AECC University College
Transforming lives through Health Sciences

External approvals and ethics review policy and procedures DRAFT

1. When is HRA and HCRW approval required?

1.1 The Health Research Authority (HRA) and Health & Care Research Wales (HCRW) are a joint oversight and management body for health and social care research conducted in England and Wales. They also manage research projects with sites in Scotland and Northern Ireland, where the primary site is in England or Wales (as will be the case for most, if not all, AECC University College research). The HRA & HCRW are partly an administrative body; overseeing the application process, via the Integrated Research Application System (IRAS),[1] for NHS Research Ethics Committees (REC) and many other approving bodies - but they are also a reviewing body in their own right.

1.2 Research that involves access to NHS facilities or requires NHS resource, including staff time, will need approval from the HRA (and the HCRW if there are research sites in Wales).

1.3 Most research requiring HRA & HCRW approval will also require NHS REC approval. You will apply for both simultaneously, via IRAS. However, they will respond separately. Following review, you will need to have favourable opinions from both bodies before you can progress to Sponsorship.

1.4 A very small number of studies will not require NHS REC review but will need HRA & HCRW review - if they involve NHS facilities or staff time but not patients or service users. In this case, you will need to apply for AECC University College ethics approval *and* to the HRA via IRAS.

2. When is external ethics review a requirement?

2.1 All studies that involve human participants, their tissue and/or data should undergo an ethical review. The following cases require review by one or more external bodies, and you will need to apply via the IRAS:

- **Study requiring access to NHS facilities and / or use of NHS time or resources.** In this case, a Health Research Authority (HRA) review will be needed. If your study meets this, but none of the other following categories, it will also require an AECC University College ethics review.

- **Study in which participants are identified due to their being NHS patients or service users.** This also applies to research using NHS data or data generated in relation to NHS services or diagnoses. An NHS Research Ethics Committee (REC) review will be required. If you are unsure whether your project involves relevant NHS activity, please see the Health Research Authority's Do I need NHS REC review? decision tool.

[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.

- **Study involving the analysis or storage of 'relevant material' under the Human Tissue Act.** An NHS REC review will be required.

- **An investigation into the safety and/or efficacy of a medicinal product.** Research of this nature requires review by an NHS REC and by the Medicines and Healthcare products Regulatory Agency (MHRA).

- **Study intended to generate data to support the licencing or marketing of a medical device.** An NHS REC review *and* MHRA review will be required. This does not apply to all research involving medical devices - the distinction is not always immediately apparent. If you think that your study *may* fall into this category, contact research@aecc.ac.uk as early as possible.

- **Research involving participants in social care who lack capacity to consent.** This study category requires a review by an NHS REC specialising in social care.

- **Research involving participants in social care.** This type of study **may** require review by an NHS REC specialising in social care. If so, this would require application via IRAS.

- **Research involving participants identified due to their being currently in prison or on parole.** This type of study requires review by Her Majesty's Prison and Parole Service (HMPPS).

2.2 If none of these criteria apply. Your research will require an AECC University College ethics review.

2.3 Not all projects are strictly *research*. If you are unsure whether you are instead proposing an *Audit* or *Service Evaluation* (which may not require REC review), you can find further guidance via the Health Research Authority's Is my study research? decision tool. The Research Team can provide advice on this.

2.4 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) must have a designated Sponsor, who takes ultimate responsibility for the oversight of the research project. If you are an employee, are studying for a PhD or are the supervisor of a Masters student at AECC University College, you can request Sponsorship by the University. If this is agreed, the Research Team will act as the Sponsor's Representatives. The Research Sponsorship Policy & Procedures explains the steps required to apply for AECC University College Sponsorship.

3. NHS REC Review

3.1 You can use the NHS REC Decision Tool to check whether your project is Research, from an NHS perspective. All projects that require NHS REC approval will require a Sponsor and an IRAS application.

3.2 Projects should generally only be reviewed by a single REC, so if you apply to NHS REC review you will not need any other Research Ethics review (other than in exceptional circumstances, such as a funder requiring review according to their own process).

3.3 Once the IRAS form is drafted, and has been approved by your Sponsor, you will need to request an appointment with a Committee, via the Online Booking Service. Depending on the specifics of your study, you may be offered a place with a committee 'flagged' for a specialist area

involved or you may simply be offered a choice of times with the next committees who have capacity. It is generally expected that the Chief Investigator[2] will be available to attend the meeting and answer any questions that the committee may have. This will always be remotely - by phone or video conference - so the location of the committee is not important.

3.4 NHS REC is required to give an ethical opinion on an application within 60 calendar days of the receipt of a valid application. If you chose not to attend the first meeting available, the 60 calendar days will start from the cut-off date for the meeting (which is 14 calendar days before the meeting date). Where the REC considers that further information is required to give an opinion, it may make one request in writing for further information. The period of 60 days will be suspended pending receipt of this information.

4. MHRA Review

4.1 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. This includes responsibility for overseeing research conducted in accordance with the Medicines for Human Use (Clinical Trials) Regulations and the Medical Device Regulations.

Clinical Trial of an Investigational Medicinal Product (CTIMP)

4.2 A Clinical Trial of an Investigational Medicinal Product (CTIMP) is any study that will generate new information about the safety and/or efficacy of one or more medicinal products. A medicinal product is a substance presented in a pharmacological form with the intention of affecting a clinical or physiological outcome. A product that a CTIMP generates information about is referred to as an Investigational Medicinal Product (IMP). This includes studies of licenced medicinal products, if they will be used in any way other than as described in their licence or if new information will be generated. This includes studies where the medicinal product is not the subject of the study, but new information will or may be generated - due to its use as a control, for example. This does not include studies of foods or food supplements. For help with determining whether your study is a clinical trial of a medicinal product, see the table and flow chart here: Is it a clinical trial of a medicinal product?

4.3 The Clinical Trial Regulations refer to this type of study as a 'Clinical Trial'. It is important to note though, that there are other commonly used definitions of Clinical Trial: the World Health Organisation (WHO) use it to refer to any interventional healthcare study; some funders, such as the National Institutes of Health (NIH), use a similar definition to WHO, some insurance policies define a Clinical Trial as anything overseen by the MHRA (thereby including CTIMPs and CIMDs). In short, when discussing 'Clinical Trials' it's always best to check what definition others are using.

4.4 Applications to the MHRA are generated via IRAS. For a CTIMP, selecting option 1 on filter question 2 will open follow-up filter questions and will add Section B1 to the main form. The details required by the MHRA will be recorded in this form and then downloaded. Once this has been reviewed by the Research Team at AECC University College, we will submit it to the MHRA - usually in parallel with the REC/HRA application.

4.5 The Clinical Trial regs require that strict Safety Reporting be observed for CTIMPs - regardless of the perceived risk of the study or the licensing status of the product.

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[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.

4.6 The MHRA are required to inspect organisations conducting CTIMPs. This will either take the form of a routine inspection, usually of a Sponsor, during which they will inspect several studies from the Sponsor's portfolio; or a triggered inspection, where a concern has been raised about the conduct of an organisation, or a specific study.

Clinical Investigation of a Medical Device (CIMDs)

4.7 A Medical Device is defined, in the Medical Devices Regulations, as:

> "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which:
>
> a. is intended by the manufacturer to be used for human beings for the purpose of:
>
> i. diagnosis, prevention, monitoring, treatment or alleviation of disease,
>
> ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
>
> iii. investigation, replacement or modification of the anatomy or of a physiological process, or
>
> iv. control of conception; and:
>
> b. does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means."

4.8 A CIMD is a study intended to generate information to support the licencing (via CE mark / UKCA mark) or the marketing of a Medical Device.

4.9 Often one of the most difficult elements of setting up a study that involved a Medical Device is determining whether it is a CIMD. If there is any uncertainty at all in this area contact the Research Team as early as possible to discuss. We will generally refer the question to the MHRA devices specialists; to do this, we will need a copy of the study protocol. *This can be an early draft of the protocol, so long as the objectives and methodology are clear.*

4.10 If the Research Team and the MHRA determine that your study is a CIMD, it will need to be submitted as such via IRAS. Please refer to the MHRA's detailed guidance on preparing a submission (PDF, 212kB).

4.11 As with other types of research, the appropriate level of Safety Reporting will depend on the specific study design; however, as a minimum, events that meet the Serious criteria and are possibly, probably or definitely related to a device under investigation must be reported to the Sponsor and, if unexpected, to the REC and MHRA. These events are referred to as Serious Adverse Device Effects (SADEs).

5. Process to follow upon submission of IRAS form

5.1 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 1 summarises the HRA processes that the Chief Investigator must follow until formal notification of approval is received.

6. Further information

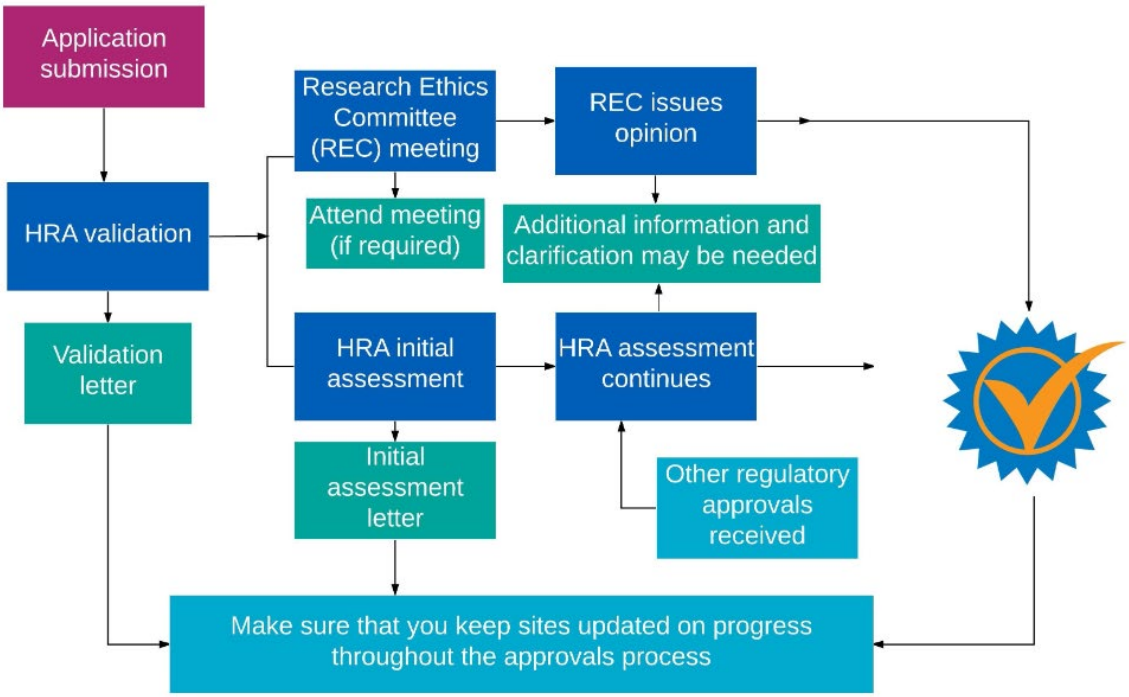
6.1. The HRA website offers extensive guidance. Their Approvals and amendments page is a good starting point. Further information and guidance are available on the RKE Hub.

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

7. Good practice

7.1 In drafting this policy and procedure, good practice has been adopted from other UK universities, including the University of Bristol: https://www.bristol.ac.uk/red/research-governance/ethics/

Appendix 1: 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
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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.