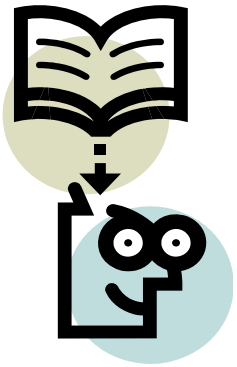
Airedale
NHS Foundation Trust

Airedale NHS Foundation Trust Research Application Submission Pack



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INTRODUCTION
Research and Development Department

The aim of the Research and Development Department (R&D) is to build research capacity within Airedale NHS Foundation Trust and to develop partnerships between the Trust, academic institutions and our partners in the local health community.

The Department assists researchers and helps to ensure that all research associated with the Trust, including clinical trials, is of high quality, ethically sound and of benefit to patient care, treatment and rehabilitation.

The Department aims to encourage all clinical professionals to adopt an evidence-based approach to clinical practice. Airedale NHS Foundation Trust has enthusiastically adopted this approach, which is led by the Research and Development Group (RDG), where proposed research is discussed and evaluated.

The aim of this pack is to provide researchers with information and guidance on setting up a research study and obtaining the correct permissions according to national guidance.

Research Governance

The **UK Policy Framework for Health and Social Care Research** published in 2017 sets out principles of good practice in the management and conduct of health and social care research in the UK. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public. It is for organisations and individuals that have responsibilities for health and social care research. This includes funders, sponsors, researchers and their employers, research sites and care providers.

This framework includes guidance relating to the Medicines for Human Use (Clinical Trials) Regulations 2004, the Human Tissue Act 2004 and the Mental Capacity Act 2005. Clinical research is part of core NHS business and is essential to creating an evidence-based decision-making culture. According to the NHS Constitution 2013 and the Health and Social Care Act 2012 the NHS in England has a statutory responsibility to promote clinical research.

Research governance concerns all those who:

- participate in research
- host research in their organisation
- fund research proposals or infrastructure
- manage research
- undertake research

The purpose of this Research Submission Pack is to provide guidance on:

- the standards required for high quality research at Airedale;
- how to apply for permission to carry out research at Airedale;
- the processes and procedures followed to ensure that research meets the high standards required;
- how research will be assessed and monitored.

Research Governance is necessary to improve the quality of research and safeguard patients, carers, staff and the public by:

- enhancing ethical and scientific quality;
- promoting good practice;
- reducing adverse incidents and ensuring lessons are learned;
- preventing poor performance and misconduct.

The Research Governance Framework for Health and Social Care document can be found at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ .

SUBMISSION PROCESS FOR RESEARCH AT AIREDALE NHS FOUNDATION TRUST

STEP-BY-STEP GUIDE

Before a research study begins, the researcher(s) MUST obtain HRA approval (if required) and the Airedale R&D Dept MUST have confirmed capacity and capability.

HRA approval is required for research that involves patients, patient data, medical devices, human organs/tissue and studies covering multiple sites. If in doubt please contact the R&D office.

STEP 1 – ASCERTAIN WHETHER YOUR PROPOSED PROJECT FALLS UNDER THE REMIT OF RESEARCH

"Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods."

Research Governance Framework for Health and Social Care, second edition, 2005

Although some research projects include evaluation, in circumstances where a project is considered to be solely audit* or service/therapy evaluation**, it will not be managed as research within the NHS. Such projects do not require ethical review by a NHS or Social Care Research Ethics Committee or HRA approval. Under these circumstances, there is no need to submit applications to the NHS Research Ethics Committee (REC) or NHS/HSC R&D office or HRA Approval.

If the project is audit, service evaluation or some other type of non-research activity such as case study, system/equipment testing or satisfaction survey, you should check with the R&D office for advice as to what other review arrangements or sources of advice apply to the project.

To help you decide whether your project is classified as research you should refer to the HRA Decision Tool or the national Research Ethics Service leaflet Defining Research.

* An audit is designed to find out whether a service or intervention reaches a predetermined standard.

** A service evaluation is designed to determine the standard a service achieves. The service evaluated must be one that is already in use.

STEP 2 – APPLYING FOR HRA APPROVAL

Planning your application for HRA Approval

Note: Before applying for HRA Approval you should have discussed the project with the Trust research support and governance staff.

For non-commercial studies, you MUST prepare the HRA Research Study Documentation for your study. Please ensure that you refer to the guidance provided when completing these documents.

For commercial studies, you should prepare the draft template agreement you propose to use with sites, the costing template and a template delegation log. For studies which are part of the NIHR CRN Portfolio you should ask the lead CRN to validate the costing template before applying for HRA Approval.

For both commercial contract and non-commercial studies applying for the NIHR CRN Portfolio, you should request inclusion on the NIHR CRN Portfolio prior to your application for HRA Approval.

How to apply for HRA Approval
Prepare your application in the Integrated Research Application System (IRAS) and electronically submit it to the HRA.

1. If you are new to using IRAS, please look at the advice on applying for approvals, and check out the e-learning package in IRAS.
2. At question 4 in the project filter select the option for ‘’IRAS Form’. The IRAS Form also covers your application for NHS REC Review where needed.
3. Before electronically submitting your application for HRA Approval you need to contact the Online Booking Service. You need to complete this step for all studies applying for HRA Approval and can be done as soon as you have received your initial assessment letter from the HRA.
4. Note: If your study requires review by an NHS REC you should also be prepared to provide information on the NHS REC portion of your application when you contact them. For example, be prepared to confirm whether your project is eligible for proportionate review.

STEP 3 – ON RECEIPT OF APPLICATION FOR HRA APPROVAL

You will receive an update to the Submission History entry on the E-submission tab for your IRAS Form confirming that the HRA have received your application.

HRA Approval includes HRA assessment and, where required, NHS Research Ethics (REC) review.

Where NHS REC review is required, your application will be checked to see whether it is complete for the purposes of review by the NHS Research Ethics Committee (REC). You will be told whether it is valid for NHS REC review no more than 5 working days after submission of your application.

At the same time, the HRA will undertake an initial assessment of your study to ensure that there is sufficient information to undertake a full assessment and identify what further information will be required. The outcome of the initial assessment is:

- An HRA initial assessment letter sent to the applicant confirming receipt of the application and the documents required, including the statement of activities and schedule of events. This is when you can formally send the local information pack to the study site(s) (see section below for minimum document set). For some studies this step will not be required and an HRA Approval letter will be issued.
- The HRA send the Initial Assessment information to the REC to provide confirmation of compliance with legislation and the level of insurance being provided.

HRA assessment will assess the study for regulatory compliance and other related matters. During this time, the HRA assessment team may contact you for more information, to request clarifications, or to discuss some aspect of your project. They will usually attempt to contact you by telephone in the first instance and follow up by email, so please ensure that you provide appropriate contact details.

Where NHS REC review is required, you will also receive communications from the REC, including notification of the outcome of the review.

Conclusion of review
Once both HRA assessment and REC review (where required) are complete you will receive notification of the outcome in the form of a letter and guidance on what you should do next.

You cannot commence your study in the NHS in England until HRA Approval has been issued and the local site(s) have confirmed capacity and capability.

If you have any concerns or queries related to the assessment of your application please contact the HRA Approval team. Please make sure that in your email you quote the IRAS ID for your study and your preferred

contact details (email/phone). If you feel you need to escalate a concern please contact hra.approvalprogramme@nhs.net.

Local Information Pack: List of Contents

The following documents comprise the **minimum document set** that is required by the Research Office before they can consider confirming capacity and capability to run the study in the Trust.

- copy of IRAS Form as submitted for HRA Approval
- current protocol and any amendments
- participant information and consent documents
- relevant model agreement (not required for academic studies)
- commercial studies only – NIHR Costing template (validated) and delegation log (including known research team names but not signatures)
- non-commercial studies only – Organisational Information Document and Schedule of Event templates
- any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
- copy of HRA Initial Assessment Letter (if one is issued) and (when issued) HRA Approval Letter and final documents.

Please note that all documents must have version numbers to prevent confusion and aid version control.

When HRA Approval has been issued, the sponsor should send the HRA Approval letter and any revised documents to the local research team, the R&D office and Local Clinical Research Network (where relevant).
Sites will confirm their capacity and capability to participate in the study after HRA Approval has been issued.

If you need to contact the Research Office to discuss your application please use the following contact details:

Mechele Couch-Upite
Research Support and Governance Manager
Research Office, Location C1 (opposite the chapel)
Airedale General Hospital
Skipton Road, Keighley, BD20 6TD

Tel: 01535 294655
Direct email: mechele.couch-upite@nhs.net
Alternative email: anhsft.researchanddevelopment@nhs.net

STEP 4 – PEER REVIEW

For academic studies only, please ensure that your University supervisor/tutor has reviewed your study. A letter or email from your University supervisor will be sufficient.

STEP 5 – RESEARCH PASSPORTS, HONORARY CONTRACTS AND LETTERS OF ACCESS

If you are not NHS staff or do not already hold an honorary contract with the NHS you will be required to apply for an honorary contract (HC). If you are NHS staff and hold a substantive contract you should complete a Research Passport application or your employer and apply for a Letter of Access (LOA) from Airedale R&D. For guidance please refer to the notes in Appendix IV. Alternatively contact the Research Office for advice or follow this link for additional information:
https://www.nihr.ac.uk/policy-and-standards/research-passports.htm.

STEP 6 – SUBMISSION FOR LOCAL CONFIRMATION OF CAPACITY AND CAPABILITY

When your application is received it will be checked to ensure it is complete. You are expected to supply any missing information or documents promptly.

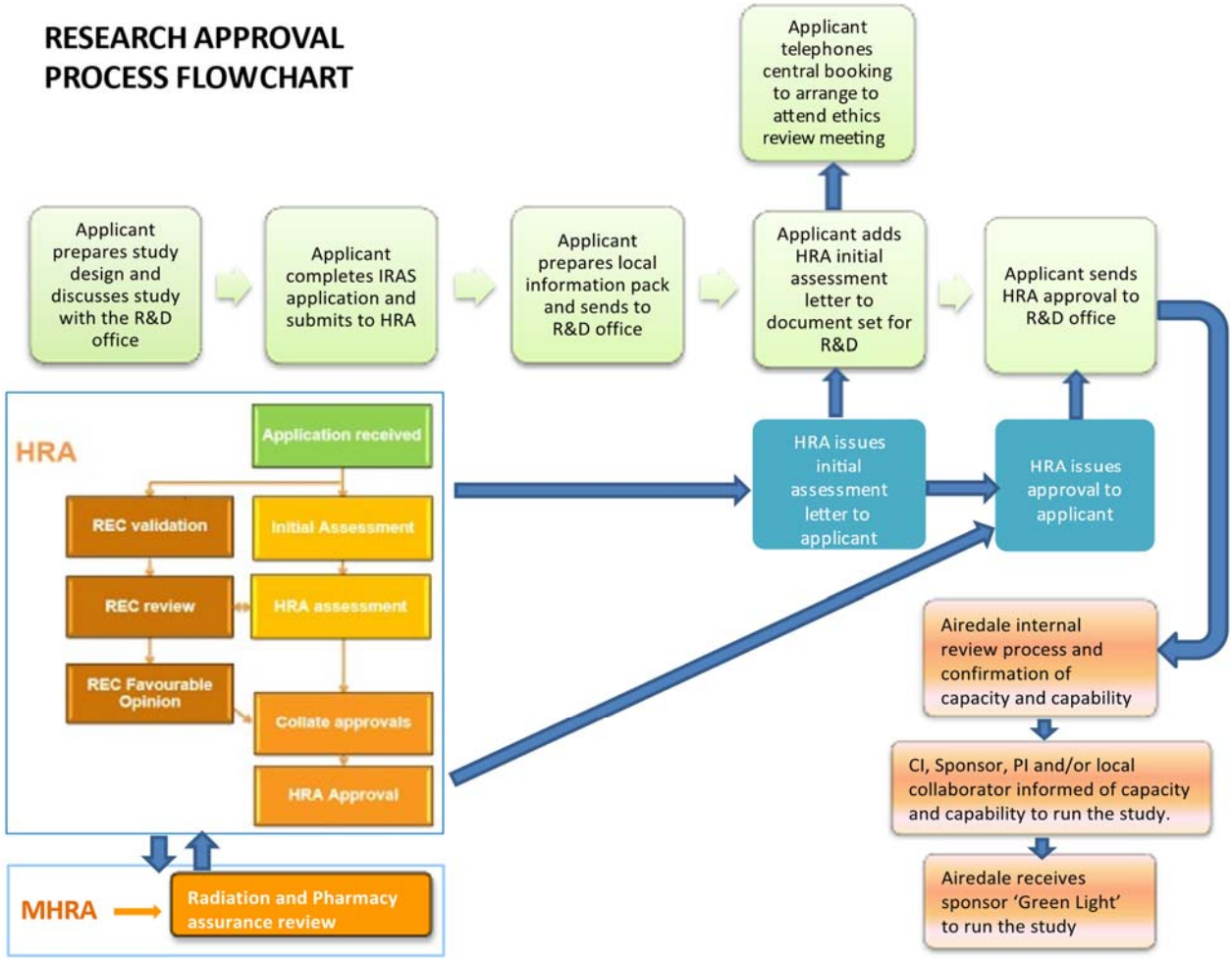
The R&D Office within each organisation will:

- Review the feasibility of undertaking the research locally, assess the logistics for the local supporting departments, undertake contract and budget negotiations (if appropriate), ensure compliance with legislation, assess local research team suitability, and issue Letters of Access or Honorary Research Contracts
- Arrange access to research nurse or other resources or financial support, as appropriate
- Support the process where research involves NHS patients taking part through private or charity providers

All documentation should be sent to the Research Support and Governance Manager (address above).

*Please refer to Submission Checklist (Appendix I)

RESEARCH APPROVAL PROCESS FLOWCHART



For further advice please contact the research team as follows:

Airedale NHS Foundation Trust
Research Support & Governance Office
C/O Research Office
Ward 12, Location A27
Airedale General Hospital
Skipton Road
Keighley, BD20 6TD
01535 294655
anhsft.researchanddevelopment@nhs.net

APPENDIX I

SUBMISSION CHECKLIST FOR R&D APPROVAL

PLEASE ENSURE THAT YOU:

- ✔ **Use the checklist available on IRAS to ensure that the correct documentation is submitted. The R&D Management Approval process will not commence until a *complete and valid application* is received.**

- ✔ **When collating please do NOT staple documents as they will need to be photocopied.**

- ✔ **The following documents may be required, depending on the type of study you are proposing.**

  - copy of IRAS Form (combined REC and R&D form) as submitted for HRA Approval
  - protocol and any amendments
  - participant information and consent documents (without local logos/ headers)
  - relevant model agreement (not required for academic studies)
  - commercial studies only – NIHR Costing template (validated) and delegation log (including known research team names but not signatures)
  - non-commercial studies only – Organisation Information Document and Schedule of Event templates
  - where excess treatment costs are identified, the sponsoring organisation will complete a Schedule of Events Cost Attribution Tool (SoECAT) which should also be included
  - any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
  - copy of HRA Initial Assessment Letter (if one is issued) and (when issued) HRA Approval Letter and final documents.

APPENDIX II

SPONSORSHIP

Does your research study have a Sponsor as defined in the Research Governance Framework for Health & Social Care?

The sponsor is responsible for ensuring that specific duties are performed, properly distributed, allocated and accepted by investigators and their employing institutions and care organisations, and for the governance of the research study from conception to final completion, including design, management, and finance. The sponsor satisfies itself that appropriate checks have been undertaken to ensure that the study meets the relevant standards, and makes sure arrangements are put and kept in place for authorisation, management, monitoring and reporting. Full details are contained in the Research Governance Framework (DH 2005) and the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031), which should be consulted for further information.

Basic Principles

1. The sponsor is the individual or institution that takes responsibility for the initiation, management and financing (or arranging the financing) of the study. In the case of academic research the University acts as sponsor. The sponsor satisfies itself that the study meets the relevant standards and ensures that arrangements are put and kept in place for management, monitoring and reporting.

2. Sponsors can formally delegate one or more of the elements of sponsorship, e.g. to the Chief Investigator, but the sponsor remains accountable for all aspects of sponsorship, whether delegated or not.

3. The factors which determine sponsorship are the nature of the funding body, the employer of the chief investigator and the duty of care to patients as outlined below.

    a) Where a commercial organisation (company) funds a study for which it retains ownership of the intellectual property rights, the company invariably acts as the sponsor.

    b) Where a study is funded by a research council, medical charity or other non-commercial body, the funder may be willing to act as the sponsor, particularly where it also employs members of the research team or retains an interest in any intellectual property that is generated.

    c) Where an investigator undertakes a study on behalf of his/her employing institution and the funding body is unwilling to act as the

sponsor, the employing organisation or academic institution may act as a sponsor.

d) Where an investigator undertakes a study in which the participants are owed a duty of care by the host rather than the investigator's employing institution, the host institution may act as a sponsor. However, the duty of care remains the responsibility of the host institution, irrespective of whether they are a sponsor.

e) Under the Clinical Trials Regulations, it is possible for an individual investigator to take on the role of sponsor. However, many institutions prohibit their employees from doing so, in view of the potential risks this might involve.

f) Where no other sponsor can be found to take on the role, the NHS care organisation concerned may act as the sponsor. If no one is willing to take on the sponsor role, the study may not proceed.

4. Where two or more organisations share a significant interest in a study, e.g. one as employer of the Chief Investigator and another as the principal host institution, they may elect to act as co-sponsors and divide the responsibilities of sponsorship between them. The allocation of the responsibilities of sponsorship will be determined by the expertise and capacity of the individual or institution to discharge them in relation to the risk posed by the study.

5. For clinical trials of medicines, the UK Clinical Trials Regulations require insurance or indemnity for liabilities of the sponsor and of the investigator to be specified. The Regulations also require the sponsor to ensure that the trial conforms to GCP as set out in Schedule 1 of the Statutory Instrument. The Regulations do not change existing liabilities.[1]

[1] Responsibilities, liabilities and risk management in clinical trials of medicines. Universities UK & DH joint statement, May 2004.

APPENDIX III

RESEARCH PASSPORT SCHEME

Do all members of the research team have substantive or honorary contracts of employment with Airedale NHS Trust?

Do members of the research team have substantive contracts with another NHS provider?

Do members of the research team have contracts with Universities or other non-NHS organisations?

The answers to the above questions will aid the R&D office in determining whether research passports, letters of access or honorary research contracts will be required. Please contact the R&D office to discuss.

Summary of legislation:

- Researchers with a substantive employment contract with one NHS organisation do ***not*** need an honorary research contract to conduct research in another NHS organisation. However, additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations, by providing them with a copy of the NHS to NHS Letter of Access.
- Researchers with an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations, by providing them with a copy of the NHS to NHS Letter of Access.
- Researchers with no contractual relationship with the NHS require an honorary research contract only if the planned activities of the researcher involve interacting with individuals in a way that has a direct bearing on the quality of their care.
- Substantive employers retain responsibility for other research activities that do not affect the NHS organisation's duty of care.
- Honorary research contracts do not provide a mechanism for access to confidential patient information without consent.
- Researchers who do not require an honorary research contract may require additional pre-engagement checks to undertake permitted research activities in NHS organisations.
- Decisions on requirements for pre-engagement checks, induction and training rest with NHS organisations but should be commensurate with the role of the researcher, the type of research and the duty of care.
- There should be a system at local level for identification and local managerial control/supervision of all individuals carrying out research in or through the NHS.