This information document has been designed to act as a guide to staff involved in Research and Development (R&D) in NHS Blood and Transplant (NHSBT). Its aim is to address the issues that scientists face on a daily basis when working within NHSBT R&D. It brings together information about the NHS Research Governance Framework, the regulatory environment and various NHSBT policies and procedures of relevance to NHSBT R&D staff into one reference document. Additional information is available from the National R&D Office at Filton and online resources highlighted within this document.

The key principles NHSBT staff should adhere to are:

- Honesty and openness in all aspects of scientific working
- Leadership to junior staff and collaborators in all aspects of NHSBT life
- Co-operation and collaboration with staff both within NHSBT and in external organisations, acting as ambassadors of NHSBT R&D
- Work to standards to ensure NHSBT research is of the highest quality
- Ensure confidentiality is maintained where appropriate
- Accurate recording, authorship and communication of NHSBT research
- Seek external funding support
- Participate actively in the global research community
- Follow health and safety considerations and maintain a safe working environment that does not harm NHSBT staff, collaborators or the environment
- Seek and obtain appropriate ethical approval for NHSBT research
- Support NHSBT’s R&D Strategy
Research Governance

Research Governance can be defined as the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality across all aspects of healthcare in the UK and worldwide. Within the NHS (of which NHSBT is a part), the Department of Health (DH) Research Governance Framework covers all health-related research in the NHS and outlines principles of good governance that apply to all research within the remit of the Secretary of State for Health. At the point of writing, the HRA was working on the development of a replacement for the Research Governance Framework (http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/replacing-research-governance-framework/). NHSBT Policy POL161 (Research Governance) and MPD871 (Research Governance) describe how NHSBT puts the DH Research Governance Framework into practice. This Research Handbook provides additional detail.

Research Governance applies to everyone connected to healthcare research, whether as a Chief/Principal Investigator, Care Professional, Researcher, students, support staff, or their employers.

Healthcare research is health-related research which involves humans, their tissue and/or data. Examples of such research would include:

- Analysis of data from a patient's medical notes
- Observations
- Conducting surveys
- Using non-invasive imaging
- Using blood or other tissue samples
- Inclusion in trials of drugs, devices, surgical procedures or other treatments

If you are involved in research of this kind, it is important that you are aware of your obligations to the healthcare research process.

Research Governance is needed to:
- Safeguard the participants in research
- Protect researchers and investigators (by providing a clear framework to work within)
- Enhance ethical and scientific quality
- Minimise risk
- Monitor practice and performance
- Promote good practice and ensure lessons are learned

The five pillars of Research Governance are described and summarised here:

1. Ethics:
   a. The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study.
   b. The Department of Health requires that research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.
   c. Informed consent is at the heart of ethical research.

2. Science:
   a. All existing sources of evidence, especially systematic reviews, must be considered carefully before undertaking research - duplication of work is unethical.
   b. All NHS research should be of high quality.
   c. All research should receive an independent expert review (peer review) prior to commencing.
3. Information:
   a. Data collected in the course of research must be retained for an appropriate period, to allow further analysis by the original or other research teams subject to consent, and to support monitoring by regulatory and other authorities.
   b. Data collected in the course of research must be handled in accordance with the Data Protection Act (1998).
   c. All those conducting health and social care research must open their work to critical review through the accepted scientific and professional channels.
   d. Once established, findings must be made accessible to those participating and to all those who could benefit from them. This may be through publication and/or other means appropriate to the type of research, should be freely available to the public and be presented in a format the public can understand.

4. Health, Safety and Employment:
   a. Participants and research staff have a responsibility for their own and other peoples’ H&S which must be their priority at all times. H&S regulations must be strictly observed.
      Individual’s responsibilities include:
      • to work safely and ensure that through their acts and omissions they do not injure themselves or others;
      • to co-operate with the employer or employing organisation and others to improve H&S;
      • not to interfere with, or misuse, anything provided for health, safety and welfare;
      • to use personal protective equipment where instructed and to take reasonable care of such equipment;
      • to use equipment provided in accordance with provided instruction and training;
      • to report to their line manager any H&S shortcomings including:- unsafe equipment or working practises; accidents and near misses.
   b. All staff must be trained, educated and possess the knowledge to carry out their roles.
   c. Staff without an NHSBT employment contract should have an Honorary Contract or Letter of Access.

5. Finance and Intellectual Property:
   a. Clear processes for financial probity should be followed.
   b. Much of the funding for research in NHSBT comes from charities and public funds and staff should work to obtain the best value for money.
   c. Organisations employing researchers must be in a position to compensate any one harmed by their negligence.
   d. Consideration must be given to the exploitation of Intellectual Property generated by research.

Each pillar has legislative and regulatory requirements to fulfil, DoH standards to meet and principles of good practice to adhere to. These are referenced throughout this document. Staff must carry out research ethically and according to the relevant legislation. Staff must follow these guidelines to provide reassurance to senior management that staff are aware of their obligations.

NHSBT endorses a quality research culture, promoting excellence, visible and strong research leadership and expert management. The key elements of a quality research culture are:

- respect for participants’ dignity, rights, safety and wellbeing;
- valuing the diversity within society;
- personal and scientific integrity;
- leadership;
- honesty;
- accountability;
- openness;
- clear and supportive management.
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1. INTRODUCTION
NHS Blood and Transplant (NHSBT) is a Special Health Authority set up to provide an integrated approach to the safe, efficient collection and provision of blood, tissues and organs for transfusion and transplantation.

In its work, NHSBT collaborates with many organisations and individuals in the UK, including other NHS staff (transfusion practitioners, hospital clinicians), universities, research institutes, government departments, non-departmental public bodies and industry.

Use of the scientific method pervades much of the service work of NHSBT. Undertaking R&D is included in NHSBT's statutory instrument and is crucial to NHSBT’s aspiration to "become the best organisation of its type in the world". NHSBT’s research findings contribute to routine, specialist and reference laboratory activities as well as the collection, processing and issue functions undertaken by NHSBT. R&D contributes to the development of improved policies and products and safer practices. Furthermore, engaging in R&D can help to develop staff expertise.

This document is for all NHSBT staff who are engaged in scientific work, including those whose primary function is undertaking R&D.

2. Definitions, Roles and Responsibilities
Staff are reminded of the NHSBT Code of Conduct for staff. This applies to all staff employed by NHSBT, and serves as a guide to indicate the standards of conduct, performance and behaviour that are expected.

In addition, research within NHSBT is regulated by the Department of Health’s Research Governance Framework (RGF) for Health and Social Care (2005) and Annex (2008). It is the responsibility of everyone involved in research to follow the law and good practice relating to the 5 pillars (ethics, science, information, health and safety, and finance), and to ensure that they are appropriately qualified for the role they play in research.

Individuals and organisations have specific roles within the Framework, as described below.

2.1. Employing Organisation
The overall role of the Employing Organisation is to remain liable for the work of employees who are involved in health and social care research

As an Employing Organisation, NHSBT is responsible for:
- Developing and promoting a high quality research culture and holding employees to account for the professional conduct of research.
- Ensuring that Principal Investigators and Researchers understand and discharge their obligations to the research process and delegated responsibilities, as set out in law and relevant guidance.
- Complying with all current employment and health and safety legislation.
- Demonstrating the existence of clear Codes of Practice for staff and mechanisms to monitor and assess compliance.
- Operating systems for continuous professional development of all staff.
- Having agreements and systems for the identification, protection and exploitation of intellectual property.
- Having systems to address and learn lessons from any errors or complaints brought against our employees.
- Permitting and assisting any statutory audits or inspections by relevant authorities arising from errors or complaints associated with our employees.
2.2. Sponsor

The Sponsor is responsible for making sure that appropriate arrangements are in place to ensure that:
- Only research of high scientific quality and good value for money is undertaken.
- An appropriate Research Ethics Committee has approved all research projects.
- Research teams have access to sufficient resources to deliver their research as agreed.
- The Chief/Principal Investigator and other key researchers have the necessary expertise and experience to conduct research as proposed.
- The research is carried out in accordance with the approved protocol (or proposal) and regulatory requirements by management and monitoring.
- The data collected is of high quality and accurate.
- Any significant developments are reported, such as serious adverse events/reactions of any kind (particularly to trial participants), or changes in the direction or scope of the research project.
- Modifications to the design of clinical studies are approved prior to implementing them.
- At the conclusion of a study, that there are plans for disseminating findings.

Sponsors can formally delegate one or more of the elements of sponsorship to the Chief/Principal Investigator, Clinical Trials Unit or another third party. However, the Sponsor remains accountable for all aspects of research, whether delegated or not.

In NHSBT, sponsorship responsibilities around the running of clinical trials has been delegated to the Clinical Trials Unit, however procedures are in place to ensure appropriate oversight of these delegated functions.

Appropriate oversight of functions is achieved by:
- Assessing that individuals or organisations are appropriately qualified and competent to carry out their functions.
- Ensuring that all parties are aware of their roles and responsibilities by clearly defining them in contracts or agreements.
- Maintaining communication to ensure obligations are met, for instance requesting progress reports.

2.3. Chief/Principal Investigator (PI)

Reference is made to the Chief Investigator in the RGF and in NHSBT these individuals are often referred to as Principal Investigator. This is a senior individual that takes overall responsibility for the design, conduct, analysis and reporting of a study. If a study involves research at more than one site, this individual takes additional responsibility for coordinating the lead at each site.

The PI is accountable to:
- NHSBT (or their employer) and the Sponsor for the design, conduct and reporting of a study.
- The organisation(s) within which the research is taking place (e.g. NHSBT, NHS Trust, University).

The PI is responsible for ensuring that:
- They have suitable experience and expertise in the conduct of research so that they can either:
  - Undertake the design, conduct and reporting of a study to the highest standards as set out in the Research Governance Framework
  - Lead and manage others with delegated responsibility for these aspects
- The research is conducted in accordance with the agreed protocol and in accordance with legal requirements.
- Work complies with all legal and ethical requirements and the principles of the RGF.
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- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge their role in the study, and their qualifications are documented.
- The R&D Office are informed that the research is planned and appropriate approvals are sought (see the sections later in this Handbook).
- The relevant NHS Trust is informed that the study is planned and their permission is obtained before the research starts.
- The study is submitted to a relevant Research Ethics Committee for ethical review and does not start without a favourable opinion.
- The research team follows the protocol or proposal approved by the relevant Ethics Committee and Sponsor (see the sections later in this Handbook if NHSBT is the Sponsor).
- Ensuring the research team gives priority at all times to the dignity, rights, safety and well-being of participants.
- The PI will ensure the R&D Office are informed of any changes that occur throughout the course of the research award.
- Incidents and adverse events are reported promptly.
- Substantive changes to the protocol or proposal are submitted to the R&D Office for review by the R&D Senior Management Team (SMT) and if necessary for ethical review and to the Sponsor for agreement.
- Procedures are in place to ensure collection of high quality and accurate data, and the integrity and confidentiality of data during processing and storage is maintained at all times.
- Arrangements are in place for the effective financial management of the study.
- Reports on progress and research outcomes are supplied to the R&D Office for the R&D SMT, R&D Committee, and if required sponsor, research funders or others with a legitimate interest, in a timely manner and to an acceptable standard.
- Findings are disseminated promptly and fed back as appropriate to participants.
- Arrangements are made for the appropriate archiving of data when research has finished.
- Students and new staff have adequate supervision, support and training.
- Ensuring that the research is conducted in accordance with the NHSBT’s financial processes and arrangements are in place for the management of financial and other resources provided for the duration of the award.

2.4. Researcher (Senior Post-Doc, Post-Doc, PhD Student, Research Assistant, Clinical Fellow)

The overall role of a researcher is to be responsible to the Principal Investigator for the day-to-day aspects of a study.

Researchers are responsible for:
- Ensuring research activities follow the current version of the agreed protocol or proposal.
- Ensuring that relevant knowledge and expertise are kept up-to-date.
- Following guidelines for Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Clinical Practice (GCP), where appropriate.
- Helping care professionals to ensure their patients receive appropriate care whilst involved in research.
- Protecting the integrity and confidentiality of clinical and other information generated by the research.
- working safely and ensuring that through their acts and omissions they do not injure themselves or others;
- Ensuring that incidents and adverse events are reported promptly.
2.5. **Participants**

Participants can be defined as patients, service users and carers, relatives of the deceased, professional carers or members of the public agreeing to take part in the study.

Participants responsibilities include:

- Informing Chief/Principal Investigators if they do not understand information and explanations given in relation to the study.
- Informing Chief/Principal Investigators about any concerns or about participation/withdrawal from the study.

3. **MANAGEMENT OF RESEARCH WITHIN NHSBT**

The organogram below shows the reporting relationships between Committees and senior staff involved in research management. PIs are responsible for the conduct of the research within their own research group.

3.1. **NHSBT Research & Development Committee**

The R&D Committee is appointed by the NHSBT Board and shall include up to three non-Executive Directors, one of whom shall be the Chair of the Committee. Voting members are:

- Up to 3 non-Executive members of the Board
- Medical and Research Director
- Director of Diagnostic and Therapeutic Services (or nominated representative)
- Director of Blood Supply (or nominated representative)
- Director of Organ Donation and Transplantation (or nominated representative)
- Three external experts in transfusion and transplantation from outside the UK
- Finance Director
Non-voting observers of the Committee include:

- Assistant Director, Research and Development
- Associate Director - Statistics and Clinical Studies
- National Research Manager, R&D (Scientific Secretary)
- Three Principal Investigators, one from each major business grouping, serving on a rotational basis for a period of two years:
  - Blood Supply Chain
  - Organ donation and transplantation
  - Diagnostics and Therapeutic Services

The Committee meet at least twice a year and has delegated authority from NHSBT’s Board to provide strategic oversight of an innovative, cohesive high quality programme of research and development which:

- Includes a balance of short and long term research aims.
- Meets the requirements of the Strategy Groups which link research, development and operational staff in each business area.
- Has Executive Team approval.
- Takes into account the work of other groups and relevant Intellectual Property held by others.
- Aims for timely translation of research findings into new products and services, to deliver improvements to the efficiency, efficacy and safety of blood, tissues, cellular and organ products and services for donors and patients, aligned with business and safety priorities.

Duties include:

- To approve, on an annual rolling basis, the R&D programme for presentation to the Board, having assurance of the quality, relevance and translation of the research, the facilities for its delivery, and the quality of the research staff.
- To make decisions on allocation of research and development funds, within the delegated financial limits of NHSBT.
- To receive annual reports and monitor progress on funded projects.
- To review, on an annual basis, the portfolio of external grants held by NHSBT’s Principal Investigators.
- To review, on an annual basis, the portfolio of research projects funded by NHSBT’s Trust Fund.
- To commission research from external sources where appropriate.
- To have assurance that appropriate arrangements are in place for staff development, research governance, agreements with academic and commercial collaborators, and protection and exploitation of Intellectual Property, reagents, and material such as cell lines.
- To determine the appropriate interval between external audits of NHSBT R&D, to commission the appropriate audit, to receive the report of the auditors and to ensure that such audits are properly conducted.
- To oversee the workplan of the R&D Senior Management Team.

3.2. **Research Strategy Groups**

Research Strategy Groups were set up after the strategic review of NHSBT R&D in 2011. They are designed to be a forum in which representatives of research, development, operations and marketing/customer relations for each specific business area of NHSBT meet, in order to ensure that:

- Operational requirements which can be solved by either research or product development are considered for inclusion in the rolling R&D programme;
- Operational support for R&D projects is considered at the planning stage, costed into research proposals, and reviewed as the project progresses;
- Operational teams are fully aware of ongoing research and are therefore able to plan for translation of the research through clinical evaluations into routine products and services.
- To consider changes to clinical care, scientific developments, the political landscape, and actions of competitors that impact on NHSBT’s product or service provision.
There are eight strategy groups aligned with the 8 Research Themes that cover different areas of NHSBT business:

- Donor Health Strategy Group
- Microbiology Strategy Group
- Appropriate and Safe Use of Blood and Components Strategy Group
- Components Strategy Group
- Diagnostics Strategy Group
- Organ Donation and Transplantation Strategy Group
- Stem Cells and Immunotherapies & Specialist Therapeutics Strategy Group
- Tissues Research Strategy Group

3.3. NHSBT R&D Senior Management Team

The role of the R&D SMT is to:

- Provide oversight of R&D being carried out in NHSBT premises, by NHSBT staff or funded by NHSBT funds.
- Provide assurance to Strategy Groups, Executive Team and R&D Committee that research is carried out within budget and to plan, and that it complies with good research governance, to high H&S standards and follow guidelines for Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Clinical Practice (GCP).
- To coordinate the production of a coherent programme of future research with detailed budgets, for presentation to the Executive Team and R&D Committee.
- To provide support and advice to NHSBT’s Principal Investigators.
- To oversee the activities of the R&D office staff in delivering research agreements with research partners and issuing of Honorary Contracts.
- To support to the R&D committee.

3.4. R&D Strategy

The R&D Strategy runs in 5 year cycles and is the responsibility of the Medical and Research Director. It is developed and approved by the NHSBT Board after thorough review of current activities in context of future operational demands and scientific advances. These reviews include discussions with the R&D Committee, Research Strategy Groups, Executive Team, PIs and R&D Senior Management Team, in addition to engagement with NHSBT external and internal stakeholders. R&D Business Partners in Human Resources and Finance facilitate the implementation of each strategy, ensuring that necessary processes and planning are in place.

At the time of writing, the R&D programme was organised into eight Themes which are strategically important to NHSBT. The next R&D Strategy will run between 1st October 2015 to 31st September 2020.

1. Donor Health and Behaviour
2. Transfusion / Transplantation Virology & Microbiology
3. Appropriate and Safe Use of Blood Components
4. Erythrocyte Biology and Immunology
5. Platelet Biology and Genomics
6. Organ Donation & Transplantation
7. Stem Cells and Immunotherapies
8. Molecular and Tissue Engineering

NHSBT research is a mixture of project based research, core-funded activities, externally funded projects and clinical trials.

Project based research is approved by the R&D Committee on the basis of a submitted proposal. Projects are defined pieces of work with clear start and finish dates (normally up to 3 years duration), outcomes and milestones. The applicant (PI) is responsible for all aspects of the project.
Workpackages or Core Funded research is also PI led and approved by the R&D Committee, but are of a longer duration with less clearly defined objectives and milestones. Their primary purpose is to carry out research closely related to NHSBT Research Strategy.

Clinical trials may be funded by NHSBT or from external sources, and these should be managed through the Clinical Trials Unit. They submit reports to the R&D SMT and R&D Committee on a biannual/annual basis.

Usually, externally funded projects are obtained by NHSBT scientists and are managed through the University that they are embedded within.

4. THE REGULATORY ENVIRONMENT WITHIN NHSBT

All study sites should have high standards of Health and Safety and, where applicable, follow guidelines for Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Clinical Practice (GCP). Research must be managed and conducted according to all relevant local, national and international guidelines, regulations and legislation governing research, including in the UK but not limited to the following:

  - e.g. Participant privacy is protected by ensuring that all research data are held securely (both physical and electronic security), in order to minimise any potential breaches in confidentiality. Members of the study team working with identifiable participant information should be reminded of their responsibility in terms of maintaining confidentiality.

4.1. Health and Safety

All participants and research staff have a duty of care under common law and Health and Safety Regulations to ensure that they follow the employing organisation’s Health and Safety management procedures and work in a way that will not place themselves, their colleagues or the public at risk. All participants and research staff must ensure that they are aware of the local Health & Safety policies and procedures in their own workplace and carry out any instructions concerning health and safety. Failure to do so could constitute gross misconduct in accordance with the NHSBT Disciplinary Policy.

All H&S risk assessments must be kept available with other scientific data for examination by others if required. This will ensure that adequate H&S measures are used throughout the research programme and that local Safety Officers and external inspection bodies (e.g. the Health and Safety Executive) are kept informed and aware of the programme and its progression.

Any H&S concerns should be raised with your local H&S Adviser and any work outside of normal practices should be discussed with them further. See also POL149 Health and Safety for the Clinical and Research Directorate, MPD432 Health and Safety Provision for NHSBT Laboratories.
4.2. **Ionising Radiation**

All new work of this nature should be discussed with the local NHSBT’s Radiation Protection Advisor or H&S Advisor, and the work must not begin until suitable arrangements have been put in place.

4.3. **Genetically Modified Organisms**

Projects involving genetically modified organisms (GMOs) require prior notification of the premises in which the work is to be carried out to the Health and Safety Executive. A Genetic Modification Safety Committee (GMSC) for the premises must be set up and a Biological Safety Officer appointed. A GMO Risk Assessment must be carried out and approved by the GMSC before work can start. The GMSC will consider the applicant’s intended use of the specified GMOs and assess the protocols and procedures outlined in their applications. If the stated procedures and containment conditions in which the GMOs are to be handled are appropriate, the GMSC will give written approval to the applicant. These written records and recommendations will be stored locally. See MPD345 Genetic Modification in Laboratories (Contained Use).

4.4. **Ethical Use of Animals in Scientific Procedures**

The use of animals in scientific procedures is regulated under the Animals (Scientific Procedures) Act 1986 (http://www.legislation.gov.uk/ukpga/1986/14/contents). All users of animals in scientific procedures must hold a Home Office licence. Applications for licences by NHSBT staff must be reviewed and approved by the local PI prior to submission to the Home Office.

NHSBT is committed to the replacement of animals in scientific procedures whenever possible. Where this is not possible the principles of reduction and refinement will be applied, to reduce the use of animals and to assure that they are used in as humane a way as possible.

4.5. **Health Research Authority**

The HRA was established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation of research. They are responsible for a wide range of projects to streamline research, and provide the Integrated Research Application System (IRAS), which is the online application system used to apply for most permissions and approvals for research in health and social care in the UK.

They are also responsible for Research Ethics Committees (RECs) who review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. RECs are entirely independent of research sponsors, funders and investigators. The Gene Therapy Advisory Committee and the Confidentiality Advisory Group, which advises on Section 251 of the NHS Act (2006), also fall under the responsibility of the HRA. RECs are managed through the National Research Ethics Service (NRES), more details can be found below.

4.6. **Biological, Toxin and Chemical Weapons, and Radioactive Materials**

NHSBT staff must not knowingly engage in research for the production, development or promotion of biological, toxic or chemical weapons. Nor must they engage in any activities which could lead to the misuse of radiological or nuclear materials. They have a duty to take action to report to the appropriate authorities any possible contravention, or attempted contravention, of any national and international legal requirements relating to the conventions, national laws and regulations concerning this issue.
5. SOURCES OF RESEARCH FUNDING

Research in NHSBT is funded from external sources and from NHSBT itself.

External funding is from
- Grant in Aid (GiA; Department of Health)
- National Institute for Health Research (NIHR)
- Research Capability Funding (RCF) (NIHR)
- NHSBT Trust Fund
- Cooksey Fund
- Commercial sponsors
- Other Charities

Internal NHSBT funding is through a levy on the price of blood and a contribution from ODT GiA to fund activities in Research Theme 6 (Organ Donation and Transplantation).

6. STUDY DESIGN AND APPLYING FOR FUNDING

6.1. NHSBT Research Funding

Applications for NHSBT funding must be made through the R&D Office on the appropriate application form. In general, the information required will include:

- Principal research question being asked;
- Relevance to NHSBT and possible routes to translation of outcomes;
- Credentials of applicants and their role in the project;
- Relevant protocols and/or detailed plan of investigation including methods to be used, samples or patients to be analysed;
- Timeline with objectives;
- Description of method of monitoring progress and judging success;
- Potential intellectual property to be generated;
- A detailed breakdown of annual financial costs (research salaries, non-pay research costs, indirect costs, consumables)
- Any Capital equipment that may be needed;
- Contracting arrangements that are needed with external organisations;
- Ethical approval, and
- Patient and public involvement (PPI) and engagement (PPE).

Each application will undergo peer review and then be submitted to the R&D Committee. Each application should be prepared in conjunction with the relevant Research Strategy Group and where relevant, have input from the Statistics and Clinical Studies. All potential applications should have the proactive input of the relevant Finance, Operations and Facilities Management personnel. Successful applications will receive an Award Letter describing the value of the award, timescale and other conditions.

The following flowchart describes the approval process for R&D core activities:
6.2. **Ethical and Regulatory Approval for Research**

When a member of NHSBT staff wishes to undertake a research project, ethical approval must be obtained if it involves investigation of human subjects, samples or data. For instance:

- clinical trials of investigational medicinal products (CTIMPs);
- research involving medical devices;
- research involving prisoners;
- research involving adults lacking capacity;
- establishment of research tissue banks;
- projects funded by the US Department of Health and Human Services (DHHS);
- establishment of research databases

If a research proposal has not received appropriate Ethics Committee approval, NHSBT will not be able to support the staff involved in event of criticism of the project or litigation arising from it. If the research proposed requires funding from a grant awarding body it is essential to check whether ethical approval is required prior to submission. Sufficient time should be allowed in order for this approval to be considered prior to grant submission.

An NHS Research Ethics Committee consists of up to 18 members, 1/3rd of whom are lay (broadly, this means their main professional interest is not in a research area, nor are they a registered healthcare professional). They safeguard the rights, safety, dignity and well-being of research participants, independently of research sponsors. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. RECs are entirely independent of research sponsors, funders and investigators.

All ethics applications must be submitted using the Integrated Research Application System (IRAS; [https://www.myresearchproject.org.uk/](https://www.myresearchproject.org.uk/)). Where NHSBT is acting as Sponsor for a piece of work this electronic submission system streamlines the approval process. Further information and guidance is available at: [http://www.hra.nhs.uk/research-community/applying-for-approvals/](http://www.hra.nhs.uk/research-community/applying-for-approvals/).

There are currently 80 RECs across the UK and a directory of RECs and their meeting dates can be found at: [http://www.nres.nhs.uk/contacts/nres-committee-directory/](http://www.nres.nhs.uk/contacts/nres-committee-directory/). An opinion will be reached 60 days after receipt of a valid application, so it is important to plan accordingly. If there are queries from the REC, the clock will stop until the queries have been resolved.

The IRAS simplifies the process of obtaining Ethics Committee and Sponsor approval. Before submitting the completed application, it must be approved by both the Chief Investigator (CI) and the Sponsor. The “approvals” tab in the project navigation page is used to request approval from these people. The system will send an email to the approvers, including the Assistant Director (R&D) who will appraise the application, and if appropriate approve, NHSBT’s role as Sponsor by digitally signing the application before it goes to the Ethics Committee. Applicants should give sufficient time (at least 7 days) for this appraisal. The National R&D Office should be notified of any submissions and relevant paperwork (e.g. Study Protocol, Participant Information Leaflets etc.) submitted for information. In agreeing to sponsorship, a number of factors are considered including the potential for financial liability ([http://www.nhsla.com/Pages/Home.aspx](http://www.nhsla.com/Pages/Home.aspx)), ethical acceptability, health and safety in respect to staff or participants, conformity with existing legislation, and consistency with NHSBT Research Strategy.

If the Chief/Principal Investigator needs to amend the submission after it has been digitally signed, this is possible but the digital signature will be revoked and the new version will have to be resubmitted for signature.

Agreed sponsorship is required for all Clinical Trials coming under European Directive 2001/20/EC ([http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm](http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm)) relating to the implementation of Good Clinical Practice. All Clinical Trials should be referred to NHSBT Clinical Trials Unit in the early stages of project planning to ensure that the mandated processes are correctly followed.
6.3. **Running Clinical Trials and Statistical Guidance in Project Design**

The NHSBT Clinical Trials Unit (CTU) has been running randomised clinical trials and conducting other types of clinical studies within NHSBT since 2001, establishing collaborative links with clinical research networks within the UK and overseas. In 2012, the CTU integrated into Statistics and Clinical Studies, and provides support to observational clinical study an randomised controlled trial design, methodology and analysis in all research areas of relevance to NHSBT, such as organ transplantation, tissues and stem cells.

The CTU Team is able to provide a resource to help develop study outlines, apply for funding and assist with pre-grant-award activity: [http://www.nhsbt.nhs.uk/clinicaltrialsunit/](http://www.nhsbt.nhs.uk/clinicaltrialsunit/). All studies that require support from the CTU by way of study design or statistical support must be adopted onto the CTU workplan, and priority will be given to studies that are in support of NHSBT’s strategic objectives. Once adopted onto the CTU workplan, studies are assigned a clinical operations manager who will undertake full project management activities.

Funding may be obtained from internal, external or commercial funders. All study budgets must include costs for the CTU trial manager, data manager and statistician as well as sufficient funds for all research sites and all study related activity. The data management team will co-ordinate the database design process and all aspects of data management and query resolution.

Support to answer statistical questions such as sample size, data validation and study design can be obtained from staff in the Statistics and Clinical Studies service of NHSBT. The team can provide advice on all aspects of the design of experimental and observational studies, as well as resources for the management and analysis of the resulting data.

In all cases, it is essential that a statistician is consulted early in the development of a study protocol. Staff in Statistics and Clinical Studies can provide help in preparing statistical aspects of the research proposal, ensure that any statistical input is properly costed, and that resources are available when the data collection process is complete. Involvement of a statistician in project design stages means they can advise on sample size and methodological issues. They will then contribute to the protocol, write the Statistical analysis plan, provide data for review by the Data Monitoring Committee, analyse the data for any interim analyses, and analyse the data at the end of the study. They will also provide the randomisation schedule for randomised studies.

The CTU ensures that a Trial Management Group is set up with responsibility for the day to day running of the Trial and dealing with operational issues as they arise. Trials should also convene a Trial Steering Committee (TSC). The role of the TSC is to provide overall supervision for the Trial on behalf of the Sponsor and to provide advice through the Independent Chairman. The ultimate decision for continuation of the trial rests with the Trial Steering Committee.

Most of the studies run by the CTU are sponsored by NHSBT. This means that NHSBT takes on the responsibility of overseeing their conduct and is ultimately responsible for ensuring compliance with all the applicable regulations. Some responsibilities of NHSBT Sponsor have been delegated to the CTU. Where a trial is sponsored by another organisation, the CTU will ensure that their obligations to keep the sponsor informed are met.

The CTU has a suite of documents that describe the various processes involved in clinical studies. These may be accessed on the NHSBT Controlled Documents Library. Quality Control must be built into all clinical trial activity, and following the various MPDs and SOPs will ensure that your trial is conducted to the appropriate standards. It is NHSBTs responsibility as Sponsor to monitor and audit studies. Other organisations that may audit your study are the R&D department at a site, the Ethics Committee and the MHRA if applicable (e.g. CTIMP studies).
6.4. **Funding from External Sources**

NHSBT staff are encouraged to actively seek external grants to both augment present R&D interests and extend activities to include new avenues of research within NHSBT R&D strategic priorities.

Grant applicants are responsible for ensuring that the implications of undertaking work under an external grant (availability of space, equipment, staff, impact on other departments etc.) are considered fully prior to applying for funding. All potential grant applications should have the proactive input of the relevant Finance, Operations and Facilities Management personnel and applications should be of a high quality.

Where there is open competition for a research contract attempts should be made to avoid the competition between NHSBT researchers. All grant applications should be forwarded to the R&D Office for information at the time of submission. PIs will be asked to include a list of both successful and unsuccessful external grant applications in the Annual Return.

7. **MONITORING RESEARCH**

7.1. **Progress Reports**

All grant-awarding bodies require periodical reports so they can assure themselves that research activities are progressing as expected and that funds are being spent appropriately. NHSBT is no exception to this.

For NHSBT funded Projects, the R&D Committee is responsible for receiving and acting on these reports for ongoing Project Grants and Workpackages. This process is administered by the R&D Office.

At the end of each reporting period, grant holders will be asked to complete Scientific and Financial reports for each Project or Workpackage that they hold. Progress reports will be requested on an annual basis as a matter of routine, however, in specific cases additional reports may be requested. Reports will be reviewed by the R&D Committee at their bi-annual meetings at which recommendations will be made on the basis of reported progress. The Committee is free to make whatever actions are deemed necessary for a specific research project. Such recommendations will include:

- continuation of the work if it is progressing according to plan;
- requesting changes if there are issues with progress;
- withdrawal of funding in cases or poor management or lack of progress.

7.2. **Change Requests**

For awards made by NHSBT, any changes to scope, timescale or budget must be approved by the R&D Committee. Minor changes, including extensions of less than 6 months, or changes of less than 10% to the overall budget are delegated to the R&D Senior Management Team for approval.

It is important that change requests are reported promptly to enable effective management of budgets as grant money underspent in one financial year cannot be recovered in the following financial year.

7.3. **Project Closure Reports**

An important part of a Research Project is the Project Closure Report. The purpose of a project Closure Report is to:

- summarise the project’s scientific achievements
- provide recommendations for the next steps or further work if any
- analysis of lessons learned as applicable to future projects
Project Closure Reports are requested after the end of the project and prior to the next R&D Committee meeting which can be up to a year after the award ends. All closure reports require sign-off by the relevant Strategy Group prior to submission to the R&D Office.

Once the Project Closure Report has been accepted by the R&D Committee the project will be closed.

8. PRACTICAL CONSIDERATIONS AROUND CONDUCTING R&D in NHSBT

8.1. Staff Recruitment

Planning and time should be allowed for hiring staff and processes of the employing organisation (NHSBT or of the partner organisation e.g. University) must be followed. The procedure within NHSBT is known as “Direct Hire” and information is available on the NHSBT intranet or through HR Direct (hrdirect@nhsbt.nhs.uk; 0117 3227700).

8.2. Honorary Staff Contracts

It is sometimes necessary to have members of staff work on a research project that are not employed through NHSBT and in these instances set procedures should be followed. Staff who are not employed by NHSBT but work on NHSBT premises or access NHSBT IT systems must have a Letter of Access. Staff that are not employed by NHSBT but come into direct contact with patients or donors and impact on patient quality of care must have an Honorary Contract (HC) with NHSBT. An honorary contract transfers liability from the substantive employer to the NHS (i.e. we accept vicarious liability for harm due to clinical negligence). Therefore, the majority of researchers at NHSBT should be covered by a LoA.

Research passports are an initiative between Higher Education Institutes (HEI) and NHS trusts. When a researcher applies for a research post at NHSBT, their substantive employer will complete a research passport. This means that pre-employment checks are carried out by the university (ID checks, CRB check and OH check as necessary) before the researcher comes to NHSBT. These passports are then sent to R&D for approval. If approved, the researcher will be issued with either an honorary contract or a letter of access (LoA). The Research Passport form and guidance can be found here: http://www.nihr.ac.uk/policy-and-standards/research-passports.htm and the R&D Office will happily respond to any queries: Research.office@nhsbt.nhs.uk. It is essential that NHSBT mandatory training is carried out by all staff holding LoA’s or HC’s.

It is important that when staff with Honorary Contracts leave, their line manager must submit a Termination Form to HR so that they may be removed from the system. The R&D Office should also be notified.

8.3. Research Contracts and Agreements with External Organisations

Relations with external collaborating organisations are formalised by execution of a contract, these can include: Research Agreements; Collaboration Agreements; Service Level Agreements (SLAs); Finance Agreements; Memorandum of Understandings (MOUs); Material Transfer Agreements (MTAs) relating to the exchange or transfer of reagents, chemicals biological agents, cell lines, plasmids etc., and Confidentiality Agreements (CDAs also known as Non-disclosure Agreements or NDAs).

All negotiations for establishing Research Contracts should be made through the R&D Office. Principal Investigators and Researchers are not authorised to sign contracts and agreements on behalf of NHSBT. If you are in negotiation with an external organisation regarding any of the above, please email research.office@nhsbt.nhs.uk who will issue you with a work request form to complete. All following negotiations will be carried out by NHSBT’s Contract Managers.
8.4. **Budgetary and Financial Information**

It is the responsibility of PIs and budget holders to ensure that research activities are conducted in line with the approved budget. Monthly Finance Reports produced by the Finance Department must be monitored and any variances reported to the R&D SMT. End-of-year reports will be provided to assist in the preparation of the annual/biannual Progress Reports.

- **Cost Centre:** A code used to identify the project or workpackage budget which the expenditure is charged against. Each cost centre has a Budget Holder responsible for maintaining the expenditure within the agreed annual budget. A cost centre may also have a number of Approved Signatories with authorised maximum sign-off limits within the agreed budget.

- **Nominal Code:** A code used to identify a type of expenditure (pay, consumables, medical gases etc.) within a cost centre. This enables management reports to be generated.

Where projects are administered through an outside organisation such as a University, purchasing and pay will be done through the University. Arrangements will be made for either the University to invoice NHSBT to recover expenditure or for payment to be made in advance to the University. In either situation it is incumbent on the budget holder to review regularly all expenditure.

It is essential that invoices are paid or accrued within the correct financial year as they cannot be carried over to the following year.

8.5. **Purchasing Capital Equipment**

Capital equipment is any item costing more than £5,000 including VAT. NHSBT’s budget to purchase Capital equipment is provided from the Department of Health (DH) in the form of a ‘loan’. Capital equipment purchases incur capital charges (a repayment to the DH) in subsequent years dependent upon the items cost and expected life.

The purchase of capital equipment requires planning and takes time. Requests from PIs for capital equipment are collated annually and prioritised by the R&D Senior Management Team against the available budget. Replacement equipment, equipment available to several users and equipment essential for the success of a project or workpackage will generally be given higher priority.

NHSBT’s Standing Financial Instructions include rules governing the processes that must be followed when purchasing Capital equipment. They are designed to allow free competition between suppliers:

- If the value is above £10,000 but below £40,000 then quotations from three suppliers are required.

- If the value is above £40,000 but below £101,000 then tenders from suppliers are required.

- If the value is above £101,000 then the OJEU process must be followed, taking several months. This involves NHSBT advertising the ‘intention to purchase’ in the European Journal.

It is not permissible to avoid these limits by splitting the order into smaller lots, although in exceptional circumstances a waiver is possible if it can be clearly demonstrated that there is only a single supplier of a particular item.

These processes can be expedited if the suppliers chosen for quotations or invited to tender are on the NHSBT Approved Suppliers list. There are significant advantages in terms of time taken to purchase if an Approved Supplier can be selected.

It should be noted that the award of funds to purchase capital equipment is not in the gift of the RDC or R&D SMT. So even if the workpackage or project is approved, and the capital equipment required receives high priority, the bid will be in competition with bids for capital funds from the whole of NHSBT.
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Further information, including current financial limits, can be obtained from R&D’s Finance Business Partner, Purchasing or the National R&D Office.

8.6. Purchasing Consumables and Equipment

Consumables and equipment with a value below £5,000 including VAT can be purchased from the revenue budget allocated to the research award.

The budget holder and other approved signatories should use the Oracle i-procurement system, ensuring that the items are coded to the correct Cost Centre.

Where a project is being administered by one of NHSBT’s academic partners, the University’s procurement procedures must be followed.

8.7. Use of Blood, Products and Components for research (Non-Clinical Issue)

The non-clinical issue (NCI) system is a process that allows NHSBT to record and track issues of donated material that are not required for clinical use.

NCI is used to issue these components to NHSBT research labs and also organisations outside the NHSBT. NHSBT’s costs for making the material available are recovered when material is provided to external organisations.

NCI customers must be pre-approved to order material by medical consultant/functional leads as described in SOP332.

New account requests and information about access to donated material should be made to nciadmin@nhsbt.nhs.uk.

Alternatively, information, guidance and an application form may be accessed at http://hospital.blood.co.uk/research/non-clinical-issue/

8.8. Research Records

NHSBT requires all staff, including honorary and contract staff, to keep clear and accurate records of scientific procedures in research and service work. Such record keeping facilitates an audit trail of work undertaken, should a later investigation of the scientific procedures be required, and is an essential aspect of good research governance.

Staff undertaking research must keep notebooks or orderly loose-leaf records. Such records can also be held electronically with hard copy back-up. Obliteration of text is not permitted in any written documentation. Unwanted text should be “struck through” in a manner that enables the deleted words to be read and corrections should be dated and initialled (see MPD385 Good Documentation Practice).

A system of regular sign-off of laboratory records must be in place. This allows for a signed record of when a particular activity or ‘discovery’ took place and is important for the purposes of securing potential intellectual property (IP) rights. The significance of an observation may not be realised at the time, therefore it is good practice to sign and date lab books on each page.

Wherever appropriate, computer software should be used that enables those who entered or amended data, or added comments, to be identified.
Records, including those held electronically, must normally be kept in secure storage for ten years after completion of the research project. For records of clinical trials and pharmaceutical manufacturing, this might be extended to as long as 30 years. The period for which internal records must be retained should be established for all research projects. Storage must be in accordance with the Report of the Working Party of the Royal College of Pathologists and the Institute of Biomedical Sciences.

Patients’ notes that relate to clinical studies must be handled in accordance with the local Trust Policy and according to protocols approved by an appropriate Ethics Committee. Caldicott guidance must also be followed.

Where appropriate, laboratory records such as request forms, worksheets, record books, relevant computerised printouts etc must be handled according to current laboratory SOPs complying with the current standards and guidelines of CPA (UK) Ltd or other relevant Quality Standard in use.

On leaving NHSBT employment, staff are required to leave behind their original data, e.g. laboratory notebooks, computer files. However, non-confidential copies of work and training folders can be made after consultation with the PI.

8.9. Reporting H&S and Quality Incidents

PIs are responsible for ensuring that all accidents and near-misses are reported promptly, doing this on behalf of the injured party if they are unable to do so themselves. Incidents must be reported using the corporate Datix reporting tool. PIs are also responsible for the investigation of accidents and near-misses, and work related ill health, ensuring any actions are implemented and staff informed of the outcomes. The expertise of the local H&S Advisor is available as required.

Quality Incidents are defined as anything that should not be happening and which could affect product quality, patient or donor safety, or seriously affect supply. Quality Incidents occurring in clinical trials where NHSBT is the Sponsor should be reported and followed up through QPulse.

8.10. Staff Training and Personal Development

Staff training and personal development operates at several levels and is an important part of Research Governance. All staff have a responsibility to complete the NHSBT mandatory training that is allocated to their post. This is in addition to the training that this mandatory to working within laboratory settings to comply with GCP, GLP and GMP. The necessity for all NHSBT staff to complete their Mandatory Training is governed by law, regulatory authorities and health and safety. It forms part of the NHSBT Induction Policy and is a contractual requirement for ALL staff (this includes Honorary Contract holders). MT compliance rates for directorates/function are reported to the Executive Team on a monthly basis.

Mandatory Training is required for all staff and is described in POL136, MPD379 and DAT1552. Mandatory training includes induction training for new staff, essential information for performing your job safely and legally (including Quality Management, fire safety, information governance, equality and diversity), and training specific for some job roles (e.g. using cryogenic gases). DAT1552 describes how frequently this training must be carried out. PIs must keep records of the training status of their staff using FRM511 Task Based Training Record. Online MT can be carried through the Training Tracker system (http://nbs.trainingtracker.co.uk/) and other modules require face-to-face training. Further information can be obtained by emailing: learning@nhsbt.nhs.uk.

Job-specific training is required to carry out specific roles or tasks, and should be organised on a case-by-case basis by the PI in consultation with the staff member. Again, records of training should be kept as it is the responsibility of the PI to ensure that all members of a team working on a research project are sufficiently trained and qualified to carry out the work within the relevant guidelines and legislation (outlined in the RGF).
Personal development of staff is required, to build up expertise, increase job satisfaction and for succession planning. In discussion with their manager, all staff should have a Personal Development Plan which should be reviewed annually in a formal Person Development Plan Review (PDPR). It is essential that PDPRs are reported here: [http://nhsbtweb/resources/personal_development/index.asp](http://nhsbtweb/resources/personal_development/index.asp). There are several ways in which staff development can occur. ‘Shine’ is the umbrella term for NHSBT’s talent and leadership development strategy. It encompasses all the ways NHSBT is supporting their staff to become tomorrow’s leaders. Outside of this organised scheme, staff are encouraged, where funds allow, to attend conferences to present their work and network with their peers, and also to attend other training courses. Authorisation to attend a conference or training course is dependent on both the need having been identified in a PDPR and an individual’s Mandatory training being up-to-date.

8.11. Misconduct and Fraud

NHSBT takes very seriously any allegation of misconduct or fraud and staff should consult the NHSBT Code of Conduct.

Science is about the pursuit of facts and the testing of hypotheses, which makes scientific fraud rather self-defeating. Scientists utilise the self-regulatory system of peer-review, and the scientific method that invites replication of published work, and public refutation if it can not be achieved.

There is no better solution than for all of those engaged in science to be completely honest and to always give due credit to the contribution of others. The importance of absolute honesty in science must be emphasised to all new employees and those engaged in studies for a higher degree as part of their training.

In order to safeguard the integrity of NHSBT and the work that it produces, it is incumbent on every member of staff to make known any actual scientific fraud of which they become aware or genuine suspicion of scientific fraud that they have. Normally, it should be possible to report such matters through a line-manager. However, NHSBT has a whistle-blowing policy to guide staff whenever they think that this route is not possible.

8.12. Acting as a Peer Reviewer

The principles of confidentiality and integrity outlined above apply when you are peer reviewing manuscripts submitted for publication, or grant applications. NHSBT staff are often called upon as expert referees and the system relies heavily on the goodwill of referees, while striving to minimise calls on an individual’s time. Referees are required to follow the appropriate guidelines of the particular scientific journal or grant awarding-body, which must always include the following rules:

- All information must be treated in the strictest confidence
- Assessors must not take advantage of any information obtained as a result of their role; in particular they must not appropriate others’ ideas or proposals for their own purposes
- Assessors must declare any conflicts of interest and, normally, should exclude themselves or withdraw from relevant discussion(s). This applies to anyone with close professional, personal or commercial interest in a piece of work
- Referees prevailed upon to give a reference where they consider their knowledge to be incomplete should stress the limits of their knowledge
- On no account must referees accept inducements or rewards from authors or their agents
9. COMMUNICATING RESEARCH RESULTS

9.1. Intellectual Property

Researchers in NHSBT should ensure that their findings make the maximum contribution to the NHS. The ultimate contribution will be the delivery of a product or service that enhances health in a practical way. Scientific papers are a good way of disseminating findings but do not, in themselves, result in a practical outcome.

NHSBT does not always have the resources or specific expertise to develop a new product or service in its final delivered form. Frequently a commercial partner is required and this partner will usually look for some sort of intellectual property position in order to protect the investment which they must make in development. The strength of the intellectual property position and consequently the attractiveness of an invention to industry will be determined by, among other factors, clarity of ownership and prior disclosures.

It is good research practice to ensure that arrangements relating to ownership of results and Intellectual Property Rights (IPRs) are put in place from the outset. Novelty is a requisite of obtaining patent protection and can be destroyed by premature disclosure. Therefore before putting results in the public domain, the researcher should also determine whether publication is the best method of knowledge transfer. If in doubt, consult the National R&D Office at the earliest opportunity (see POL160 Intellectual Property).

If an invention is recognised as having exploitable IPR, the normal practice will be to file a patent for 1 year duration providing NHSBT some protection, whilst during this time have further discussions on the feasibility of further patenting or collaboration with a commercial partner. At the end of 1 year a decision can be made to let the patent lapse, extend or expand the patent, or enter a collaborative venture. This approach minimises the cost to NHSBT whilst maximising the potential for exploitation.

Whilst the default position is that NHSBT owns all the results generated by its employees, research collaborations involving more than one institution often lead to issues over ownership and how commercial revenues will be shared. The National R&D Office can provide advice and assistance on setting up contractual arrangements with academic and commercial partners from the outset. It is often too late if these arrangements are left until after the research collaboration has commenced.

When working with commercial organisations acting as sponsors/co-sponsors of scientific activity there are special considerations that need to be borne in mind prior to commencing any collaboration. These considerations include ensuring NHSBT’s position as an independent scientific authority, its role in the NHS and its adherence to probity and transparency in its partnerships. Should there be any perceived conflicts of interest whilst establishing a scientific collaboration, staff are advised to consult the National R&D Office.

9.2. Publishing and Presenting your work

Peer-reviewed publication of research carried out within NHSBT is of paramount importance and it is expected that all staff will take a responsible attitude to authorship. There must be robust mechanisms for quality control of publications.

The emphasis on publications as a performance indicator for scientists and other staff has meant that authorship may sometimes become a contentious issue. All those named as authors should have made a significant, identifiable contribution to the work. It may be appropriate to indicate the individual contributions of authors, and it is recommended that authors agree and record their respective contributions prior to submitting a paper. Some journals have recently instituted descriptions of individual contributions and may also require ‘guarantors’ for the work.
Omission of a significant contributor is a common cause of disputes between colleagues, and every effort should be made to avoid this. ‘Honorary’ authorship, (e.g. putting all the members of a team on a paper irrespective of their individual contributions), is unacceptable as is ‘ghost’ authorship in which the true author’s name is omitted.

All the authors must accept responsibility for all of the paper’s content. It is the clear view of journal editors that such acceptance of responsibility is crucial and NHSBT agrees that such responsibility is collective. All authors must therefore have sight of the final draft of a paper and be given adequate opportunity to comment on the contents before the paper is submitted. They should also agree the order of authors’ names on the paper.

Authors should pay particular attention to the ‘Acknowledgements’ section of a paper and ensure that minor contributors are duly thanked. This is also the appropriate way to indicate the contribution of scientists who have given advice or commented on the manuscript.

It is very important that funding bodies are acknowledged, because many use this metric to formulate future grant-awarding policy. Certain funding bodies require a disclaimer in the acknowledgement (e.g. “The views expressed in the publication are those of the authors and not necessarily those of the Department of Health”). It should also clearly state NHSBT contributions.

Authors may be required to declare any potential Conflict of Interest relevant to the subject matter of the manuscript. This statement must be considered with due care and be frank and informative.

In some instances articles that have had multiple input from different parts of NHSBT may be authored as ‘NHSBT’. Working Parties or Groups can also be ‘authors’ with the membership listed elsewhere in the paper. It is only acceptable for one or more authors to present work on behalf of Working Parties or Groups if all contributors and group members agree and approve the final document. If not a note must be included to that effect. As with papers with named authors, all members of the Working Party or Group must accept responsibility for the paper’s final content.

Where NHSBT has provided data or other services which are incorporated in non-NHSBT authored publications, staff should formally request in writing that the contribution of NHSBT is duly acknowledged. Failure to attribute or mistaken attribution may cause ill feeling between groups and individuals.

Information about publications will be collected in Annual Returns that each PI and Senior Scientist will receive on an annual basis. It is also good practice to inform the R&D Office when a manuscript has been accepted by a journal for publication.

9.3. Where to Publish and Impact Factors:

Scientific publication is an effective means of reporting the output of NHSBT’s R&D Programme. Every effort should be made to publish original, high-quality work and to do so in appropriate journals. Care should be exercised in choosing which journals to submit articles to. Some journals are more prestigious and widely read than others and the impact factor is used as a measure of this. Impact factors are increasingly being employed as performance indicators both for journals and authors who publish in them. Up-to-date impact factors lists are generally available from subscription websites.

NHSBT staff should publish their work where it is likely to be read in the appropriate and if necessary specialised journal. The best and most important work of NHSBT staff should appear in high ranking journals.

A submission to a journal should be made in its own ‘house style’ and it is unacceptable to submit a paper concurrently to more than one journal. NHSBT staff should not attempt to deal with two journal editors simultaneously. Such parallel submission negatively affects authors’ credibility and damages the reputation of NHSBT.

Similar considerations may apply to non-peer reviewed publication, such as web-based journals, conference abstracts and postings on other websites.
9.4. **Relations with the Media**

In a diverse organisation such as the NHSBT, which deals with a wide range of high-profile news stories, it is essential that the picture portrayed to the media, the public and stakeholders is one of consistency. To achieve this it is essential that media handling across NHSBT is co-ordinated. This will ensure that NHSBT’s position on any specific issue will be clear and will also offer protection to any NHSBT staff who are carrying out media interviews.

It is therefore essential that communication with the media, either written or oral, is handled by the Press Office team. This does not necessarily mean that it is always a representative of the press office who speaks with the media. It is also important that any outputs from NHSBT that are likely to attract media interest (such as the publication of important scientific papers, presentations at conferences, publication of data etc) are notified to the Corporate Communications team so adequate planning can be carried out and suitable timing for such announcements can be identified and coordinated with other NHSBT media activities ([http://nhsbtweb/group_services/communications/index.asp](http://nhsbtweb/group_services/communications/index.asp)).

All incoming media enquiries should be directed towards Press Office (01923 367600 or 01179 692444) as soon as possible. This includes both phone calls and emails. The press office should approve any written material intended for distribution to a journalist.

NHSBT scientists may be approached directly for Freedom of Information requests or by government departments, MPs or their researchers to provide information for Parliamentary Business. Such requests should also be forwarded immediately to the Press Office.

Where information and advice of a scientific nature needs to be posted on websites and in non peer-reviewed publications it is essential to ensure that it is of good quality and is not contradicting other NHSBT advice.

10. **References and Further Information**

External websites

Department of Health Research Governance Framework [Click](http://nhsbtweb/group_services/communications/index.asp)
Health Research Authority [Click](http://nhsbtweb/group_services/communications/index.asp)
Human Tissues Authority [Click](http://nhsbtweb/group_services/communications/index.asp)

NHS Confidentiality Code of Practice [Click](http://nhsbtweb/group_services/communications/index.asp)
Caldicott Guardians [Click](http://nhsbtweb/group_services/communications/index.asp)

IRAS (Integrated Research Application System) (Ethics approval) [Click](http://nhsbtweb/group_services/communications/index.asp)
National Research Ethics Service (NRES) [Click](http://nhsbtweb/group_services/communications/index.asp)
"Is your project research?" (National Research Ethics Service) [Click](http://nhsbtweb/group_services/communications/index.asp)

Good Manufacturing Practice (GMP) Medicines & Healthcare Products Regulatory Agency [Click](http://nhsbtweb/group_services/communications/index.asp)

HSE Radiation [Click](http://nhsbtweb/group_services/communications/index.asp)

Animal Procedures Committee - [Click](http://nhsbtweb/group_services/communications/index.asp)
Association of Medical Research Charities - [Click](http://nhsbtweb/group_services/communications/index.asp)
Fund for the Replacement of Animals in Medical Experiments (FRAME) - [Click](http://nhsbtweb/group_services/communications/index.asp)
Universities Federation for Animal Welfare (UFAW) - [Click](http://nhsbtweb/group_services/communications/index.asp)
Nuffield Council - [Click](http://nhsbtweb/group_services/communications/index.asp)
NHSBT Documents

- Research Governance Policy POL161
- Research Governance MPD871

- Information Governance Reporting Arrangements INF494
- Information Charter POL13 (for Donors)

- Adverse Event / Quality Incident Report FRM1
- Reporting and Managing Adverse Events SOP3406

- H&S for the Clinical and Research Directorate POL149
- Health and Safety Policy - Part 2 Delegated Responsibilities

- H&S Provisions for NHSBT Laboratories MPD432
- Ionising Radiation MPD360
- Genetic Modification in Laboratories MPD345
- DATIX reporting tool for accidents / incidents [Click](#)
- DATIX Risk Assessment forms [Click](#)

- R&D Project Request (on request to R&D Office)
- R&D Project Grant Application (on request to R&D Office)
- R&D Project Progress Report (on request to R&D Office)
- R&D Project Change Request (on request to R&D Office)
- R&D Project Closure Report (on request to R&D Office)

- Clinical Study Site Set-Up Procedures MPD989
- CTU-IMP Management and Accountability MPD1093
- CTU – Gaining Regulatory Approvals MPD982

- Mandatory Training Policy POL136
- Mandatory Training MPD379
- Mandatory Training Annex

- Non-Clinical Component request FRM256
- NCI Customer Component Authorisation List DAT64

- Intellectual Property POL160
- Users Guide to Intellectual Property DAT2086
- Invention Record / Disclosure Form FRM4097
NHSBT Contacts

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H&S Advisers: Names and contact details can be obtained locally or from 0161423 (5) 4344. See also Contact Information sheet on the intranet

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