AECC University College
Transforming lives through Health Sciences

Research sponsorship policy and procedures DRAFT

1. Purpose and scope

1.1 This policy must be read in conjunction with AECC University College's External Approval & Ethics Review Policy & Procedures.

1.2 It is a requirement of the UK Policy Framework for Health and Social Care Research (PDF, 380kB) that any research governed by it (broadly speaking any research that requires an IRAS application[1]) must have a designated Sponsor, who takes ultimate responsibility for the oversight of the research project. The Sponsor will usually be:

- an academic organisation,
- an NHS Trust,
- or a commercial company (typically a pharmaceutical company).

1.3 The Sponsor must be in a position to ensure that the design and implementation of the study meet required standards and provide assurance. The Policy Framework states that Sponsors are ultimately responsible for:

a. identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications and ensuring that research proposals and protocols:
    - take into account systematic reviews of relevant existing research evidence and other relevant research in progress,
    - make appropriate use of patient, service user and public involvement and
    - are scientifically sound (e.g. through independent expert review) (For educational research, the scientific validity and quality may be established by the chief investigator (i.e. the supervisor) at a level appropriate to the nature of the course), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing;

b. satisfying itself that the investigators, research team and research sites are suitable;

c. ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented;

d. ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project; and

e. ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate,

[1] The Integrated Research Application System (IRAS) (https://www.myresearchproject.org.uk) is a single system through which you can apply for many of the approvals required to conduct Health and Social Care Research in the UK.

to participants (For educational research, registration, accessibility of data and tissues, and dissemination may be limited to institutional arrangements);

f. ensuring that, where expected or required, the research has approval from a research ethics committee (Whether outright or following a provisional opinion, resubmission or appeal) and any other relevant approval bodies before it begins;
g. verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner;
h. putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management;
i. ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

1.4 The Sponsor is responsible for ensuring that arrangements are in place to indemnify the Investigator(s) against claims for harm arising from negligence. The employer of the Investigator(s) may also be liable for non-negligent harm to study participants. NHS bodies are unable to provide indemnity for non-negligent harm. Certain other kinds of sponsor (e.g. universities) may be able to offer indemnity for non-negligent harm but the need for insurance against this risk will be determined by an NHS Research Ethics Committee (REC) following consideration of the risks associated with a particular study. A detailed risk assessment must always be performed when planning a new study and practical advice on risk assessment can be found on the NIHR Clinical Trials Toolkit webpage.

1.5 Commercial Sponsors are generally also the Funder of the project, but the Funder of a project is not necessarily the Sponsor. A Non-Commercial Sponsor (NHS or academic) would generally be the employer of the Chief Investigator[2] - however, this is not automatic. The organisation must be asked to take on the role of Sponsor and will only agree to do so if they believe that it is in the best interests of their organisation.

2. Application for AECC University College Sponsorship

2.1 If you are an employee or are a postgraduate student at AECC University College, you can normally request Sponsorship by the University. Undergraduate student projects are no longer being accepted for NHS REC review or Health Research Authority (HRA) and Health & Care Research Wales (HCRW) approval.

2.2 AECC University College usually assumes sponsorship when a university employee / postgraduate student has designed the study and/or is acting as the Chief Investigator. If the University is not the substantive employer of the Chief Investigator, then the University will not sponsor the study, unless the criteria in paragraph 2.3 is met.

2.3 The University may consider acting as sponsor for a study where an AECC University College registered doctoral student is acting as Principal Investigator[3] and the supervisor is the Chief Investigator and is an AECC University College employee, provided the exceptions detailed within the UK Policy Framework for Health and Social Care Research have been met. This

[2] The Chief Investigator (CI) as defined by SI 2004/1031 is the health professional who takes primary responsibility for the conduct of the trial at all trial sites.

[3] The Principal Investigator is an individual who is responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the Chief Investigator and the Principal Investigator will normally be the same person.

decision will be taken by the Research Team, following recommendation from the student's supervisor.

2.4 For Master's students, students and their supervisors should complete the student research toolkit in the first instance, to check eligibility. Some health and social care research applications from students working at Master's level are no longer being accepted for NHS REC review or HRA and HCRW approval.

2.5 If AECC University College agrees to act as Sponsor, the Research Team will act as the Sponsor's Representatives. This policy explains the steps required to apply for AECC University College Sponsorship.

2.6 The flow chart in Appendix 1 outlines the steps required to obtain acceptance of Sponsorship from AECC University College. The first step for request for AECC University College to Sponsor a study will be to contact the Research Team.

2.7 A member of the Research Team will discuss your project with you. They will review your study documents (e.g. study protocol, participant information sheets, consent forms, etc) and your IRAS form and will manage your application process. They will also be able to advise you on appropriate collaboration agreements for any external research sites.

Start date for the research

2.8 Once all required approvals and agreements are in place, the Research Team will issue a confirmation of Sponsorship. This will form part of your study document pack and will need to be uploaded to IRAS.

2.9 You must not carry out any study-related procedures until confirmation of Sponsorship is in place.

Peer review

2.10 It is a responsibility of the Sponsor to ensure that appropriate peer review has been conducted. For most funded research, this will have been conducted through the funding process and the Research Team will ask to see confirmation of this. However, if your research is unfunded or the funder did not require a peer review, this does *not* mean that we do not require proof of independent peer review. The only exception to this is educational research: if an academic supervisor is acting as Chief Investigator they may attest to the scientific validity and quality of the study.

Safety reporting

2.11 As part of the application process, the Research Team will review the intended safety reporting process in your protocol. This should be proportionate to the nature of your study while meeting any applicable REC/MHRA[4] expectations.

Submission of IRAS form

2.12 Once your IRAS form is submitted, the system will prompt you to book an NHS Research Ethics Committee (REC) review. The flow chart in Appendix 2 summarises the HRA processes that the Chief Investigator must follow until formal notification of approval is received.

[4] The Medicines and Healthcare Products Regulatory Agency (MHRA) are a national oversight body who oversee the safe and appropriate use of medicinal products and medical devices in the UK.

Breaches

2.13 A Breach is any deviation during the course of the study from your approved study protocol or from the Conditions and Principles of Good Clinical Practice. If a Breach occurs, you must notify the Research Team as soon as possible after your becoming aware of it. We will then, as Sponsor Representatives, determine whether any further reporting is required, or if it is sufficient to document the Breach along with all Corrective and Preventative actions taken in response to it.

Monitoring

2.14 Monitoring is a formal process of reviewing the conduct of a research project, usually during that conduct but sometimes retrospectively. Your study may be monitored because a concern has been raised or, more commonly, because it has been randomly selected as part of an annual monitoring exercise. It is a requirement that all necessary records are made available to the Monitors; this includes participant records - agreement to this access should be included in consent forms.

Amendments

2.15 If you need to make any change to a study over the course of its conduct, this is referred to as an Amendment. This could be, for example, a change to protocol procedures, to participant-facing documents, to key study-staff, to the sites conducting the study, etc. For any such change you will need to complete the Amendment Tool. You can find the current version of the tool in the IRAS Help pages. This may be updated without warning, and you are expected to submit using the current version, so please download from IRAS each time, rather than saving a local version.

2.16 Once you have selected the appropriate categories to describe the nature of your amendment, the tool will determine for each of the bodies that approved your study whether this is a Substantial Amendment, requiring full review; a Non-Substantial Amendment, requiring formal submission and acknowledgement; or a non-Notifiable Amendment, which will be managed by your Sponsor.

2.17 Categories will be checked as part of Sponsor Review, to ensure that they are the most accurate available descriptions of the intended changes.

2.18 It is a requirement that the Sponsor organisation review Amendments prior to their being submitted. Once you have drafted the Amendment Tool, please send it to mailto:research@aecc.ac.uk, in its original Excel format. Leave lines 8 & 9 and all of Section 3 blank**,** these will be completed by the Sponsor.

2.19 Once the form has been reviewed and agreed, it will be returned to you as a pdf. It should then be submitted via the IRAS amendments system, for which you will need to create an account, in addition to your regular IRAS account.

Annual reports and end of study/trial

2.20 All NHS REC approved studies are required to submit an annual progress report, to the approving REC, each year after approval is granted. More details are provided by the HRA. At the end of the study, an End of Study notification must be submitted to the approving REC. More details can be found at the HRA. For AECC University College Sponsored studies, the Research Team will prompt you when these are due, but it is the Chief Investigator's responsibility to ensure that they are submitted.

Archiving and destruction

2.21 After closure, documents and data should be archived as described in your IRAS submission and Protocol, and in accordance with any requirements that your funder may have. So long as the process is as planned, you do not require any approval to do this. It is not required that you retain things in multiple formats, if paper records have been digitised, they can be destroyed – however, it is required for Clinical Trials of an Investigational Medicinal Product (CTIMPs), and recommended for all studies, that validation / QA be conducted to ensure that scans are complete, accurate and legible, prior to the destruction of paper copies.

2.22 After the archiving period has elapsed, records can be destroyed completely, but you must first seek the approval of the Sponsor and the Chief Investigator.

AECC University College as a host site

2.23 If a study is being Sponsored by another organisation but research procedures will be conducted at AECC University College premises or facilities, then AECC University College will need to be setup by the Sponsor as a host site. You will need to contact the Research Team to discuss the study so that we have the necessary details to register the study and to determine whether any additional oversight is required.

3. Withdrawal of Sponsorship

3.1 AECC University College has the discretion to withdraw Sponsorship of a study where information or application of the study protocol changes without prior approval by the Sponsor representative or person acting on behalf of the sponsor. This includes but is not limited to changes to: Partners and collaborators; the Chief Investigator; funding arrangements; participant recruitment and data protection arrangements.

3.2 In addition, Sponsorship may also be withdrawn if there is a failure to comply with any internal or external requirements in relation to research sponsorship, including the UK Policy Framework for Health and Social Care Research; relevant legislation, research site requirements, and University College policies and procedures

4. Arrangements for the Chief Investigator leaving AECC University College

4.1 Where the Chief Investigator leaves AECC University College before the closure of the study, the Chief Investigator role should be transferred to another AECC University College researcher via the amendment procedure detailed under section 2.15, preferably within two weeks of notice of termination of employment, but at a minimum of one month prior to Chief Investigator's contract end date.

4.2 Where the study has closed, every effort should be made to ensure all reporting requirements are completed prior to the Chief Investigator leaving the University. Where this is not possible, as in the case of final closure reports, which may be submitted within a year of the study closure date, arrangements should be made to ensure another employee can submit the report on the Chief Investigator's behalf. The Research Team should be notified where such arrangements are necessary.

5. Further information

5.1 Further information and guidance are available on the RKE Hub.

5.2 The Head of Research and the RKE Manager can also provide guidance and can be contacted via the email address: research@aecc.ac.uk.

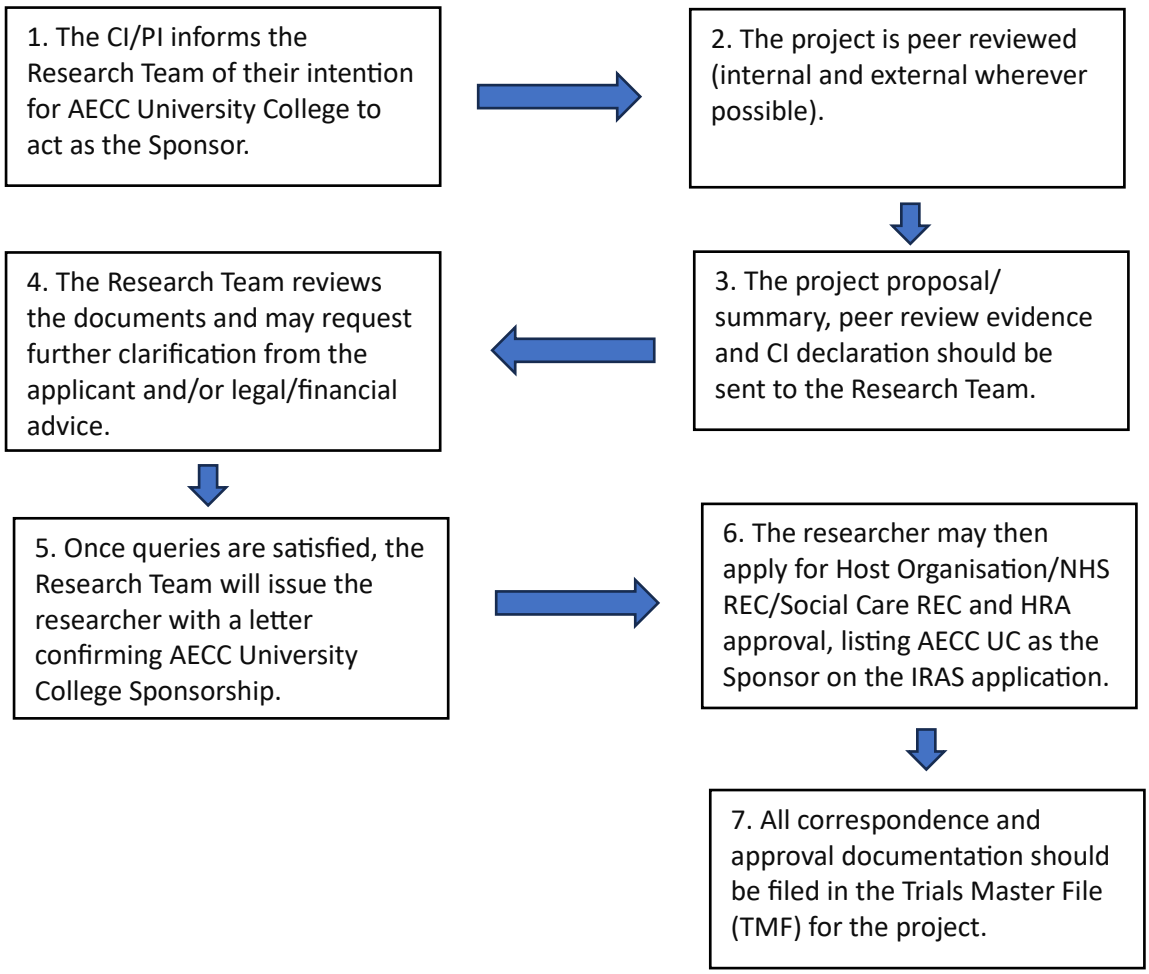
6. Good practice

6.1 In drafting this policy and procedure, good practice has been adopted from the NHS, HRA and UK Government, as well as from:

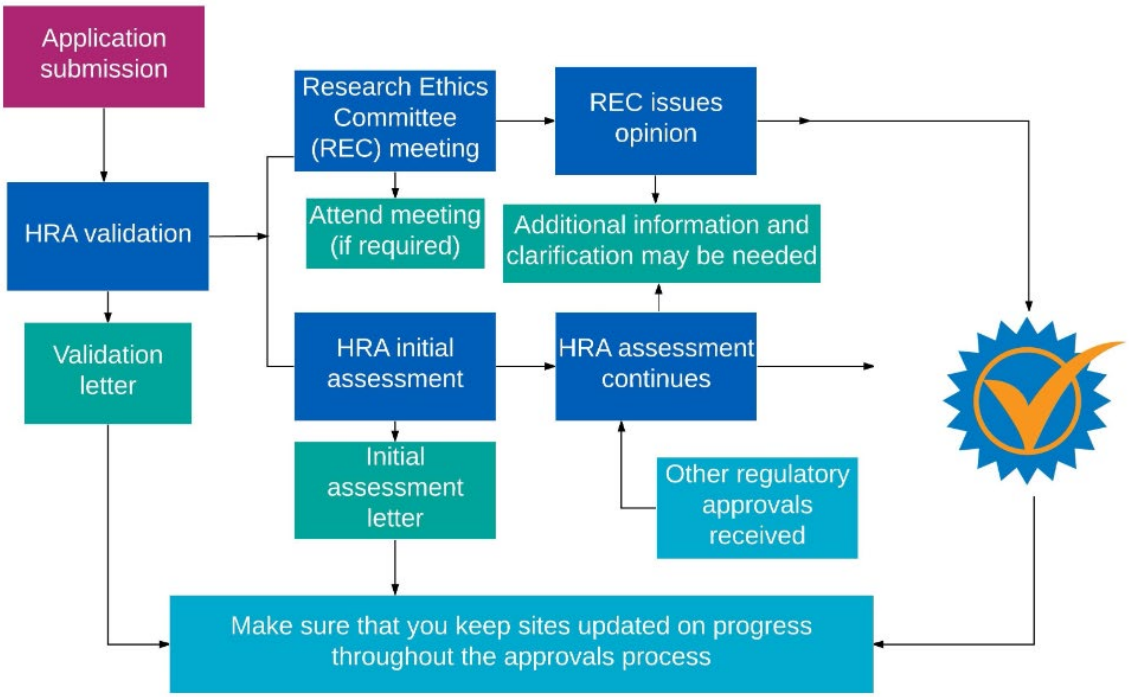
- University of Bath: https://www.bath.ac.uk/guides/obtaining-sponsorship-from-the-university-of-bath-guidance/
- University of Bristol: https://www.bristol.ac.uk/red/research-governance/ethics/
- University of Hull: https://www.hull.ac.uk/work-with-us/research/site-elements/docs/research-sponsorship-policy.pdf

Appendix 1: Flow chart for obtaining Sponsorship from AECC University College

The time required to undertake a Sponsor review will vary considerably depending upon the nature and complexity of the study, but you should allow for up to four weeks for review and revisions, once all relevant documents (IRAS, Protocol, Participant Information Sheet, Consent Forms, etc.) have been provided to the Research Team.



Appendix 2: Flow chart of the HRA process steps that the Chief Investigator must follow until formal notification of approval is received.



Version	1
Approved by	Endorsement – RIC – May 2024 Approval – Academic Board – June 2024 (TBC)
Originator/Author	Research Team
Owner	Head of Research
Reference source	Exemplars from the HE Sector and NHS guidance
Date approved	26 June 2024
Effective from	01 July 2024
Review date	2024/25
Target	AECC University College staff and students conducting research
Policy location	Staff Information Portal (SIP)
Equality analysis	This Policy has been developed with due regard to the University College's general equality duty and no direct impact has been identified.