forms and administrative records and, where appropriate, confirm the necessary arrangements will be made in order to process copyright material lawfully.
- Provide a specific location at which research data will be stored during the project

Data retention

• What provisions have been considered for the secure retention of sensitive or personal data? State how long study information including research data, consent forms and administrative records will be retained, what format the information will be kept in and where the data will be stored.

- Any personally identifiable data that is held on any mobile device should be encrypted. This includes data stored on USB memory sticks, laptop/netbooks, pcs, smart phones, servers and emails.
- Where results are collected individually, but the outcomes are anonymised, what data protection procedures are in place to ensure the protection of personal details and at what point and how will these be destroyed?

APPENDIX 2: RESEARCH WITH CHILDREN AND YOUNG PEOPLE

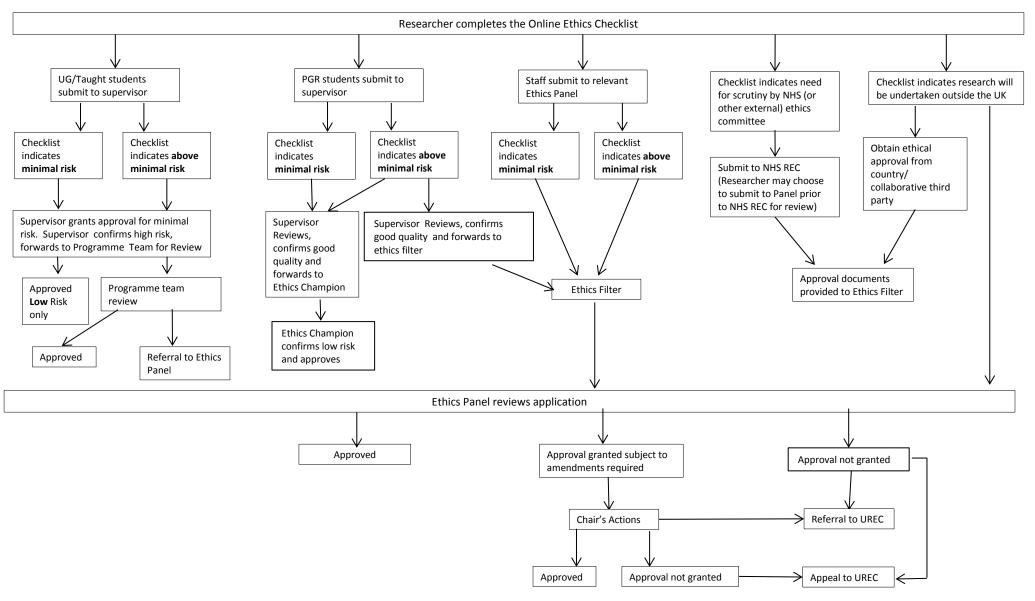
For research involving children and young people (under the age of 16), the researcher must always ensure that the best interest of the person is the primary concern. Researchers must consider the following issues: children have the right to be properly informed and where possible, their fully informed consent must be obtained and checked as appropriate throughout the research study. It is recognised that whether a child under the age of 16 is considered as 'vulnerable' depends on several factors such as the child's circumstances, their susceptibility to coercion or feelings of obligation, the type of research being undertaken and how the research is being undertaken. Researchers must therefore take all of these factors into consideration when assessing whether child participants under the age of 16 should be deemed as 'vulnerable'.

In situations where a child is too immature or vulnerable to give such consent or where any other circumstances may limit the extent to which this can be obtained from him or her, the researcher must seek the support and approval of those who are caring for the child (assent should be obtained from younger children as appropriate). Any legal requirements in relation to those responsible for the child must be adhered to. Also steps must be taken to put such individuals or organisations at their ease. If any distress occurs, the research process must immediately be halted.

It is therefore recognised that most research studies with children and young people will require consideration by an Ethics Panel. Careful consideration of projects involving young people remains a key requirement of the ethics procedures and UREC maintains the discretion to make decisions on what level of approval is required on a project by project basis.

Academic Schools are empowered to produce school-specific protocols for research involving children and young people, which take into account different local factors, such as students on courses providing a professional qualification related to under 16 year olds.

For all projects involving children and young people, researchers are recommended to refer to the guidance for researchers produced by the National Children's Bureau <u>Guidelines for Research with</u> <u>Children and Young People</u>.



APPENDIX 3: RESEARCH ETHICS REVIEW AND APPROVAL PROCESS

8B - Research Ethics Code of Practice: Policy and Procedure