Airedale NHS
NHS Foundation Trust

Research and Development Strategy 2013-16

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RESEARCH AND DEVELOPMENT STRATEGY 2013/16

1.0 Introduction

Research is essential to generate new knowledge for the benefit of patients, the modernisation and promotion of services in the NHS and the development of evidence-based patient care. The establishment of the National Institute for Health Research (NIHR) and the Comprehensive Clinical Research Network (CCRN) as part of the Department of Health Research Strategy, 'Best Research for Best Health' (2006) has provided the support and infrastructure to enable the institutions of the NHS to conduct high-quality research alongside high-quality patient care. The CCRN consists of a number of Comprehensive Local Research Networks (CLRNs) which are managed locally and support participation in a national portfolio of clinical trials. Each CLRN provides funding, training and support to provide the environment, infrastructure and staff to promote high quality research within the NHS.

More recently, the 2010 White Paper 'Liberating the NHS' and the 2012 Health and Social Care Act has reaffirmed the commitment of the Government to supporting health research. There is now a duty on the Secretary of State to promote research in the NHS and there is also a duty on the new clinical commissioning groups to demonstrate their commitment to facilitating research. A new Health Research Authority (HRA) has been formed as a result of the 2012 Act, with a remit to protect and promote the interests of patients and the public in health research.

From now onwards, NHS organisations in receipt of NIHR funding will have to demonstrate that they play their part in a National system of research governance requiring timely initiation and delivery of clinical trials. To facilitate this, a Research Support Services Framework has been adopted and guidelines have been issued to all NHS R&D Departments.

2.0 Strategic Context

As a result of the establishment of the CLRNs in 2007 and the influx of funding for research there have been considerable changes in the management, governance and staffing of research within Airedale NHS Foundation Trust. The West Yorkshire CLRN (WY CLRN) provides core team funding which has facilitated an expansion of the Research Team leading to increases in the number of patients recruited onto clinical trials, the number of clinicians taking part in research and the number of specialty groups involved.

Through the NIHR there is a drive towards improving the quality, speed and coordination of clinical research and to integrate research into patient care so

that patients and healthcare professionals have the opportunity to take part in research and benefit from it. A major objective is to ensure that the time required for clinical studies to be approved within NHS institutions and the time to first patient recruited onto each trial is reduced considerably, and NHS organisations will be performance-managed on these targets. The RSS framework was designed to streamline and standardise research governance and approval processes across NHS organisations to help achieve the NIHR objectives. At Airedale, since 2011, we have embraced the RSS guidance and fully integrated their recommendations into our local research governance systems and processes.

The purpose of this document is to set out a new and updated Research and Development (R&D) Strategy for Airedale NHS Foundation Trust, to build on the 2010/13 Strategy. The updated strategy sets out an action plan for R&D in the Trust, reflecting the changes taking place in research governance Nationally and the new performance targets the Trust is expected to achieve.

This R&D strategy sets out how these targets will be achieved and affirms our commitment to providing a thriving research culture. The aim is to have a system whereby health research and patient care are fully integrated and where health professionals consistently apply the principles of evidence-based practice.

2.1 Research Activity within Airedale NHS Foundation Trust

The Trust is actively involved in research across a range of specialties including:

- Oncology/Haematology
- Stroke
- Diabetes
- Paediatrics
- Gastroenterology
- Orthopaedics
- Neo-natal care
- Gynaecology

A large proportion of the R&D core team funding is generated through research directly linked to participation in clinical trials which are on the NIHR portfolio. However, non-portfolio trials and commercial research are also undertaken. Income from commercial research is divided between R&D, R&D capacity-building and the Departments and Clinical Specialties involved.

The R&D Department also supports smaller studies, including individual research undertaken as part of higher qualifications, such as MSc or PhD. This involves guidance through the R&D approval process and ethics review and the provision of advice and training. As part of their continuing professional development many staff aim to progress through higher qualifications and/or research work. All staff

undertaking research are encouraged to publish their findings in peer-reviewed journals, and this is reflected in the list of publications published in the R&D annual report to the Trust Board.

As a result of the activity-based funding received via the WY CLRN it has been possible to expand the research team and provide support for service departments within the Trust. It is expected that this will lead to a further increase in research activity over the coming and subsequent years. The team structure is shown in Appendix 1.

3.0 Research Governance

Research governance (RG) is one of the core standards for healthcare organisations. The RG Framework (2nd ed: DH 2005) outlines the principles of good governance under which all research undertaken within the Trust should be carried out. The R&D approval process provides assurance that all reasonable steps to ensure the well-being, dignity, rights and safety of participants in research have been taken both prior to, during and following the course of any research. Research at Airedale NHS Foundation Trust follows the guidelines set out in the Research Governance Framework (RGF) and adheres to the internationally recognised Good Clinical Practice (ICH GCP) guidelines as summarised in EU Directive 2001/20/EC, article 1, clause 2:

"Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects."

The Government's 'Plan for Growth' in 2011 recognised that it had become far too difficult and time consuming to navigate the complex approval processes for health research. As a means of streamlining research approval processes, towards the end of 2011 the NIHR Research Support Services (RSS) produced a new set of guidelines for research governance in the NHS. These guidelines were fully implemented at Airedale early in 2012 and new standard operating procedures are in place to underpin these processes. Another part of creating a more streamlined and unified research approvals process was the establishment of the new Health Research Authority (HRA). The HRA incorporates the National Research Ethics Service and will ultimately develop a unified approval system and the development of an ethics e-submission process for research through the IRAS system.

The Trust is legally bound to comply with the requirements of legislation and guidelines relating to conduct of clinical trials involving investigational medicinal products and may be inspected at any time. In the UK, the MHRA GCP Inspectorate is responsible for inspecting clinical trials for compliance with Good Clinical Practice. This legislation also requires the trust to be able to provide

assurance that all staff undertaking clinical trials have received adequate and recognised training in GCP standards and have regularly updated this training.

3.1 Trust Compliance with the Research Governance Framework and European Union Legislation

It is the responsibility of the Trust R&D Department to guide all researchers through the research application and approval process and to offer advice, support and guidance where required. This includes the provision of information as to what documentation is required, how to use the online application process and how/when to seek ethics approval. It is recognised that this service will be particularly important where new or prospective researchers are putting in applications for the first time and also where experienced research nurse support is not available. The services provided by the R&D Department are communicated across the Trust via regular newsletters and bulletins. All managers should be aware of the R&D approval process and an application information pack is available on request. Additionally the Trust Intranet Sharepoint site provides more information and the relevant documentation.

All research within the Trust must be registered with the R&D Unit and is recorded on an electronic database. Using a risk-based approach, the Research Governance Coordinator ensures that all research meets the required standards of compliance with local, national and international regulations and that the appropriate documentation and ethics committee approvals are in place.

The checklist for documentation issued to prospective researchers is included in Appendix 2 and the Trust research approval process is summarised in Appendix 3.

3.2 Equality and Diversity

Airedale NHS Foundation Trust is committed to the overarching principles of Equality and Diversity. The Trust is committed towards ensuring all forms of prejudicial, unfair basis and/or actions which result in discriminatory practices are eliminated. The Trust makes this stand based not only on meeting its legislative duties but also a moral strand on ensuring equitable outcomes for all of its staff and patients

The Trust is continually working towards eradicating all forms of harassment, discrimination, exclusion, victimisation and bullying based on negative prejudices and ignorance. As a provider of health services, serving a variety of multi faith communities, the Trust is proactively working towards promoting equality of opportunity and good relations within and between all our communities and ensuring that an equitable process for all is adhered to by all members of staff.

The Trust treats any complaints it receives very seriously and as such any complaint received in respect of this policy (in terms of its application or adherence) will be investigated by Trust Staff, on an equitable basis. The process undertaken will also aim to ensure that complainants, patients, relatives and carers are not discriminated against on the grounds of disability, gender, marital status, sexuality, colour, race, nationality, ethnic origin, religious belief or age. Additionally, the Trust will ensure that no individual is treated in a detrimental manner as a result of having made a complaint.

The policy has been developed and will be continually reviewed on the basis that it does not discriminate and is not prejudicial on the grounds of disability, gender, marital status, sexuality, colour, race, nationality, ethnic origin, religious belief or age. Using the guidance produced under the auspices of Equality legislation, this document has also been impact assessed to ensure there is no detrimental or adverse impact upon any of the equality strands mentioned. The Equality and Diversity Impact Assessment is attached at the end of the document (Appendix 4).

3.3 Intellectual Property and Innovation

The Department of Health's Research Governance Framework encourages the NHS to develop innovations that can lead to new products, and places an emphasis on the responsibility of research active organisations for the protection and exploitation of Intellectual Property (IP). These activities will be managed through the development and implementation of a Trust IP and Innovation Policy in collaboration with a firm Corporate Lawyers who will advise on IP rights. The Trust R&D Department has the responsibility for disseminating information on IP rights, promote awareness of IP rights across the Trust and offer advice as required.

3.4 Reporting Structure

The Trust R&D Committee is responsible for assessing new research projects prior to R&D approval and to ensure high standards as promoted within the Research Governance Framework. This committee is chaired by the Director responsible for R&D or by the designated Clinical Lead for research. The terms of reference and membership of this committee are included in Appendix 5.

Clinical trials on the National portfolio are also overseen by the R&D Committee which is responsible for scrutinising proposed studies and ensuring that robust research governance processes are in place. It considers issues such as scientific rigour, cost implications and the involvement and capacity of support departments. Where a topic-specific network exists, such as the Yorkshire Cancer Research Network (YCRN), or Yorkshire Stroke Research Network (YSRN) the Trust works closely with their representatives.

The R&D committee reports into the Quality and Safety Operational Group (Q-SOG) and an annual report is submitted to the Trust Board. Additionally, recruitment figures and potential income generation opportunities are presented to the Corporate Delivery Assurance Group on a quarterly basis and a quarterly governance report is submitted to the Quality and Safety Advisory Committee (QSAC).

4.0 Strategic Aims

In line with the NIHR Clinical Research Network High Level Objectives (Appendix 7), the NHS Operating Framework and the Health and Social Care Act 2012, the broad aims for the R&D Unit at Airedale are as follows:

- To promote and facilitate research activities across the Trust to establish R&D as part of the core business of the Trust;
- To improve our research profile within the research community and foster a vibrant research culture within the Trust;
- To facilitate the provision of high quality research-related training and education for researchers and those interested and taking part in research;
- To actively promote the engagement of patients and the public in setting the research agenda at all stages of the research process from inception to dissemination of findings;
- To achieve an annual increase of 20% in patient recruitment to portfolio clinical trials over the baseline figure for 2009/10;
- To achieve all National targets for R&D approval times and recruiting patients to time and target;
- To actively seek industry-led clinical trials with the dual aims of ensuring that R&D continues to be a self-sustaining function and providing a source of income for the Trust.

4.1 Strategic Objectives

From the strategic aims outlined above, the following specific objectives have been set and these are reflected in the Action Plan included in section 5.0.

- To disseminate information about research and research-related activities across the Trust via regular bulletins and publicity events;

- To engage more clinicians in clinical trials, by broadening the research portfolio into new specialties and consolidating research activity in the new areas developed since 2010;

- To work with the Trust Health Information Specialist in building on the current in-house training programme and to provide a venue for local and regional training events hosted by external providers;

- To actively engage with patients and the public through publicity events, patient support groups and the patient and carer panel to promote their awareness of and involvement in research design, implementation and dissemination;

- To work closely with the Trust Communications Team and Foundation Trust Office in communicating information about research and related events to our NHS partners in other organisations, including Primary care, and to Governors, Foundation Trust members, patients and the public;

- To consistently achieve the National target of 70 days from submission of a valid research application to recruitment of the first patient onto a clinical trial.

- To demonstrate a year-on-year increase in commercial income from Industry-sponsored trials, of £25,000 per year, preferably, but not solely, from trials on the National Portfolio.

- To continue to encourage individual and academic research and innovation by publicising support, guidance and training services to staff within the Trust.

- To encourage all research-active staff to publish their work in peer-reviewed publications and to present their work at conferences, either as oral or poster presentations.

5.0 R&D Action Plan 2013-2016

Strategic Objective	Action	Lead
To ensure that information about research and research-related activities is widely disseminated across the Trust;	▪ Regular distribution of newsletter ▪ Engagement with Communications team ▪ Publicity via Staff brief, website, intranet ▪ Use of posters and display boards	R&D Mgr Admin staff Comms/FT office
To engage more clinicians in clinical trials	▪ Establish dialogue with Lead Clinicians ▪ Face to face meetings with potential lead researchers to discuss support available ▪ Include research activity in job plans/KPI	R&D Mgr Dir S&BD Medical Dir
Build on education and training programme	▪ Work with Health Information Specialist to provide in-house programme ▪ Liaise with network partners to host research courses at Airedale ▪ Train GCP facilitators	R&D Mgr Health info specialist
Engage with Patients and the Public	▪ Involve the Patient Reader Panel in the writing and design of research material ▪ Raise awareness of research amongst patients and the public via publicity and PPI events ▪ Local press articles and newsletters	R&D Mgr PPI officer Comms/FT office
Improve communication and dissemination of research information	▪ Regular Newsletter and targeted bulletins ▪ Research Conference ▪ General staff communications	R&D Mgr Comms/FT office
Work to achieve the National target of 70 days from valid submission to 1st patient recruited	▪ Ensure that trial set up and initiation meetings are timely ▪ Ensure that the responsible nurse and PI are screening clinics regularly ▪ Maintain current 30 day approvals	R&D Mgr RG Coord R&D team
Achieve an average annual increase of 20% in patients recruited to trials from the 2009/10 baseline	▪ Proactively seek out suitable trials from the portfolio database ▪ Engage new clinicians as PIs ▪ Ensure sufficient staff available for recruitment of patients ▪ Work closely with WY CLRN portfolio development officers	R&D Mgr R&D team
Increase commercial income	▪ Establish dialogue with interested Clinicians ▪ Actively investigate available commercial trials ▪ Incentivise clinical staff (income)	R&D Mgr Clinical leads Finance
Support academic research	▪ Establish dialogue with Lead Clinicians ▪ Publicise guidance and support available ▪ Face to face meetings with researchers ▪ Intranet and sharepoint ▪ Produce user-friendly documentation and information sheets	R&D Mgr RG Coord R&D Mgr Admin staff
Encourage staff publications	▪ Establish dialogue with Lead Clinicians ▪ Publicise all staff publications ▪ Regular call for notification of publications ▪ Annual Research conference	R&D Mgr

5.1 Short-Term Objectives

Based on the strategic objectives summarised above, the following short-term objectives have been set.

	Target	Lead	To be achieved by
1	Achieve 70 day target of submission to 1st patient recruit in > 90% of cases	R&D Team	30th Sept 2014
2	Increase commercial income by > £25,000	R&D Mgr	31st March 2014
3	Engage with patients and the public at the Trust open day and one other research-specific event.	R&D Mgr	31st March 2014
4	Provide in-house training programme including GCP introductory and update training	R&D Mgr Senior RN	31st March 2014
5	Involve at least one new specialty in portfolio research	R&D Mgr	30th Sept 2014
6	Increase patient recruitment to portfolio trials by > 20% above the figure for 2012/13	R&D Team	30th Sept 2014

6.0 Research Funding and Resource Implications

A summary of funding received for research since 2006/7 is included in Appendix 6.

6.1 Current Funding Sources

WYCLRN Core Funding
Since April 2007 Department of Health funding for research has been devolved to the Comprehensive Local Research Networks (CLRNs). Airedale NHS Foundation Trust receives funding from the West Yorkshire CLRN (WYCLRN) based on the number of patients recruited to trials on the national portfolio and the complexity of these trials. This funding supports salaries for the core team.

WY CLRN Research Management and Governance (RM&G) Funding
This is provided to support Research Governance salaries but Trusts are expected to cover the remainder of RM&G salaries.

WY CLRN Key Support Service (KSS) Funding
This funding stream is available to support KSS functions such as Clinical Diagnostics. Currently the Trust receives KSS funding for the following posts:

Pharmacy backfill, Band 7, 0.4 WTE
Pharmacy Clinical Trials support Band 5, 0.68 WTE
Pharmacy Clinical Trials support Band 5, 0.3 WTE
Pharmacy Dispensary Assistant Band 3, 0.5 WTE
Pathology Clinical Trials support Band 5 0.3 WTE.
CT Radiographer Band 7, 0.5 WTE
Radiographer Band 5, 0.3 WTE
Radiography assistant Band 3, 0.5 WTE
Consultant Radiologist 0.2 WTE

NIHR Research Capability Funding
Individual bids for additional funding to support recruitment to a specific trial (or trials) can be made throughout the year as the need arises and enable the Department to respond flexibly to changing needs and demands upon support services.

Commercial Income
Income is available through commercial clinical trials. Once all services and support for the trial is paid for, the remaining income from industry research is divided equally between R&D and the research account of the consultant acting as the Principal Investigator on site. This income supports the remaining RM&G salary costs, non-pay expenses and capacity building for the R&D team and provides an incentive to clinicians who engage in research.

Charitable Trust Funds
In the past, use has been made of Charitable Trust funds to support posts in cancer research. In 2012/13 Trust Funds were provided to support an administrative post for the Cancer Research Team.

6.1.1 Use of New Funding Streams

It is recognised that the additional research staff and a concomitant increase in research activity puts a burden on the Trust in terms of accommodation, financial and human resources services. Therefore an annual management fee representing 20% of 'core' WY CLRN funding will be paid to the Trust as a management fee to provide this infrastructure. The overhead element of core funding is sufficient to cover the Trust management fee.

6.2 Potential Sources of Funding

Since the establishment of the WY CLRN in 2007 and the new funding streams, the focus has been on recruiting patients to non-commercial national portfolio trials rather than commercial studies because CLRN funding was provided exclusively to support portfolio trials and the amount was based on the level of

activity at each trust. However, many more industry studies are being adopted onto the national portfolio. These studies represent a potentially rich source of income with the added advantage of increasing patient recruitment to portfolio trials. Therefore a priority for the period 2013-2016 is to increase commercial portfolio activity, particularly in clinical areas where research activity is low.

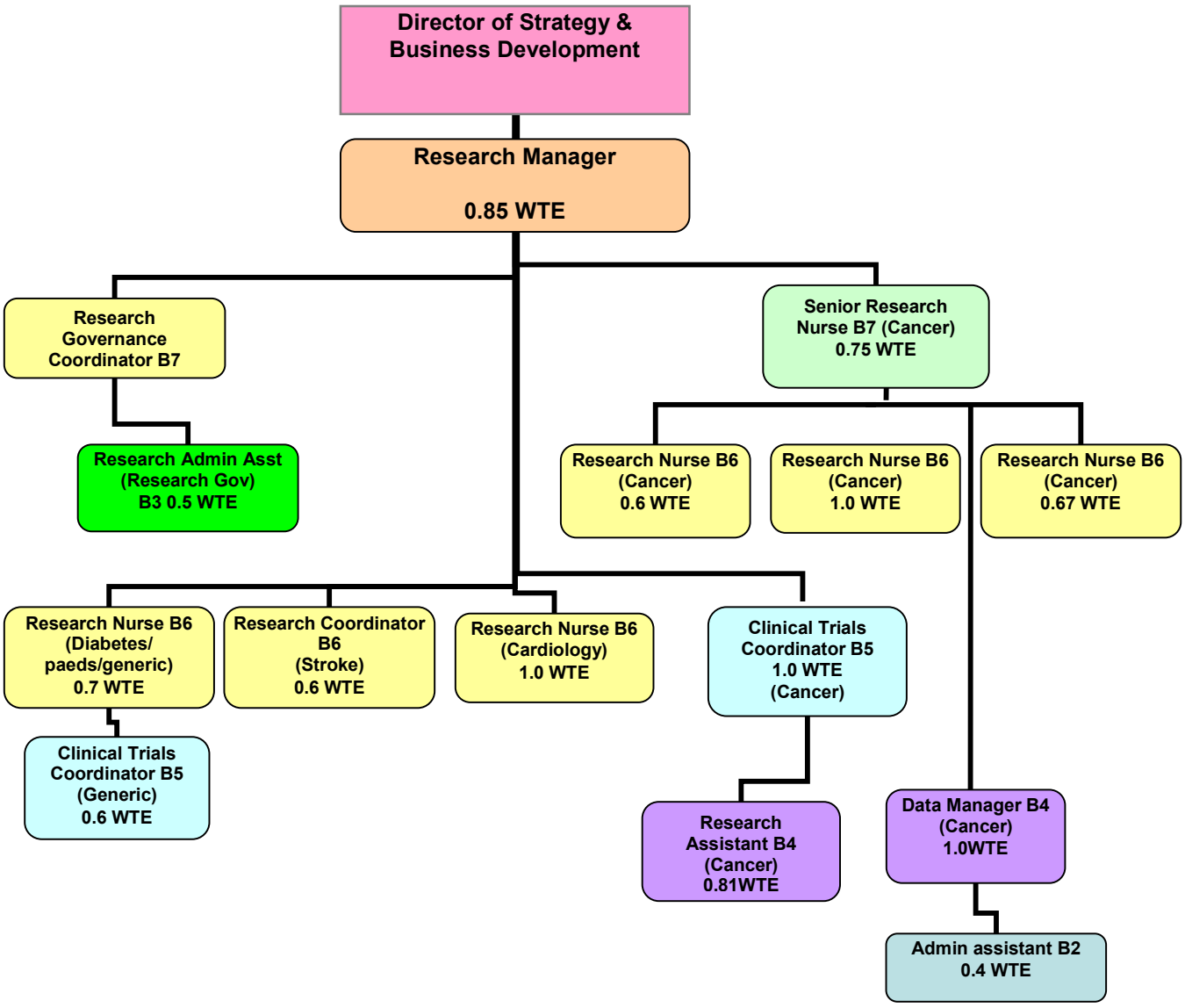
Other commercial trials which are not on the National portfolio will also be undertaken as they provide income for the Trust and a capacity building income stream to support other research. Commercial income will provide support for Research Management and Governance posts which are not covered by WY CLRN funding.

The NIHR provides a number of programme grants, including Research for Patient Benefit, and training fellowships. NIHR funded research automatically qualifies for adoption onto the National Portfolio. Although it is recognised that the application process for these grants is highly competitive, success would be prestigious for the trust and the team involved and will be encouraged.

7.0 Summary

This document sets out the strategy for promoting high quality research within Airedale NHS Trust which will benefit patients, carers, service users and staff. It reflects the need for robust research governance and outlines the systems and processes in place to deliver this. Finally, it details the current and prospective sources of funding and sets out an action plan which will deliver increases in research activity and further commercial opportunities over the next 3 years.

APPENDIX 1: R&D TEAM ORGANISATION CHART



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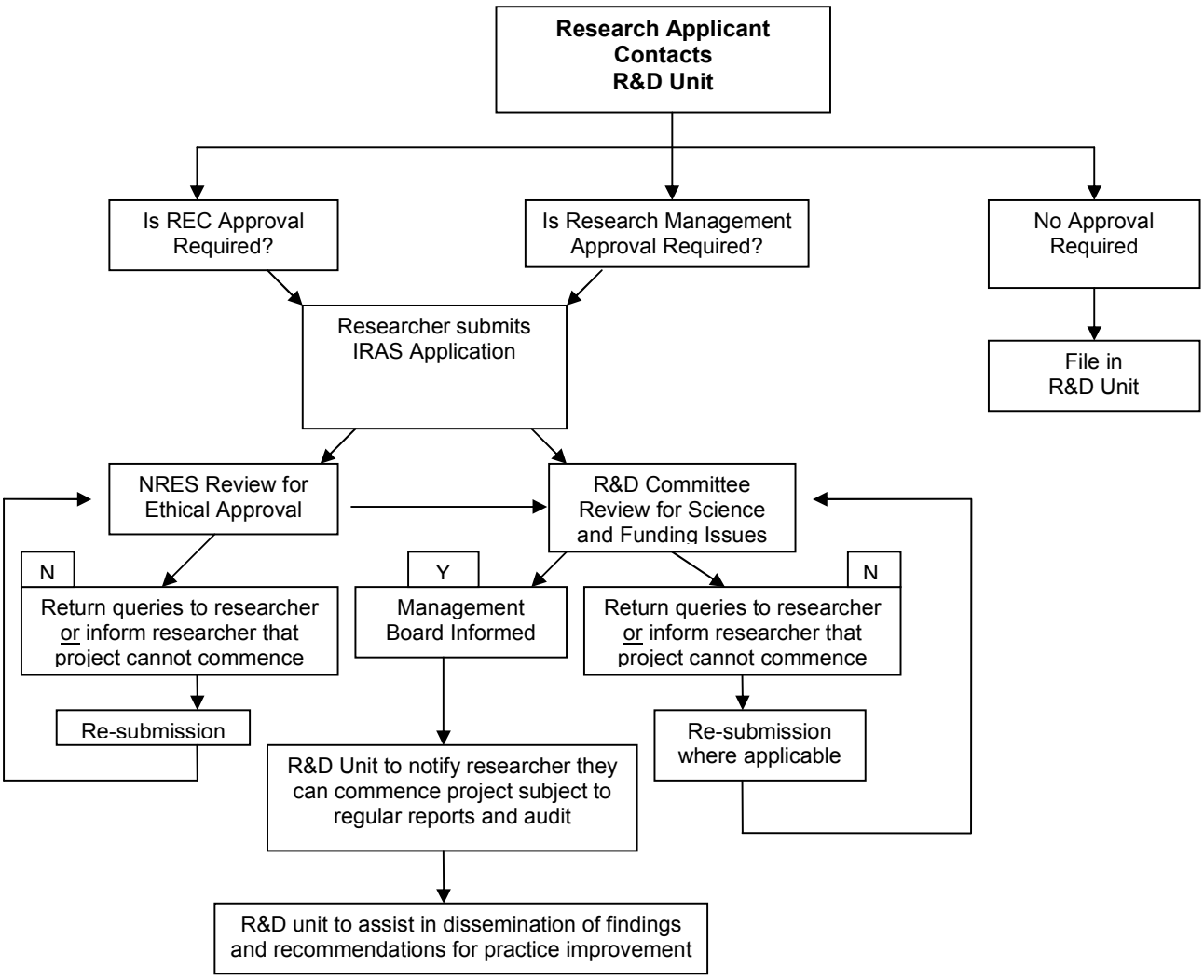
APPENDIX 2

SUBMISSION CHECKLIST FOR R&D APPROVAL

Covering Letter	**Yes**	**No**
National NHS REC Application Form	**Yes**	**No**
National NHS R&D SSI Form	**Yes**	**No**
Main REC Approval Letter	**Yes**	**No**
Letter from Sponsor	**Yes**	**No**
Letter from Funder	**Yes**	**No**
Research Protocol	**Yes**	**No**
Clinical Trials Agreement	**Yes**	**No**
Form of Indemnity (for pharmaceutical/ industry Sponsored studies)	**Yes**	**No**
MHRA Authorisation (for clinical trials involving medicinal products or medical devices)	**Yes**	**No**
Peer Review	**Yes**	**No**
Questionnaires	**Yes**	**No**
Letters of invitation to research participants	**Yes**	**No**
Participant information sheet	**Yes**	**No**
Participant consent form	**Yes**	**No**
Data collection sheet/ proforma	**Yes**	**No**
Summary CV for site Principal Investigator	**Yes**	**No**
Honorary Contract Pending	**Yes**	**No**
Other (please specify)	**Yes**	**No**

APPENDIX 3: Research Approval Process.



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APPENDIX 4:

Equality Impact Assessment – Initial Assessment Form

Name of Document	**Date of Assessment**
Research and Development Strategy	**2/08/12**
Assessment undertaken by	**Department**
Carole Paley	**Research.**

Please ✓ the appropriate box to indicate appropriate nature of document.	**Function of the service**	**Policy**	**Procedure**	**Strategy**	**Other (please state)**
				✓	

Please provide brief details of the main aims, objectives and intended outcomes/benefits of the document being assessed

Research is essential to generate new knowledge for the benefit of patients, the modernisation and promotion of services in the NHS and the development of evidence-based patient care. The establishment of the National Institute for Health Research (NIHR) and the Comprehensive Clinical Research Network (CCRN) as part of the Department of Health Research Strategy, 'Best Research for Best Health' (2006) has provided the support and infrastructure to enable the institutions of the NHS to conduct high-quality research alongside high-quality patient care. The CCRN consists of a number of Comprehensive Local Research Networks (CLRNs) which are managed locally and support participation in a national portfolio of clinical trials. Each CLRN provides funding, training and support to provide the environment, infrastructure and staff to promote high quality research within the NHS.

More recently, the 2010 White Paper 'Liberating the NHS' and the 2012 Health and Social Care Act has reaffirmed the commitment of the Government to supporting health research. There is now a duty on the Secretary of State to promote research in the NHS and there is also a duty on the new clinical commissioning groups to demonstrate their commitment to facilitating research. A new Health Research Authority (HRA) has been formed as a result of the 2012 Act, with a remit to protect and promote the interests of patients and the public in health research.

From now onwards, NHS organisations in receipt of NIHR funding will have to demonstrate that they play their part in a National system of research governance requiring timely initiation and delivery of clinical trials. To facilitate

this, a Research Support Services Framework has been adopted and guidelines have been issued to all NHS R&D Departments.
The purpose of this document is to set out a new and updated Research and Development (R&D) Strategy for Airedale NHS Foundation Trust, to build on the 2010/13 Strategy. The updated strategy sets out an action plan for R&D in the Trust, reflecting the changes taking place in research governance Nationally and the new performance targets the Trust is expected to achieve.

From the document being assessed who will benefit and in what way

The policy outlines the standards of safety, risk management, security and confidentiality which will apply to the management, approval and monitoring of all research across the Trust and will therefore benefit patients, carers, staff, researchers and the reputation of the Trust.

Please list any stakeholders in relation to the document being assessed.

National Institute for health Research
West Yorkshire Comprehensive Local Research Network.

Please check the document and assess it for any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of race, gender, disability, age, faith and sexual orientation.

The following information will help ascertain if the Function / Policy / Procedure / Strategy is sensitive in respect of outcomes for members of the community. This process should also help in identifying improvements required to ensure the process is compliant with equality legislation.

Please ensure that the comments section lists evidence (either presumed or otherwise, irrespective of "Yes" or "No")

Please ✓ if there are concerns that the document being assessed could have a differential impact on groups due to:

	Yes	*No*	*Comments*
1.Race		✓	From the assessment review of the strategy there is no evidence to suggest that there are any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of race.

2.Gender	✓	From the assessment review of the strategy there is no evidence to suggest that there are any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of gender.
3.Disability	✓	From the assessment review of the strategy there is no evidence to suggest that there are any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of disability.
4.Sexual Orientation	✓	From the assessment review of the strategy there is no evidence to suggest that there are any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of sexual orientation.
5.Age	✓	From the assessment review of the strategy there is no evidence to suggest that there are any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of age.
6.Religious Belief	✓	From the assessment review of the strategy there is no evidence to suggest that there are any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of religious belief.
7.Dependants / Caring Responsibilities	✓	From the assessment review of the strategy there is no evidence to suggest that there are any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of dependants/caring responsibilities.
8.Transgendered or Transsexual	✓	From the assessment review of the strategy there is no evidence to suggest that there are any statements, conditions, rules or requirements which could potentially exclude or when applied, cause an adverse impact against any group of individuals, in respect of transgenderd or transsexual orientation.

Could the differential impact identified in the points above amount to there being the potential for adverse impact in the document being assessed?	**YES**	**NO**	**Comments (please explain)**
		✓	

If you have ticked "Yes" to any of the above statements, the document being assessed may be considered to be discriminatory and require reviewing / a full impact assessment to ensure compliance with legislation. Please provide details of the action that will be undertaken to mitigate the risks in order to minimise adverse impact.

Proposed action	***Timeframe***	***Resource implications***	***Lead***

Signed (completing officer) _____

Signed (Lead Officer) _____

Appendix 5

R&D Committee Terms of Reference and Membership

1. Purpose

To ensure that research is proactively promoted, facilitated and monitored within the Foundation Trust and to provide assurance that robust risk-managed research governance systems and processes are implemented.

2. Powers

The Research and Development Committee has the power to withhold research approval or to request further assurance from researchers that the high standards of research governance are being met.

The Committee also has the power to withdraw approval for ongoing research which no longer meets the required standards of governance.

3. Duties and Responsibilities

- Facilitate, promote and monitor research within the Foundation Trust.
- Provide assurance to the Board of Directors (via Q-SOG) on compliance with the Research Governance Framework which underpins the standards for research required by the Care Quality Commission.
- Ensure compliance with all regulatory and legal requirements in clinical research.
- Provide financial accountability and monitoring of R&D core funding and other income streams.
- Scrutinise individual research applications and discuss, as necessary, any significant impacts of each project in terms of infrastructure, health & safety and financial implications.
- Streamline the research approval process using an agreed risk-based approach to granting permissions and monitoring progress.
- Agree and implement the research strategy for the Trust and undertake a regular review of progress on the action plan contained therein.
- Provide strategic direction to maintain a strong link with the Clinical Effectiveness group, thus ensuring that R&D supports the working of the Trust.
- Monitor progress and developments in R&D and ratify the annual R&D report to the Board of Directors

- Promote research activities and dissemination of knowledge within the Foundation Trust by providing an agreed programme of training and educational opportunities.

- Foster a culture of multidisciplinary cooperation and collaboration through research activities.

- Involve patients and the public in all aspects of the research approval and governance process.

- Provide a forum for the dissemination of information from and to the wider research community and facilitate discussion on local issues affecting research.

4. Reporting Framework

The minutes of the meeting will be reported to Q-SOG.

5. Membership

5.1 Core Membership

- Director of Strategy and Business Development (Chair)
- Research Manager (Deputy Chair)
- Research Governance Coordinator
- 2 research-active senior medical representatives
- Senior Pharmacist (Clinical Trials)
- Senior radiologist
- Pathology Service lead
- Radiation Protection Services Advisor
- Research Nurse representatives (2)
- Clinical Trials Coordinator
- Nurse consultant
- PCT R&D representative

5.2 To be invited to attend as required

- Other members of R&D team
- Library representative
- PPI project officer
- Additional medical/nursing staff as appropriate
- Assistant Director of Healthcare Governance
- Finance Representative
- Therapy Services representative

6. Attendance

It is expected that each member will either attend all meetings or send a representative who has sufficient authority/knowledge to act on their behalf.

7. Quorum

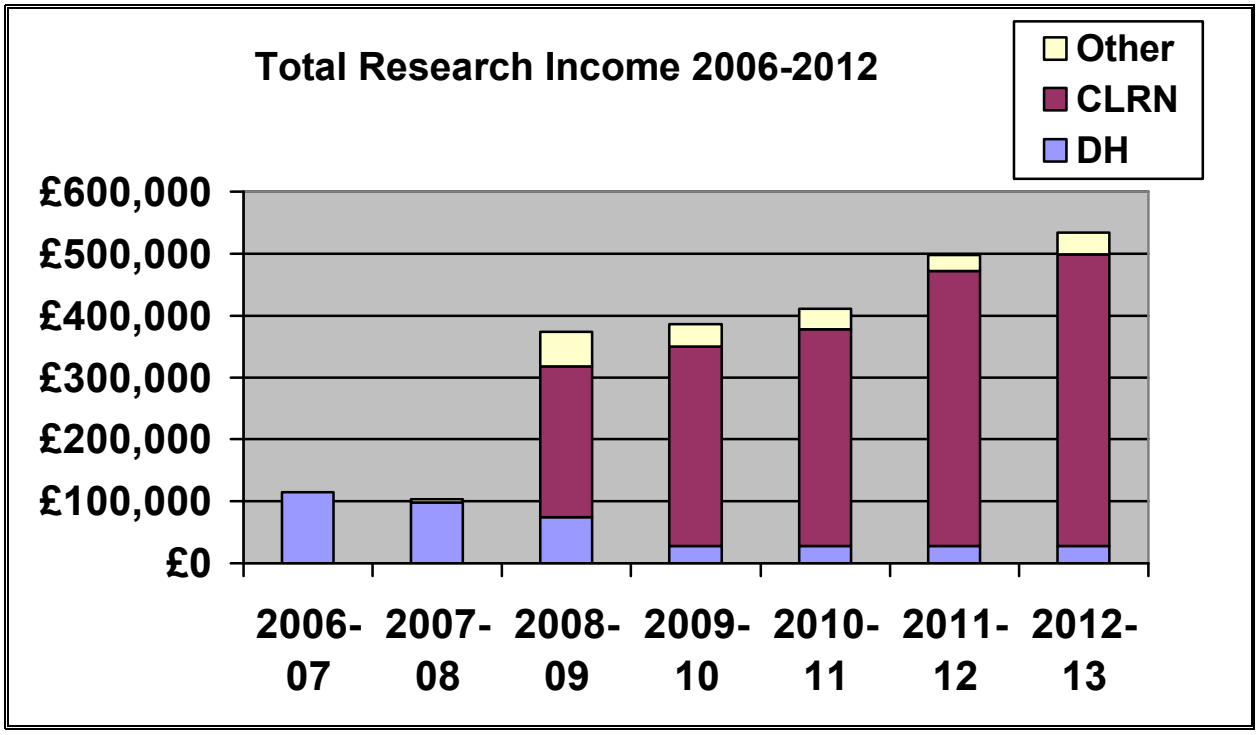
The meeting will be quorate on attendance of at least 5 members which must include:

- Director of Strategy and Business Development ***or*** Research Manager
- Research nurse representatives (2)
- Representative from clinical diagnostics support dept
- Senior medical representative (research-active Consultant or Clinical Director)

8. Frequency of meetings

The R&D Committee will meet on a two monthly basis.

APPENDIX 6: Funding Summary 2006-2012



Note:
The 'Other' category for 2012-13 is an estimated figure based on predicted income from commercial studies.

Appendix 7

THE NATIONAL INSTITUTE FOR HEALTH RESEARCH CLINICAL RESEARCH NETWORK HIGH LEVEL OBJECTIVES

Objective		Measure	Goal	Timescale
1	Double the number of participants recruited into NIHR CRN Portfolio studies	Number of participants recruited in a reporting quarter into NIHR CRN Portfolio studies	125,000	4 years (31 March 2014)
2	Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time	**2A:** Proportion of **commercial** contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed Network sites	80%	2 years (31 March 2012)
		2B: Proportion of **non-commercial studies managed by Registered CTUs** achieving or surpassing their recruitment target during their planned recruitment period	80%	3 years (31 March 2013)
		2C: Proportion of **non-commercial studies not managed by Registered CTUs** achieving or surpassing their recruitment target during their planned recruitment period	80%	5 years (31 March 2015)
3	Increase the percentage of commercial contract studies delivered through the NIHR CRN	Number of commercial contract studies on the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA approvals for Phase II–IV studies, on an annual basis	60%	4 years (31 Dec 2013)
4	Reduce the time taken to achieve NHS permission through CSP for NIHR studies	Proportion of studies obtaining NHS permission within 40 calendar days (from receipt of a valid complete application)	80%	3 years (31 March 2013)
5	Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies	**5A:** Proportion of **commercial** contract studies achieving first participant recruited within 30 calendar days of NHS Permission being issued, at confirmed Network sites	80%	2 years (31 March 2012)
		5B: Proportion of **non-commercial studies managed by Registered CTUs** achieving first participant recruited within 30 calendar days of NHS Permission being issued	80%	3 years (31 March 2013)
		5C: Proportion of **non-commercial studies not managed by Registered CTUs** achieving first participant recruited within 30 calendar days of NHS Permission being issued	80%	5 years (31 March 2015)
6	Increase the percentage of NHS Trusts participating in NIHR CRN Portfolio studies	Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio studies	98%	3 years (31 March 2013)