Research Ethics Policy and Procedures

1. SCOPE AND PURPOSE

1.1 The AECC Research Ethics Policy and Procedures applies to all staff (those undertaking research and those involved in the supervision of student research) and all undergraduate (first qualification chiropractic students) and postgraduate taught and research students undertaking research under the auspices of the AECC.

1.2 AECC recognises the importance of reviewing and approving the ethical aspects of all research conducted at the College. The purpose of ethical approval is threefold:

- Reflects AECC's commitment to good ethical practice
- Assists researchers and supervisors undertaking research to identify appropriate ethical issues and address these in the development of research proposals;
- 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 This Policy is designed to provide guidance about conducting ethical research and to provide details of the AECC process and procedure for ensuring appropriate consideration and ethical approval of research by staff and students.

1.4 Ethical approval covers the ethics of conducting a research study and how research data and observations are handled in ethical terms. Ethical approval does NOT consider the merits (or otherwise) of a research study in terms of feasibility, design, and methods of collection of data or observations and methods of analyses.

1.5 All researchers and research supervisors must read this Policy prior to commencement of their research. If further clarification or guidance is needed, the Chair of the Research Ethics Sub-Committee (RESC) should be consulted. Further details on the RESC are given in AECC Academic Committees Membership and Terms of Reference.

1.6 Not all empirical study requires ethical approval (see Guidance on Ethics Approval under separate cover). However, even if approval is not required, for example clinical audit and service evaluation studies, there most probably are ethical issues to consider, e.g. anonymity of participant data, and secure data storage.

1.7 Failure to conduct research in accordance with this Policy may result in personal disciplinary or legal action taken against the researcher, supervisors or the AECC. Section 10 provides detailed guidance on non-compliance and misconduct.

2. KEY RESPONSIBILITIES

2.1 Responsibility for drafting and reviewing research ethics policies and procedures as set out in this document lies with the Academic Audit Committee, approved by Academic Board. Implementation of these policies and procedures is the responsibility of the Research and Staff Development Committee with delegated authority to the RESC.

2.2 This document is part of AECC's Academic Regulations, Policies and Procedures which govern the College's academic provision.

3. RESEARCH ETHICS PRINCIPLES

3.1 Research should be designed, reviewed and undertaken to ensure integrity, value and quality.

3.2 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).

3.3 Participants should be fully informed about the purpose, methods and intended possible use of the research. Section 7 provides detailed guidance on informed consent.

3.4 Researchers should respect the human participants involved in their research as persons of worth whose participation is a matter of their autonomous choice (Section 7.4 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, and the DDE principles and practice as detailed in the College's DDE Policy.

3.5 Research participants must normally participate voluntarily, free from coercion. 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.

3.6 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.

3.7 The confidentiality of information supplied by participants must be respected. Any limits to confidentiality must be explained to participants.

3.8 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.

3.9 All research must comply with the Data Protection Act 1998. All 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.

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

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

3.12 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, and in the information to participants.

3.13 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 AECC's disciplinary procedures for students and staff (as appropriate).

4. RESEARCH ETHICS DEFINITIONS

4.1 Research ethics are the moral principles guiding the planning and conduct of research, the publication of outcomes and post-project storage and/or disposal of data or observations.

4.2 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. Thus, ALL research involving human participants requires ethical approval.

4.3 Types of research or activities requiring ethical approval include, but are not limited to, those listed below:

- Staff Research: an agreed programme of research undertaken by a member of AECC staff
- Postgraduate Doctorate Research Degrees: a research degree involving a programme of research undertaken by a postgraduate student at AECC even though that student may be registered at another institution
- Undergraduate and Postgraduate Taught Dissertations or Projects: a research programme for a project or dissertation undertaken by an undergraduate (including first qualification programmes) or postgraduate students at AECC.

4.4 If, after reading the Guidance on Ethics Approval you are unsure if your study is considered as research, you should consult with a member of the RESC 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 AECC's standard ethical procedures are followed (see Section 8). In the event that ethics approval is either not appropriate or necessary, this will be communicated through the RESC or Projects Panel (see section 8).

5. RESEARCHER RESPONSIBILITIES

5.1 **Responsibility for obtaining ethical approval and ethical conduct of the study 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
- Read this Policy.
- 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). Where ethics approval is sought either through the NHS, or from recognised ethics approval bodies in the country in which the research is being conducted, there is no need to apply for ethics approval through the College's own procedure
- Complete an Ethics Application Form and follow College procedures (unless seeking approval elsewhere) (see section 8).
- Obtain ethical approval BEFORE any data collection commences for the project
- Ethics approval cannot be sought retrospectively (i.e. after data collection has commenced)

Throughout the research project, the researcher must:

- Operate in an ethical manner with due regard to the ethical considerations and challenges relevant to the 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 RESC 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 dissemination of the findings is appropriate in terms of anonymity and confidentiality.

5.2 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 further approval.

5.3 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 Data Protection Act 1998. *Appendix 1: Research Data Storage and Retention* provides detailed guidance on data storage and retention.

5.4 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 study.

RESC, PROJECTS PANEL AND SUPERVISOR RESPONSIBILITIES

5.5 It is the responsibility of supervisors, the Projects Panel and/or the RESC to determine whether a research project is ethically sound and grant approval based on the following:

- That every effort has been made to protect participants against harm and injury as a result of being involved in the study
- That participants are appropriately, clearly and fully informed of what is involved should they agree to participate, and their rights in agreeing or refusing to participate
- That informed consent to participate is appropriately obtained, and that no coercion is brought to bear
- That participants are appropriately protected with reference to anonymity and disclosure (confidentiality) of their data, both in terms of its storage and its use
- That information is provided on how any data obtained as part of the study are eventually destroyed

5.6 Supervisors, the Projects panel and the RESC should regard the following aspects of research as involving **above minimal risk** and therefore likely to require a more thorough ethical review prior to approval (see Appendix 3):

- Research involving potentially vulnerable groups for example children and young people, those with a learning disability or cognitive impairment, and mental incapacity.
- Research involving sensitive topics such as participants' sexual behaviour.
- Research involving secure data, e.g. patient records. (In most cases, a light touch review confirming approval by the body holding these data, and anonymity and security of data will be sufficient.)
- Research involving groups where permission of a gatekeeper is normally required, e.g. school head teacher, sports coach, parent.
- Research involving deception or covert research that is conducted without the participant's fully informed consent.
- Research involving access to sensitive or confidential information.
- Research that may induce psychological stress, such as anxiety, or cause more than minimal pain.
- Research involving interventions not normally experienced as part of everyday life or clinical practice.
- Research involving interventions where those administering the intervention are not qualified to do so, but are doing so in supervised conditions.
- Research that has the potential to cause harm to the participant or to the researcher, or the potential to compromise the participant's safety.
- Research involving visual or audio-taping where an individual can be recognised.
- Research undertaken outside the UK.

This list is not exhaustive and supervisors and members of the Projects Panel/RESC can only make judgements on ethical issues based on their knowledge and experience.

5.7 Supervisors overseeing research studies have a responsibility to discuss research ethics with their student(s) and ensure the student prepares an Ethics Application Form if required. Supervisors have a responsibility to review the student's Ethics Application Form to ensure the research project is in line with basic research ethics principles and the AECC Research Ethics Policy.

5.8 It is the responsibility of the person granting approval (supervisor, Chair, Projects Panel or Chair, RESC) to forward a copy of the signed Ethics Application Form to the administrator of the RESC for filing for auditing purposes.

6. INFORMEDCONSENT

6.1 Informed 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.

6.2 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.

6.3 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.

6.4 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 Mental Capacity Act 2005, these projects must be reviewed by National Research Ethics Service (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 institutionalized 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 researcher at an educational institution 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.

- 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.

6.5 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 in some randomised controlled trials, 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 the RESC. Researchers must provide convincing reasons why such research should proceed without the necessary informed consent.

6.6 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 Data Protection Act 1998 and provide researcher contact details.

6.7 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. A document on how to prepare a participant information sheet and a sample consent form are available under separate cover to this policy (How to Prepare Your Participant Information Sheet and Sample Consent Form).

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

6.9 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.

6.10 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.

6.11 For recorded interviews, written consent should be obtained.

6.12 It is acknowledged there may be circumstances in which participants give their consent by their on-going involvement in the research. For example, informed consent is implicit in survey research through the completion and return of questionnaires.

PROCEDURE

7. RESEARCH ETHICS REVIEW AND APPROVAL PROCESS

7.1 An Ethics Application Form is available under separate cover.

7.2 *Appendix 3* details the procedure for the review and approval process for all researchers (staff and students) applying for ethical approval. Details of the ethical review and approval process are outlined below:

- **Undergraduate/First Qualification Taught** students submit an Ethics Application Form to their supervisor, and if minimal risk is identified, the supervisor will conduct a light-touch review and grant approval (see 5.8). If above minimal risk is identified, a Projects Panel reviews the application. The Projects Panel comprises of at least three people, one of whom acts as Chair,

who will meet to review the submitted form and attachments, and either approve this (see 5.8) or return it to the applicant for further detail or amendments.

- **Postgraduate Taught and Research** students submit an Ethics Application Form to the Chair, RESC. If minimal risk is identified, the Chair will conduct a light-touch review and grant approval (see 5.8). If above minimal risk is identified, the Form is submitted to the RESC via an Ethics Filter (normally the Chair), who ensures the relevant documentation and attachments are contained within the proposal. If approval cannot be given outright, Chair's Actions will be initiated.

- **Staff** members submit an Ethics Application Form to the Chair, RESC and if minimal risk is identified, the Chair will conduct a light-touch review and grant approval (see 5.8). If above minimal risk is identified, the ethics approval form is submitted to the RESC via an Ethics Filter, who ensures the relevant documentation and attachments are contained within the proposal. If approval cannot be given outright, Chair's Actions will be initiated.

- **NHS/ external ethical approval:** Projects which require NHS or another external ethical approval, the researcher submits their application to the relevant body. Research involving the NHS, including patients (see 8.3), carers or data must gain ethical approval from NRES. The approval document must be submitted to the RESC via the Chair as evidence for auditing purposes.

- **International research**: All research conducted outside of the UK is subject to ethical review in the country in which the study will be conducted. Approval documents must be sent to the RESC via the Chair as evidence for auditing purposes. If the country does not have established ethical guidelines, the researcher must submit an Ethics Application Form and process this in accordance with the College's procedures (section 8).

7.3 Patients attending a private clinic (e.g. chiropractic clinic) are not, for the purposes of ethical review, classed as NHS patients. In these cases, the researcher must submit an Ethics Application Form and follow the procedure outlined in this section.

7.4 Studies involving further analysis of existing data (secondary analysis) will require ethical approval. These studies will normally be considered as minimal risk, and the use of such data allowed if:

- The data are completely anonymous when provided to the researcher and it is not possible to identify participants from any resulting write-up
- The data are stored securely and appropriately destroyed (see Appendix 1)

7.5 Studies involving existing data collected as part of routine practice will require ethical approval. These studies will normally be considered as minimal risk, and the use of such data allowed if:

- The data are anonymised and it is not possible to identify participants from any resulting write-up
- The data are stored securely and appropriately destroyed (see Appendix 1)

7.6 All applications referred to the RESC via the Ethics Filter will be circulated to two members who will independently review the application, and give a decision on approval to the Chair.

7.7 All ethics applications deemed to be above minimal risk will be reviewed either by the RESC or by the Projects Panel against the criteria listed under 6.1. All applications are reviewed for adherence to ethical principles only and not on issues of research methodology including research questions, research design, and data collection and analysis methods.

8. APPEALS

8.1 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.

8.2 Where an application for ethical approval is not approved by the RESC, the researcher has the opportunity to appeal to the Principal. The decision of the Principal is final and the matter is concluded at this point.

9. NON-COMPLIANCE AND MISCONDUCT

9.1 The College expects that all research carried out in its name complies with sound ethical principles.

9.2 A serious breach of research ethics is considered misconduct and will be dealt with according to BU's Misconduct in Academic Research Policy and Procedures for Postgraduate students, the College's Academic Offences and Disciplinary Procedures for students on undergraduate/first qualification chiropractic programmes, and the College's disciplinary procedures for staff. 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;
- Unauthorised use of information acquired confidentially;
- The misuse of research findings which may result in harm to individuals
- 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 misconduct.

10. OTHER DOCUMENTS

- AECC Ethics Application Form
- Access to AECC Patient Records Form
- How to Prepare Your Participant Information Sheet
- Sample Consent Form

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APPENDIX 1: RESEARCH DATA STORAGE AND RETENTION

The data collected during research projects falls into two categories:

1. Personal Identifiable Data: Participant information sheets, consent forms and similar; Project documentation: completed questionnaires, audio tapes, transcripts, video and still images and similar.
2. Anonymised data: Normally electronic databases with coded entries.

Personal Identifiable Data:

In keeping with the Data Protection Act, data retention periods should be kept to an absolute minimum. 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. 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**: 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. AECC RESC 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 researcher is responsible for the data up to, and including 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 are safe.

Data Protection Act 1998: Sensitive Personal Data and the Data Protection Principles To ensure compliance with the Data Protection Act 1998 participants must be informed about what information will be held about them and who will have access to personal, identifiable information.

The following points should be considered in research ethics applications:

Data security and records management

- 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, and how data will be destroyed at the end of the study.
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Anonymised Data

Once data has been anonymised and there is no link through personal data, including birth date and record numbers, to an individual, and all codes to enable any linking have been destroyed, research data can be held indefinitely on secure computers and servers.

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 Committee. Careful consideration of projects involving young people remains a key requirement of the ethics procedures at the College.

APPENDIX 3: RESEARCH ETHICS REVIEW AND APPROVAL PROCESS