St. James's Hospital
Research Governance and Support Framework
2017 – 2019

ST. JAMES'S HOSPITAL

Wellcome Trust - HRB
Clinical Research Facility
at St. James's Hospital

St. James's Hospital Research Governance & Support Framework 2017 – 2019

Table of Contents

SECTION 1

1.1 Introduction

The St. James's Hospital (SJH) Research Governance and Support Framework 2017 – 2019, is a 3-year plan outlining initial research related objectives and priorities, as well as implementation considerations for the hospital. The framework aims to build on the strong existing research culture, capabilities, and collaborations of the hospital and to utilise the expertise within the recently established St. James's Hospital Research and Innovation (R&I) Office (formerly the R&D Hub).

The main benefits to the hospital of clinical research, and an associated research framework, are improved patient care, in addition to increased oversight, safety, quality, regulatory compliance, and financial governance. Clinical research is a key factor in ensuring that the quality of patient treatment and the care delivered is effective, efficient and continuously improving. Healthcare performance is enhanced in research-active organisations, which promote the latest evidence-based practice. Organisations participating in research are considered desirable places to work, attracting skilled staff, and these sites benefit from research related buildings, facilities, and equipment, all of which are of benefit to patients. Research active-organisations have been shown to result in better patient outcomes[1,2], including a reduction in overall patient mortality, and participating patients receive increased levels of support and monitoring, and earlier access to novel treatments and technology.

1.2 Background

SJH is the largest academic teaching hospital in the Republic of Ireland, with a commitment to achieving excellence in the three areas of clinical practice, education, and research & innovation. Although the core business of the hospital is patient care, research is a key supporting element of this, and helps with the development of specialist services. Research is also a statutory element of hospital board responsibility, and the hospital Vision, Purpose and Values all make reference to research and innovation as part of being a leading healthcare organisation. In 2016, 180 research applications were received by the hospital, a figure that is almost 40% higher than in 2015 (Appendix 1).

While one objective is to continue to strive for pioneering research, the hospital maintains a commitment to research ethics and quality, to ensure the safeguarding of hospital patients, Principal Investigators and staff, as well as the hospital's reputation and resources. Research activity and practices have grown organically over decades within the hospital with individual research teams traditionally being grant funded. As a result research is currently decentralized, resulting in some examples of duplication of effort. It had been identified that there was a need to provide a central support structure for research in the hospital, to promote and facilitate high quality research, to provide a research identity, and to provide increased recognition and visibility of research outputs from the hospital. To this end, the SJH R&D Hub (now R&I Office) was launched in August 2015 as a joint venture between SJH and the Wellcome - HRB Clinical Research Facility (CRF) at St. James's Hospital. The R&I Office has streamlined the hospital research application approval processes, increasing oversight and enhancing adherence to regulatory requirements. The CRF has supported this with staff time, expertise and input on both Operational Groups and Steering Groups.

1.3 Research Landscape

There are regulatory changes on the horizon that will affect future research conduct and the hospital needs to be cognisant of these and plan for their implementation, ensuring that it is audit ready. There are numerous regulations, guidelines and best practice recommendations, as well as external parties that impact on research conduct, including EU and national legislation, Good Clinical Practice Guidelines, the Health Products Regulatory Authority (HPRA), Ethics Committees, the Health Information and Quality Authority (HIQA), the Data Protection Commission, and the State Claims Agency. The hospital also has many research stakeholders, and needs to make future plans that complement the research objectives of its academic partner; Trinity College Dublin (TCD). Furthermore, future developments within the hospital and CRF pharmacies, MISA, the proposed Cancer Institute, and the Joint Research Ethics Committee (JREC) also need to be considered.

The development of an internal strategic research focus, robust internal structures and processes that are fit for purpose, in addition to researcher supports, will facilitate increased research output that is of value to the hospital and its patients. A defined research framework will also provide a competitive advantage, making the hospital an even more attractive place to conduct research. The associated developments will help to showcase research capabilities, which will further assist with attracting and retaining staff, collaborations, and funding, as well as allowing the intellectual property (IP) generated to be capitalized upon. The execution of the hospital's research framework will primarily be via the R&I Office and Steering Group. The R&D Hub was renamed the Research and Innovation Office to be more inclusive, and to reflect and house the broader spectrum of current and future innovation.

SECTION 2

2.1 Mission

The research Mission of the hospital is to support and increase the output, oversight, visibility and utilisation of high-impact, high-quality research that is of value to patients and to SJH staff.

2.2 Vision

The Vision is to leverage the hospital's scale, creating an environment where research is valued, and to establish robust governance structures and processes to support safe, quality assured, innovative research.

SECTION 3

3.1 Strategic Objectives

In order to realize the aims of the Mission and Vision, four key objective areas will be developed with workstreams that focus on financial governance, support, approval and communication (Table 1). The retention of focus on these objective areas will be supported by an associated governance structure based on actions provided for in policy and organisational structure, in addition to institutional collaboration (Figure 1).

Objective Areas
1. Financial Governance
2. Support
3. Approval
4. Communication

Table 1.

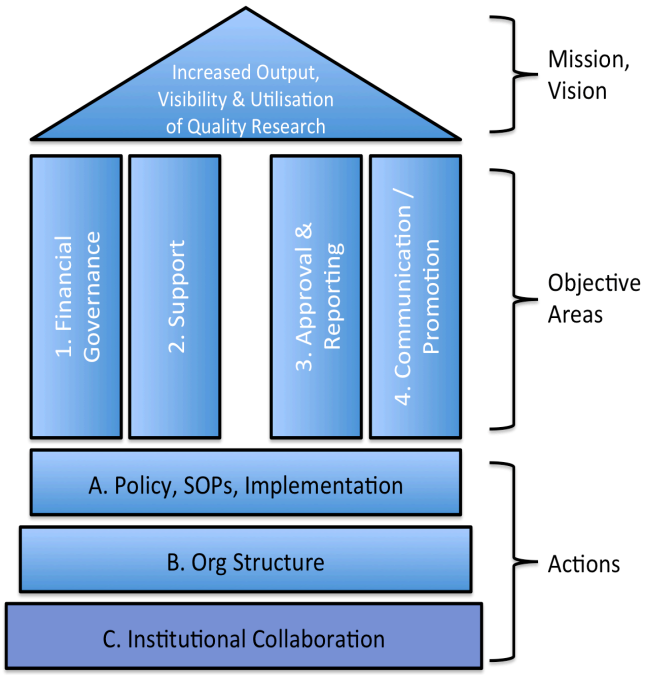


Figure 1.

3.2 Policy, SOPs, Implementation

The workstream sub-elements that should be considered include:

3.2.1 Financial Governance

- Protection of PIs and hospital resources.
- SJH Finance Department (Management Accounting and Financial Accounting) and financial management system (SAP Internal Orders) involvement in research management to increase funding visibility and costing/billing consistency.
- Optimization of the funding related information captured on the research application form.
- Micro-costing exercise of clinical research.
- Engagement prior to grant application.
- Engagement at contracting stage.
- Application of overhead & VAT.
- Account set up.
- Invoicing (including unscheduled expenses outside of protocol), monitoring, reporting, preparation and engagement with external audit.
- Review of processes required to hire and backfill staff using research funding: VAFs and HR involvement.

3.2.2 Research Support

- Support with hospital approval applications.
- Advice on legal issues, insurance and contracting.
- Advice on regulatory issues.
- Advice on ethics applications.
- Financial budgeting and contracts.
- Webpage information repository.
- Horizon scanning for PI opportunities.
- EPR based recruitment software.

3.2.3 Approval & Reporting

- Transition of R&I guidance document to policy.
- Research application approval: approval criteria, review committee SOP and TOR, use of risk assessment tools, supporting documentation requirements, study extensions / amendment requirements, review times, issuing approval letters.
- Storage of submitted documents.
- Principal Investigator (PI) requirements and responsibilities.
- Staff affiliation, locums.
- Types of studies requiring ethical approval.
- Pharmacy requirements, management, production and dispensing of drugs.
- Contracts, budgets, indemnity, institutional non-disclosure agreements.
- Data protection.
- Data manager controlled database access.
- Research progress reports (interval reports, incident reports, and end-of-trial reports: information required, approval committee review and use of information).
- Review of application form backend database content for planning purposes.
- Consider inclusion of additional forms of research, e.g. systematic reviews and case studies.
- Quality assurance of R&I Office activities

3.2.4 Communication Strategy

• Engagement with internal and external PIs, collaborators, organisations and industry.
• Patient / Public Involvement (PPI): "OK To Ask" campaign, patient experience review, identifying barriers to research, engagement with CRF PPI programme and the HRB/TCD PPI Ignite Programme.
• Use of data collected on current research activity to showcase research capabilities.
• Establish researcher profiles, capture publications, dissemination of findings and shared learning.
• Use of communication avenues: webpages, email distribution lists, social media, staff handbook, patient leaflet, and promotional materials.
• Service user feedback

3.3 Organisational Structure

To facilitate advancement within the strategic areas of financial governance, support, approval and communication, and the development of associated policies and implementation plans, a number of organisational structure changes will be phased in (described below).

3.3.1 R&I Programme / Office

A primary goal is to provide support to PIs through an established R&I Office (Figure 2) as part of an R&I Programme / Directorate (Figure 3) with a defined position on the Directorate Organisational Chart, and with reporting responsibilities to the SJH CEO. The additions required to make this transition may involve additional human resources, e.g. managerial, clinical, and financial. There are currently further opportunities to coordinate and reallocate posts in conjunction with the CRF via "in-kind" funding and the matching of funding through the HRB.

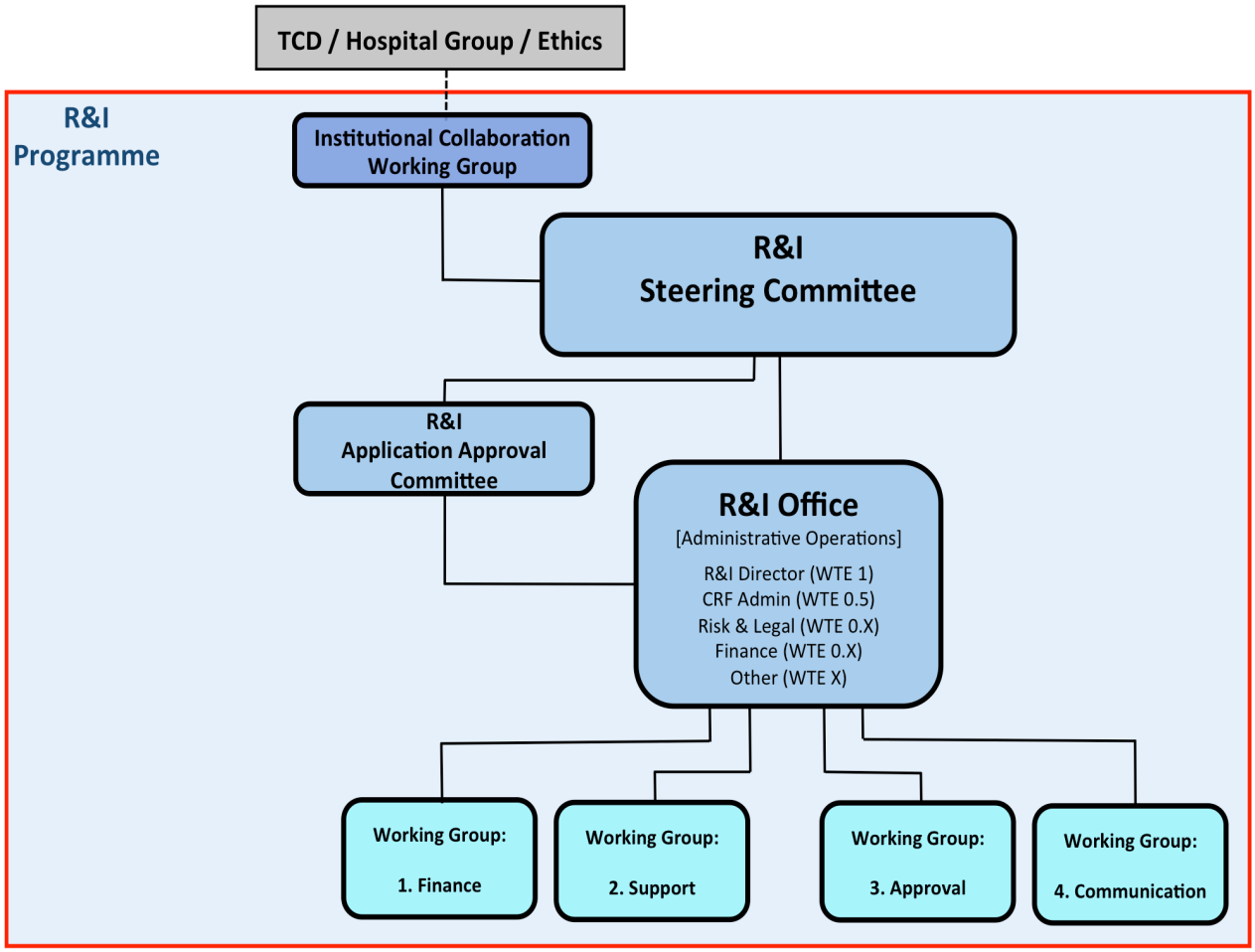


Figure 2.

3.3.2 R&I Committees

It is proposed that a new sub-committee of the R&I Steering Committee (formerly the R&D Hub Steering Group) will form an R&I Application Approval Committee, to review and approve hospital research submissions (Figure 2).

The former R&I Operational Group could be added to and divided into a number of Working-Groups under new terms of reference to address and develop the required policies and implementation plans (particularly the Approval and Communication workstreams).

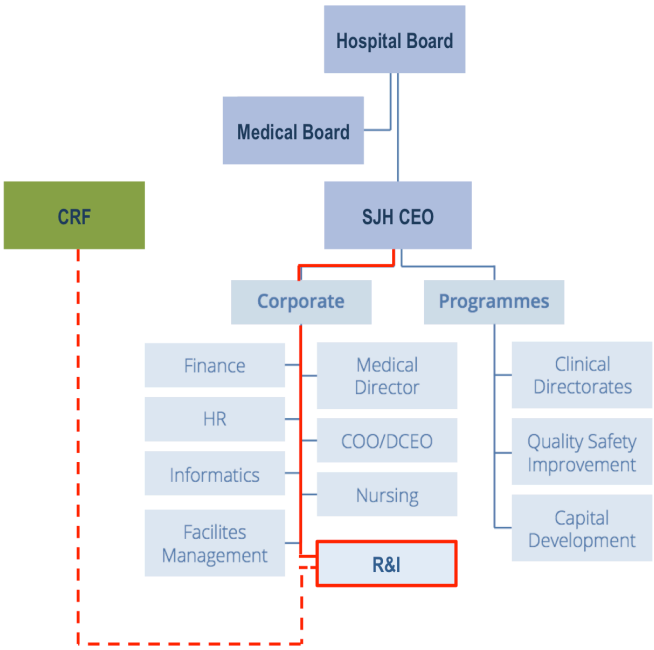


Figure 3.

3.4 Institutional Collaboration

To work optimally with its academic partner, to be able to fully support PIs, and to prevent any duplication of effort, the hospital will need to formally engage further with TCD and others, and should now revisit and expand upon the existing Affiliation Agreement / Memorandum Of Understanding. SJH will need to work with the TCD "Research Task-Force", TTMI, and the Dublin Midlands Hospital Group Executive Management Team, to build upon the previous work of Trinity Health Ireland. An engagement plan will need to be drawn up, and preparation done to identify linked priority items for discussion. Some of the key related issues include patient access, sponsorship and insurance, contracts, journal access, statistical support, grant management and overheads, staff affiliation status, and intellectual property (ownership sharing, researcher reward, disclosure of IP and permission to publish, patenting, defence, licensing and spin-out).

SECTION 4

4.1 Future Direction

After the execution of this framework, the next phase from 2020 onwards may consider working towards the expansion of the R&I Programme Office, to relocate and aggregate certain research staff (particularly administrative staff), moving from the current decentralized model to a "shared services" model, facilitating the utilization of expertise more broadly across clinical areas. This could allow for the provision of more hands-on support to PIs (administration, data management, grant application submission, protocol design, research methods, study initiation and feasibility studies), as well as training. Other considerations could include the facilitation of protected time for staff to engage in research projects, increased optimization of resource usage, the development of tailored KPIs, internal audit, and an examination of bio-banking requirements.

SECTION 5

5.1 Summary

In summary, this 3-year hospital research framework focuses on the development of structures and process to facilitate research excellence, and aims to increase the quantity of high impact research activity and output, by addressing the issues of oversight, support and promotion.

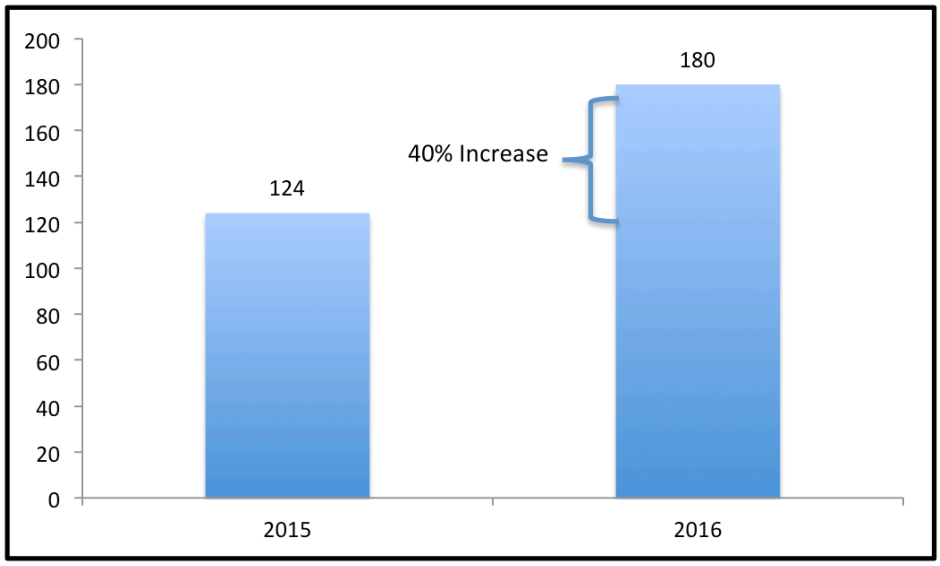
Execution within the objective areas will be facilitated by a supporting governance structure, based on the development of policy and implementation plans, starting with Financial Governance (specifically, a study micro-costing exercise) and Research Approval, and then followed by Support and Communication. A complimentary facet will include the reconfiguration of existing R&I committees, and the expansion of the R&I Office. In parallel, issues of collaboration and further PI support will be addressed through formal institutional engagement with the hospital's academic partner and through the Hospital Group.

References

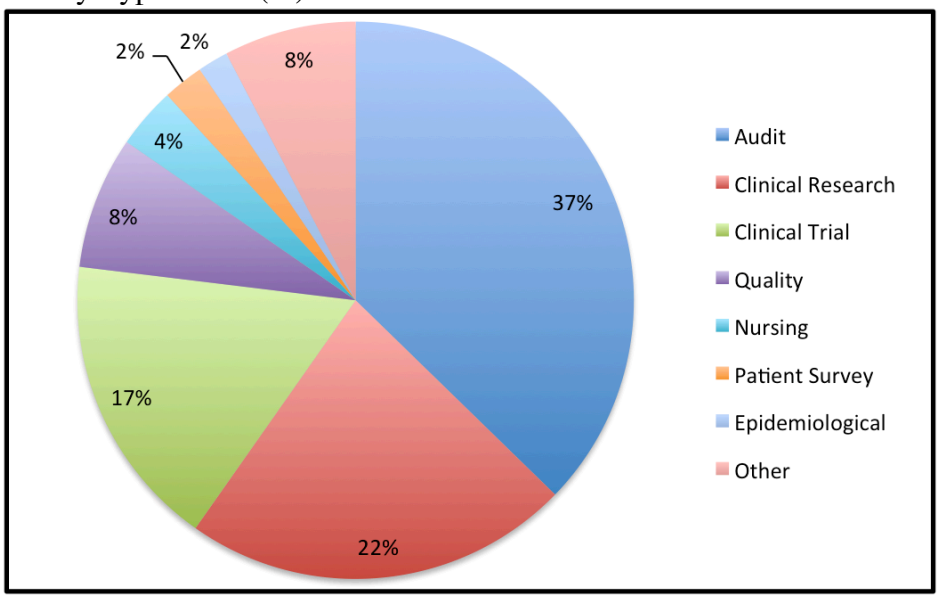
1. Ozdemir et al PLOS ONE, Feb 2015 – 'Research Activity and the Association with Mortality' – Recent NHS trust data published in public access journal.
2. Majumdar et al, JAMA Arch Int Med 2008; 168(6): 657-662 'Better Outcomes for Patients Treated at Hospitals that Participate in Clinical Trials'.

Appendix I

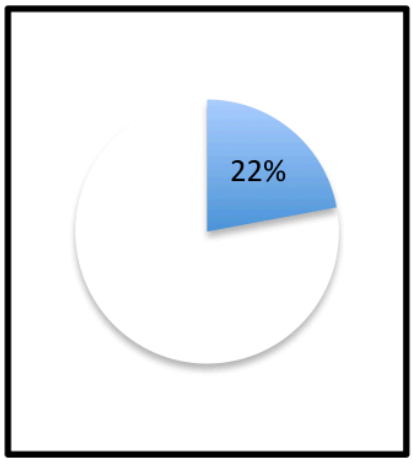
Research Submissions Received 2016 (No.)



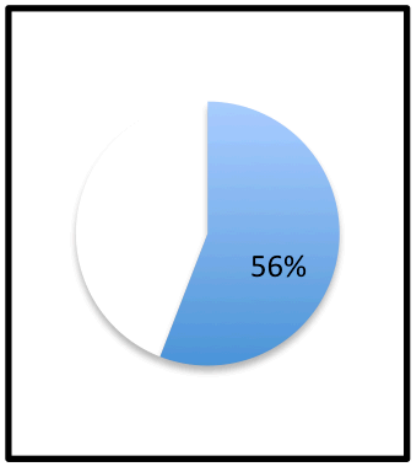
Study Types 2016 (%)



CRF Studies 2016 (%)



Ethics 2016 (%)



Funded 2016 (%)