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

CONTENTS

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 its staff and students. The purpose of ethical approval within BU is threefold:

1.2.1 It 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 BU;

1.2.2 Assists researchers and supervisors undertaking research to identify appropriate issues and address these in the development of research proposals;

1.2.3 Acts as a safeguard to researchers and supervisors who can be confident of the ethical propriety of their project once it has been approved.

In fulfilling these aims, the ethical approval process will also signpost researchers and supervisors to requirements as to the design or implementation of their research study which arise under the data protection legislation and related BU policies on use of personal data or other information.

1.3 The RECP is designed to provide guidance about conducting ethical research to ensure:

1.3.1 All staff and students undertaking research at BU are made aware of BU's policies and procedures regarding research ethics;

1.3.2 All staff and students undertaking research at BU have a common understanding of their respective roles and responsibilities with regard to the conduct of research;

1.3.3 Policies and Procedures are promoted which protect BU's reputation as a research institute.

1.4 All researchers and research supervisors must read the RECP prior to commencement of research. If further clarification or guidance is needed, academic members of the Research Ethics Panels (henceforth referred to as Ethics Panels) should be consulted.

1.5 BU requires that all research (as defined in Section 5) is subject to appropriate ethical reflection, leading if necessary to formal approval via the online ethics checklist. Approval must be obtained prior to the commencement of research. 'Approval' includes internal ethical approval as well as external approval where necessary (e.g. external approval from the NHS Research Ethics Committee (REC)). Sections 10.5 and 10.6 provide detailed guidance on external approval.

1.6 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, supervisor(s) or BU. Section 13 provides detailed guidance on non-compliance and misconduct.

1.7 If you do not have ethical approval, the University's insurers may not cover you for legal action or claims for injury. Proceeding without ethical approval, may also lead to debarment

from membership of some professional or statutory bodies and may exclude Researchers from applying for some types of employment or research funding opportunities.

1.8 The RECP is revised by the Research and Knowledge Exchange Office (RKEO) 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 Research Ethics Blog.

2. KEY RESPONSIBILITIES

1.10 Responsibility for drafting and reviewing research ethics policies and procedures as set out in this document lies with RKEO, in consultation with BU Research Ethics Committee (UREC). Implementation of these policies and procedures is the responsibility of Ethics Panels and is monitored by UREC and RKEO.

1.11 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 Panels and Supervisor Responsibilities, Section 8.

3. LINKS TO OTHER BU DOCUMENTS/RESOURCES

3.1 This document is part of BU's Academic Regulations, Policies and Procedures which govern BU's academic provision. Each document has a unique section of the series it belongs to.

3.2 Other documents and resources which may have relevance to this one include:

- 6M – Research Misconduct: Policy and Procedure
- 8A – Code of Practice for Research Degrees
- Data Protection Policy
- BU Code of Good Research Practice
- BU PREVENT Policy
- Reseach Ethics Blog

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 project follows the ethical guidelines of an appropriate professional practice recognised by their Faculty where applicable. Faculties 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' (maximise possible benefits and minimise possible harms) 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 must 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 8.1.2 provides further guidance on research on participants who lack the capacity to consent). The process of securing informed consent to participation in research upholds the principle of respecting autonomy. Special consideration needs to be given in circumstances where a participant is unable to fully appreciate or comprehend the implications of participating in research.

4.7 Research participants must normally participate voluntarily, free from coercion (Section 9.8 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 9.5.4 provides further guidance on reimbursement of research participants.

4.8 Participants also have a right to withdraw from participating as well as the right not to answer particular questions. Researchers should inform participants of their right to withdraw from participation at any time. They should also identify if, when and to what extent a withdrawing participant can also choose to withdraw their personal data from the study. This may mean stating that data cannot be withdrawn at all, can be withdrawn up to the point of anonymisation of the dataset or another key point in the use of the study dataset i.e. any point at which it will not be possible to identify and extract a participant's data from the study at all or without compromising the integrity or validity of the research.

4.9 Researchers must consider the physiological, psychological, social, political, economic, cultural, environmental and spiritual impact of their research on participants. Efforts must be made to protect participants as far as possible, so that no harm comes to them as a result of being involved in the study.

4.10 The confidentiality of information supplied by participants must be respected, except where the requirements of professional practice determine otherwise. Any limits to confidentiality must be explained to participants.

4.11 Issues of anonymity and anonymisation of results should be fully considered and implemented at the earliest stage possible without compromising the integrity and value of the research., Where it is intended that individuals would be identifiable from results or other study outputs, or there is any real possibility of such identification, this must be discussed with the participants and their specific consent to this obtained. Pseudonyms do not always prevent identification and researchers need to ensure that the nature and level of any personal information disclosed in outputs is not such as to make the participant identifiable. Further guidance is available via the Research Ethics Blog.

4.12 All research must comply with the current Data Protection Legislation. This is made up the EU General Data Protection Regulations (GDPR) and the UK Data Protection Act 2018. All

funded, contractual or collaborative research must comply with the specified requirements for data storage and retention. *Appendix 1: Management of Research Data* provides detailed guidance on data storage and retention. See also Data Protection at BU.

4.13 The health and safety of researchers and participants should be considered in the design and execution of research projects.

4.14 Research outcomes should be disseminated in a manner which makes them accessible to participants.

4.15 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.

4.16 Researchers should comply with BU's guidelines on authorship of publications, which is clearly outlined in the Publications Policy and Procedures.

4.17 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 BU's Research Misconduct: Policy and Procedure document.

5. RESEARCH ETHICS DEFINITIONS (for this purposes of this policy)

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, course evaluation, demonstrations and general coursework assignments, but does apply to undergraduate and postgraduate taught research dissertations, or projects made publically available outside BU.

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 interpreted 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:

5.4.1 Funded Research: research that is funded in whole or in part by an organisation (both internal and external funding);
5.4.2 Staff Research: an agreed programme of research undertaken by a member of staff under the auspices of BU that is not 'Funded Research';
5.4.3 Postgraduate Research Degrees: a research degree involving a programme of research undertaken by a postgraduate research student registered at BU;
5.4.4 Undergraduate and Postgraduate Taught Dissertations or Projects: a research programme for a dissertation undertaken by an undergraduate or postgraduate taught student registered at BU;
5.4.5 Institutional Research: any research conducted or commissioned by BU;
5.4.6 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;
5.4.7 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;

5.4.8 Applied Research: work undertaken in order to acquire new knowledge.

5.5 If you are unsure if your project or activity is considered to be 'research', for the purposes of this policy 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. BU RESPONSIBILITIES

6.1 BU 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 postgraduate researchers are made aware of their obligations including the completion of the research ethics e-module(s) training:

6.3.1 Ethics 1: Good Research Practice is mandatory for all academic staff and all students (including end of course quiz).
6.3.2 Before conducting any research study involving working with human participants, Researchers (staff/all students) must undertake Ethics 2 module.

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 the Ethics Panels are set out in detail on the Research Ethics Blog along with their terms of reference. The chief responsibilities of UREC and both Ethics Panels for research ethics are:

6.8.1 Policy development;
6.8.2. Development and communication of good practice;
6.8.3 Debate and developmental work relating to research ethics issues;
6.8.4 Determination of specific ethical issues;
6.8.5 Developmental opportunities for UREC and Ethics Panel members, including lay and/or external members;
6.8.6 Approval of research proposals;
6.8.7 Oversight of research ethics processes;

6.8.8 Guidance and recommendation on misconduct related to research ethics/integrity;
6.8.9 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:

To abide by the RECP at all times when undertaking research under the auspices of BU.

Prior to commencing the research project, the researcher must:

7.1.1 In the case of students, ensure you discuss the project with your supervisor prior to taking the rest of the steps towards ethical approval as outlined in this section;
7.1.2 Complete the Online Ethics Checklist (https://ethics.bournemouth.ac.uk/);
7.1.3 Ensure compliance with any other additional requirements relating to the proposed project (such as those set 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);
7.1.4 Obtain all required ethical approval before any data collection commences for the project.
7.1.5 Ensure an appropriate risk assessment has been undertaken.
7.1.6 Consider whether you need to carry out a privacy impact assessment to ensure that you identify and manage risks around the use of personal data.

Throughout the research project, the researcher must:

7.1.7 Operate in an ethical manner with due regard to the ethical considerations and challenges relevant to the research project;
7.1.8 Operate within the provisions of the ethical approval granted;
7.1.9 Ensure that where the scope of the research project changes, that such changes are discussed with a member of an Ethics Panel or Supervisor to ensure the ethical approval granted remains appropriate (the Researcher must re-submit for ethical approval if changes to the research project mean that previous ethical approval may no longer be valid) See 7.3 below. This also applies to the risk assessment of the project.

Following completion of the research project, the researcher must:

7.2 Ensure that personal data is managed in accordance with the Data Protection Legislation and BU's Data Protection Policy. This includes storing data securely, applying appropriate retention/destruction principles and controlling use of and access to the data so as to ensure it will only be used as necessary for the research project and in accordance with information provided to research particpants *Appendix 1: Management of Research Data* provides more detailed guidance on these requirements. See also Data Protection at BU.

7.2.1 Ensure dissemination of the findings is appropriate in terms of anonymity and confidentiality.
7.2.2 Ensure authorship of publications is in accordance with the Publications Policy and Procedures. 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.

7.3 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. See also, Section 9.12.

7.3.1 All Amendments should be requested via the online ethics checklist and approved online. See Research Ethics Blog.

7.4 All researchers must take full responsibility for ensuring appropriate storage/security and retention/destruction arrangments for all study information, including research data and participant agreement forms. All such arrangements must comply with the Data Protection Legislation and relevant BU policies. *Appendix 1: Management of Research Data* provides detailed guidance on data storage and retention. See also Data Protection at BU.

7.5 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 PANELS AND SUPERVISOR RESPONSIBILITIES

8.1 It is the responsibility of Ethics Panels and Supervisors to determine whether a research project is ethically sound. Before research can commence, approval must be granted by either:

- An appropriate Ethics Panel (Staff *above or below minimal risk* and PGR *above minimal risk projects*),
- Faculty Ethics Champion (PGR *minimal risk projects*);
- Supervisor (*minimal risk projects*) and Ethics Programme Team (*above minimal risk projects*) (UG and PGT).

As recommended by the ESRC Framework for Research Ethics, Ethics Panels/Ethics Champions and Supervisors/Ethics Programme Teams should regard the following aspects of research to be considered as involving above minimal risk and therefore will require a more thorough ethical review prior to approval:

8.1.1 **Research involving potentially vulnerable groups**, for example, children and/or 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:

8.1.1.1 Carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients or people in residential care or supported accommodation;
8.1.1.2. Health care professionals and their patients or clients;
8.1.1.3 Teachers and their students;
8.1.1.4 Prison authorities and prisoners;
8.1.1.5 Governmental authorities and refugees;
8.1.1.6 Employers or supervisors and their employees;
8.1.1.7 Service-providers (government or private) and especially vulnerable communities to whom the service is provided (e.g. homeless, rough sleeping).

8.1.2 **Research involving those who lack capacity**. All research involving those who lack capacity (as defined under the Mental Capacity Act 2005 Part 1 Section 2), or who during the research project come to lack capacity, must be approved by an 'appropriate body' operating under the Mental Capacity Act 2005. 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 Social Care REC (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.

8.1.3 **Research involving sensitive topics**, for example participants' sexual behaviour, their illegal behaviour, their experience of violence, their abuse or exploitation, their mental health or their gender or ethnic status and certain illnesses and/or including bereavement. This list is not intended to be exhaustive.

8.1.4 **Research involving deceased persons, body parts or other human tissues including bodily fluids (e.g. blood, saliva).** Research using human tissue is subject to the Human Tissue Act 2004. The type of study and the types of material being used will impact on what permissions and licences are required before conducting the project. All project based research in the UK conducted within the NHS requires Health Research Authority (HRA) approval, and all projects involving NHS patients or service uses will require NHS REC Approval. In some circumstances, a Human Tissue Authority (HTA) licence will be required.

8.1.5 **Research using administrative data**. Researchers using these data sets (data held by BU which was originally collected for administrative purposes) will need ethical approval and to 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 the research will involve linking datasets and in any circumstances where the data to be used is not anonymised when received by the researcher and/or it may be possible to identify participants from the intended research outputs.

8.1.6 **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.

8.1.7 **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 9.8 provides detailed guidance on conducting covert research.

8.1.8 **Research involving access to records of personal data** i.e. information relating to identifiable living individuals. Particular care needs to be taken in the use of special category data (i.e. personal data which relates to health/disability, religion, ethnicity, sex life or sexual orientation, political opinions, trade union membership or genetic or biometric data used as unique identifiers) and data relating to the alleged or confirmed commission of criminal offences ("criminal offences data").

8.1.9 **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.

8.1.10 **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.

8.1.11 **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.

8.1.12 **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 ethics in community-based participatory research.

8.1.13 **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.

8.1.14 **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.

8.1.15 **Other research involving visual/vocal methods** particularly where participants or other individuals may be identifiable in the visual images used or generated.

8.1.16 **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.

8.1.17 **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 include academic staff and lay members who have experience and expertise in providing guidance on research ethics and reviewing submissions for ethical approval.

8.2.1 **Only** in exceptional circumstances will applications for retrospective approval be considered.

8.3 Supervisors overseeing the research projects of PGRs 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 research ethics principles and ensure the student is prepared

to submit an ethics checklist to an Ethics Panel or Faculty Ethics Champion for approval as appropriate.

8.4 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 an Ethics Programme Team.

8.5 BU provides research ethics training to supervisors to ensure they have the appropriate knowledge to inform their students regarding basic research ethics principles. See APPENDIX 3 *Research Ethics Review and Approval Process*

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 participant agreement 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 participant agreement 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 Participants also have a right to withdraw from participating as well as the right not to answer particular questions. Researchers should indicate a point at which a participant may withdraw e.g. up to the point of anonymisation when a participant's data cannot be excluded from the study or destroyed.

9.5 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.

9.5.1 **Children and young people under the age of 16 years**: If children or young people are involved in a research study, they should be included in key aspects of the process of assent (e.g. have information on the study explained in terms they are able to understand and provide their assent). The child's parent/legal guardian must be informed and give their consent for their child/legal ward to participate in the study. *Appendix 2: Research with Children and Young People Under the Age of 16 Years* provides detailed guidance on research with children and young people.

9.5.2 **Adults lacking capacity to consent to research**: In the case of research with adults who lack capacity as defined by the Mental Capacity Act 2005 these projects must be reviewed by HRA/NHS REC. 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.

9.5.3 **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.

9.5.4 **Other factors which may affect voluntariness**: Voluntariness can be called into question when other pressures may be an influence, for example, when a university lecturer 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.

9.5.5 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.

9.6 The circumstances outlined in Section 9.5 may require the researcher to obtain a Disclosure and Barring Service (DBS) check (formally Criminal Records Bureau). BU's DBS Guidance document provides further information on the DBS. Additionally, Ethics Panels can provide guidance on this.

9.7 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.

9.8 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:

9.8.1 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;

9.8.2 Researchers must consider the ethical and moral implications of such work, and, as far as possible, ensure the welfare of the participants;

9.8.3 Debriefing should normally follow participation where it is possible to identify those who participated;

9.8.4 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;

9.8.5 Researchers should be mindful of the potential risks to themselves as well as participants when using covert methods;

9.8.6 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.

9.9 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, and the right to withdraw from the study. The Information Sheet should also explain how information relating to the participant will be used in the research and its outputs, refer to their rights under the Data Protection Legislation and provide a link to the BU Research Participant Privacy Notice, provide researcher contact details and outline the complaints procedure. Participants should also sign a participant agreement 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 participant agreement forms for participants; however, as outlined earlier, such studies must obtain the approval of an Ethics Panel. Templates of both the Participant Information Sheet and participant agreement form and further guidance are available on the Research Ethics Blog. The templates can be downloaded, saved and adapted to meet project needs.

9.10 Participants should be given sufficient time to understand the information, to ask questions and to express any concerns that they may have.

9.11 In all cases of research, researchers (other an where covert research is approved) should inform participants of their right to refuse to participate or withdraw from the investigation whenever and for whatever reason they wish. See 9.4 above.

9.12 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.

9.13 Where a participant is interviewed as part of any research they should be informed of the nature and purpose of the project, given a clear explanation as to why they have been asked to contribute and be informed as to the areas of questioning.

9.14 For recorded interviews, written consent should usually be obtained. 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. However, for significant contributions to research, participants should always sign a participant agreement form to formalise the terms of their participation.

9.15 Participants should be informed about the intended outputs of the research, including whether and how their information may be included in published outputs. Their consent should be obtained if they will be or there is a real risk that they will identifiable from the use of their information in outputs e.g. in photos, or film footage or through use of quotes linked to their name. 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 broadcast

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 https://ethics.bournemouth.ac.uk. 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 Research Ethics Blog.

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:

10.3.1 **Undergraduate and Postgraduate Taught** students submit their ethics checklist to their Supervisor and if it is minimal risk, the Supervisor grants approval. If the project is above minimal risk, an Ethics Programme Team review and approve 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 Ethics 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 meeting to discuss the decisions made.

10.3.2 **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/Department Ethics Champion for approval. If above minimal risk is identified, the ethics checklist is forwarded to the relevant Ethics Panel via the Research/Clinical Governance Adviser ("Ethics Filter"), who ensures the relevant documentation and attachments are contained within the proposal. The PGR, together with the Supervisor, attends the Ethics Panel meeting to respond and discuss the application further in order for approval to be given. A schedule of Panel meetings can be found on the Research Ethics Blog. If approval cannot be given in the meeting, Chair's Actions will be initiated and referral to UREC can be made in this process.

10.3.3 **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 instant 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. A schedule of Panel meetings can be found on the Research Ethics Blog.

10.3.4 **BU collaborations (UK)**: The protocol for ethical review of research undertaken within the UK where the researcher is collaborating with a third party and the third party is responsible for ethical approval, BU approval is not necessary where standard review is comparable. Approval documents must be sent to the Research Ethics Panel via the Ethics Filter as evidence for auditing purposes.

10.3.5 **HRA/NHS/ external ethical approval:** Projects which require HRA Approval or another external ethical approval, the researcher submits their application to the relevant body and the approval document must be submitted to the relevant Ethics Panel via the Ethics Filter for intelligence and auditing purposes. Section 10.5 and 10.6 provides further guidance on research involving the NHS.

10.3.6 **International research:** The protocol for ethical review of research undertaken outside the UK:

10.3.6.1 Where the researcher is collaborating with a third party and the third party is responsible for the ethics, BU approval is not necessary where standard review is comparable. Approval documents must be sent to the relevant Ethics Panel via the Ethics Filter as evidence for auditing purposes;

10.3.6.2 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 sent to the relevant Research Ethics Panel via the Ethics Filter as evidence for auditing purposes. BU ethical approval is also required and the researcher should submit an ethics checklist for review;

10.3.6.3 If the researcher/ BU is the project lead and the country does not have established ethical guidelines, BU ethical approval is required and the researcher should submit an ethics checklist for review.

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 HRA approval and/or NHS REC Approval . Further information on HRA approval review requirements can

be found on the NHS HRA website, which includes a decision tool to determine if approval is required. Studies investigating medicinal products or devices may need Medicines and Healthcare products Regulatory Agency (MHRA) approval. The Research Governance team within RKEO is available for support and guidance.

10.6 The UK Policy Framework for Health and Social Care Research (Nov 2017) states broad principles of good research governance in health and social care. Research which falls within the scope of the 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 Research Ethics Committee (NHS REC). If the project is being undertaken by a student or Postgraduate Researcher, then in accordance with the framework, the Supervisor should be the Chief Investigator, with BU as the Sponsor. If the student is employed by a health or social care provider, they make take the role as Sponsor. See Standard Operating Procedures (SOP) for obtaining approval for BU Sponsorship for further guidance.

10.7 Projects that fall under the auspice of Public Engagement or Research Impact 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 Research 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 ethics in community-based participatory research and Code of Good Research Practice.

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 Human Tissues Act 2004 and the Animals (Scientific Procedures) Act 1986) 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 Research Ethics Supplementary Guide: For Reference by Researchers Undertaking Journalism and Media Production Projects. 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 (Staff and PGR applications)

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.

11.2.1 Disagreement with the academic judgement of the Ethics Panel assessing the application, does not constitute grounds for an appeal.

12. APPEALS (UG and PGT student applications)

12.1 If at any stage of the application for ethical approval is likely to be rejected, this will normally be referred back to the student researcher with the deficiencies of the application identified, giving the student researcher the opportunity of a further submission.

12.2 Where an application for ethical approval is not approved by a Supervisor and/or Ethics Programme Team, the student researcher has the opportunity to appeal and should refer to the appropriate Academic Assessment Regulation.

12.3 Where a Supervisor and/or Ethics Programme Team cannot agree on a suitable outcome, matters should be referred to the Deputy Dean for Education & Professional Practice (or equivalent).

13 NON-COMPLIANCE AND MISCONDUCT

13.1 BU 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 Faculty or University level to resolve this.

13.2 In the interests of openness, good practice and the reputation of BU, members of staff and students of BU, 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 by email to researchgovernance@bournemouth.ac.uk.

13.3 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 potential research misconduct. Further detail can be found in BU's Research Misconduct: Policy and Procedure document.

13.4 If you do not have ethical approval, the University's insurers may not cover you for legal action or claims for injury. It may also lead to debarment from membership of some professional or statutory bodies and may exclude Researchers from applying for some types of employment or research funding opportunities.

13.5 A serious breach of research ethics is considered research misconduct and will be dealt with according to BU's Research Misconduct: Policy and Procedure document. The following are **examples** of what constitutes a serious breach of research ethics (this is not an exhaustive list):

13.5.1 Deliberately attempting to deceive when making a research proposal;

13.5.2 Failure to obtain appropriate permission to conduct research with ethical implications;

13.5.3 Failure to follow protocols contained in ethical consent and/or unethical behaviour in the conduct of research;

13.5.4 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;

13.5.5 Unauthorised use of information acquired confidentially;

13.5.6 Failure to follow any procedures and health and safety protocols that avoid unreasonable risk or harm to humans, animals or the environment;

13.5.7 The misuse of research findings which may result in harm to individuals, populations, animals or the environment;

13.5.8 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;

13.5.9 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;

14. ACKNOWLEDGEMENTS

14.1 The review of the policy and procedures for research ethics at BU has drawn heavily on a number of publically available sources, with many contributions from these sources now incorporated with aspects of the previous policy and procedures to produce BU'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: MANAGEMENT OF RESEARCH DATA

The information collected or generated during research projects falls into two main categories:

1. Governance documentation: research protocols, recruitment literature, participant information sheets, participant agreement forms and similar;
2. Project documentation: completed questionnaires, audio tapes, transcripts, video and still images and similar. These materials are likely to include significant amounts of personal data which will be subject to requirements under the Data Protection Legislation.

Guidance on filing and storage of all research data

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 BU's 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 on the BU network.

In cases where BU has full control, the following are indicators of retention periods which may be appropriate for particular categories of research activity:

- **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.

These periods should be treated as starting points for consideration. Retention periods should be determined specifically for each project, having regard to the nature of the data to be collected/generated and the nature and purpose of the research, as well as internal audit and external requirements as discussed above.

Consideration should be given to the management of data if the responsible researcher leaves BU. Departments and Faculties should consider how they will identify and manage either a transfer of data from BU to a researcher's new employer or learning provider or the application of retention/destruction arrangements where data remains stored on BU systems after the researcher leaves the organisation.

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 and any other confidential information (e.g. commercially sensitive information) must be securely destroyed. The data owner is

responsible for the data up to the point of secure 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..

Personal Data: compliance with the Data Protection Legislation

What is the Data Protection Legislation?

The Data Protection Legislation applies to all "**personal data"**, which is data relating to identifiable individuals. An individual is obviously identifiable from their name, but it is often possible to identify individuals from information even if their name is not given, e.g. if a number of other data fields are used which together would indicate the identity of the individual.

The Legislation relates to any "processing" of personal data. This is a very broad term which encompasses all activities in relation to data, including storage/retention. The Legislation sets requirements which apply to all processing of personal data, and also sets additional safeguards around the processing of "**special category data**": this is personal data consisting of information about an individual's: race or ethnicity; religious or philosophical beliefs; political opinions; trade union membership; health or disability; genetic or biometric characteristics; or sex life or sexual orientation. There are also specific provisions around processing of personal data about criminal convictions or the alleged commission of criminal offences.

The Data Protection Legislation comprises the EU General Data Protection Regulation and the UK Data Protection Act 2018. It sets out the circumstances in which, or purposes for which, personal data can be processed and the safeguards which must be applied to such processing. These apply to any "data controller", i.e. any individual or organisation which is responsible for determining the purposes for which data is processed or the way in which it is processed.

It is essential that the collection, generation and management of research data within your research project complies with the Data Protection Legislation. Breach of the Legislation could have significant consequences for individuals, for you and for BU, and may be a disciplinary matter for individual BU staff. In addition, if you are processing data in breach of the Data Protection Legislation this will usually not be ethical research activity.

For further information on data protection requirements and frameworks within BU, please see Data Protection at BU, and in particular the Data Protection Policy

Requirements of the Data Protection Legislation

The Data Protection Legislation sets out the following core principles which apply to all processing of personal data:

1. Personal data shall be published fairly, lawfully and transparently;
2. Personal data shall be obtained only for one or more specified, explicit and legitimate purposes, and shall not be processed in any manner incompatible with that purpose or those purposes. The Data Protection Legislation gives descriptions of specific purposes or circumstances in which processing of data is legitimate;
3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed. This is referred to as the principle of 'data minimisation'. See further guidance below;
4. Personal data shall be accurate and, where necessary, kept up to date;
5. Personal data (i.e. data in a form which permits identification of individuals) shall not be retained for longer than is necessary for the purpose or purposes for which it is being processed, subject to some exception with regard to longer storage of data for archiving and research purposes in the public interest;

6. Personal data must be processed in a manner that ensures appropriate security of the data. This includes applying appropriate technical and organisational measures to protect against unauthorised or unlawful processing of personal data and accidental loss or destruction of, or damage to, personal data;
7. A data controller must be able to demonstrate compliance with these principles at any time. This means that BU must be aware of the data processing being undertaken by BU, its staff and students, and be able to demonstrate the legal basis for that processing (i.e. that it is for purposes which are specified in the Data Protection Legislation as legitimate) and that it is complying with the other key principles.

Other key requirements of the Data Protection Legislation are:

- Personal data must 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.

- Data controllers must comply with the rights of data subjects (i.e. the individuals identifiable from personal data). These include:

    - Right to be informed about use of their data, through appropriate transparency or privacy notices
    - Right to access their personal data as processed by the data controller
    - Right ask for personal data to be rectified or erased, or to object to continued processing of the data

    Other than the right to be informed, the rights are subject to certain exceptions, including exceptions to allow the continued use of data for research purposes if erasing the data or ceasing its processing would compromise the integrity or validity of the research. However, it is still necessary to fully consider requests to exercise these rights and to explain and be able to justify any decision not to comply with the request.

Implications of data protection for management of research data

The following points should be considered in the design of and planning for research studies and reflected when making research ethics applications:

Use of personal data and study design

- Has the researcher clearly identified the nature and scope of personal data that will be processed within the research project, and whether this includes special category data or criminal offences data?
- Is there a clear reason for using identifiable data, and in particular for using special category or criminal convictions data: how is this relevant and necessary for the research?
- Has the legal basis for processing of the data been considered and identified, and does it fall within the description in the BU Research Participant Privacy Notice?
- How has the principle of data minimisation been applied in the design of the research? What consideration has been given to limiting the scope of data collected and/or applying masking, pseudonymisation or anonymisation techniques to personal data at the earliest possible stage?

Transparency

- How will individuals be provided with the legally-required information about the use of their personal data and access to the BU Research Participant Privacy Notice? Has the researcher produced participant information sheet and agreement forms as records of consent as required by the RECP?

Data security and access management

- What steps will be taken to ensure the confidentiality and/or anonymity of personal information? Give details of access controls/permissions, pseudonymisation and anonymisation procedures and other physical and technical security measures. Personal data held on mobile devices must be encrypted. See Mobile Device Security Guide (Staff) and Mobile Device Security Guide (Students).
- Who will have access to personal information relating to the study? How will access be limited to what is necessary for the research? 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, participant agreement 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 indicative retention periods are proposed? In identifying the proposed retention periods, has the researcher applied the retention principles set out above? The researcher should state how long they intend to retain study information and why providing separate justifications for any special category data and criminal offences data. They should state what format the information will be kept in and where the data will be stored.
- What arrangements are being put in place to ensure that data is retained securely? Any personally identifiable data that is held on any mobile device must 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?
- Who will be responsible for retention/destruction decisions if the lead researcher leaves BU or is absent for another reason?

Archiving Clinical Research Records

- According to Good Clinical Practice (GCP) guidelines, it is recommended that clinical research records for studies *not* investigating an Investigational Medicinal Product are archived for five years once the research study has ended.
- Studies that are investigating an Investigational Medicinal Product where the documents will *not* be submitted as part of a marketing authorisation, are likewise archived for 5 years.
- Studies that are investigating an Investigational Medicinal Product where the documents will be submitted as part of a marketing authorisation, are archived for 15 years after completion or discontinuation of the trial, or for at least 2 years after the granting of the last marketing authorisation.

ADVICE AND FURTHER INFORMATION

Please contact BU's Data Protection Officer (dpo@bournemouth.ac.uk) for further advice on data protection requirements and compliance.

LINKS TO OTHER BU DOCUMENTS/RESOURCES

- 6M – Research Misconduct: Policy and Procedure
- 8A – Code of Practice for Research Degrees
- Data Protection at BU
- Data Protection Policy
- BU Code of Good Research Practice
- BU PREVENT Policy
- Reseach Ethics Blog
- Mobile Computing Policy
- Information Security Policy
- Mobile Device Security Guide (Staff)
- Mobile Device Security Guide (Student)
- Information Classification Policy

APPENDIX 2: RESEARCH WITH CHILDREN AND YOUNG PEOPLE UNDER THE AGE OF 16 YEARS

For research involving children and young people under the age of 16 years, Researchers must always ensure that their best interests are the primary concern and be competent in researching with children and young people. Researchers must consider the following issues: children have the right to be properly informed and, where possible, their assent must be obtained and checked as appropriate throughout the research study. It is recognised that whether a child under the age of 16 years is considered 'vulnerable' depends on several factors such:

- a as the child's circumstances
- their susceptibility to coercion or feelings of obligation,
- their cognition and intellectual abilities (presence to absence of developmental delay)
- the type of research and how it is being undertaken.

Researchers must therefore take all of these factors into consideration when assessing whether child or young person participants under the age of 16 years should be deemed as 'vulnerable'.

In situations where a child is too immature or vulnerable to assent to participant or where any other circumstances may limit the extent to which this can be obtained from him or her, researchers must seek the support and approval of those with legal responsibility for the child or young person. 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 research studies with children and young people under the age of 16 years will require consideration by an Ethics Panel or Ethics Programme Team. Careful consideration of projects involving children and 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.

Faculties are empowered to produce faculty/department-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.

APPENDIX 3: RESEARCH ETHICS REVIEW AND APPROVAL PROCESS