Achieving Excellence in Clinical Research

The Way Forward

Research Strategy Document

2009-2014
<table>
<thead>
<tr>
<th>Reference Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>FINAL Version 1.0</td>
</tr>
<tr>
<td>Name of responsible (ratifying) committee</td>
<td>SMT</td>
</tr>
<tr>
<td>Date ratified</td>
<td>January 2011</td>
</tr>
<tr>
<td>Document Manager (Job Title)</td>
<td>Anoop Chauhan Director Research</td>
</tr>
<tr>
<td>Date issued</td>
<td>January 28th 2011</td>
</tr>
<tr>
<td>Review Date</td>
<td>January 2012</td>
</tr>
<tr>
<td>Electronic location</td>
<td></td>
</tr>
<tr>
<td>Related Procedural Documents</td>
<td></td>
</tr>
<tr>
<td>Key Words (to aid searching)</td>
<td>Research Clinical Trials R&amp;D Strategy</td>
</tr>
</tbody>
</table>
Contents

Foreword ..................................................................................................................5
Executive Summary .................................................................................................6

Introduction .............................................................................................................7

The purpose of this strategy document...............................................................7
How this strategy has been developed.................................................................7
About Portsmouth Hospitals NHS Trust...............................................................7
Why should Portsmouth Hospitals be involved in Clinical Research? .............8
Who should be involved in delivering Clinical Research in Portsmouth Hospitals NHS Trust?.................................................................11
What sort of Clinical Research should we be undertaking at Portsmouth Hospitals NHS Trust?.........................................................................................12

Where we are now ..................................................................................................13

Where we want to be & how we are going to get there .................................14

Our Vision .............................................................................................................14
Our Mission ............................................................................................................14
Our Plan ................................................................................................................14

Our Goals ..............................................................................................................15

GOAL 1: Embed Research ..................................................................................16
GOAL 2: Increase Opportunity, Participation, & Performance .......................18
GOAL 3: Develop Capability, Capacity & Infrastructure ..................................20
GOAL 4: Improve Standards ..............................................................................22
GOAL 5: Maximise Benefits ..............................................................................24

References ............................................................................................................26
Glossary ..................................................................................................................28
Appendices A-E: .................................................................................................29
Foreword

Research was one of the founding principles of the NHS and it has remained a core function ever since, and will remain so even as we move into a new era for the NHS.

There are many examples of how this research has led to advances in the diagnosis, treatment and prevention of disease, and has made the NHS an unparalleled place for health research in the 21st century. There is also good evidence that health research in the UK makes a significant contribution to the wealth of this nation.

Portsmouth plans to make a significant contribution to research in the NHS.

The Executive Team and Board of Portsmouth Hospitals NHS Trust are fully committed to create an environment to enable all health professionals to conduct research in Portsmouth as both leaders and collaborators, and to provide patients with increased opportunities to participate in cutting-edge research. However, a co-ordinated and organised Research Strategy, taking into account new funding opportunities from the National Institute of Health Research, Research Councils and Charities, and other opportunities of collaboration with Universities and pharmaceutical companies is required to deliver on these ambitions.

This document sets out our strategy, which was originally written following the first Research Away Day in 2008, but since developed and co-ordinated by our Research Department with workshops and meetings with key stakeholders.

It confirms the determination of the Trust to succeed in research by identifying 5 strategic goals and related objectives that will ensure Portsmouth is recognised as a centre of research excellence, improves research capacity and capability by retaining and rewarding the best health professionals, improves systems of research governance and engages in research that is focused on patients leading to improved local health and care.

This research strategy can only be successful with the support and commitment of our research staff and patients (and we thank them for their efforts of the past and in our future endeavours), so we can ensure our delivery matches the promise.

I hope that upon reading this Strategy that you too are able to contribute to the legacy of research in the new NHS.

Ursula Ward
Chief Executive
Executive Summary

Key Messages

• Clinical research is critical to the NHS; to advancing our knowledge and to the development of health care.

• The public and patient benefit from a thriving and innovative research culture is evident in real clinical gains.

• Participating in research is a quality driver and reflected in the NHS Constitution. The benefits of this participation extend from direct patient care, to staff satisfaction and economic reward, which are crucial in the current climate.

• The National Institute for Health Research (NIHR) recognises that there must be a strong commitment to clinical research in the UK, and the past few years have seen a significant investment and dramatic increase in research infrastructure.

• Participating in clinical research is in our local interests as an NHS organisation, and we have a duty to contribute.

• Portsmouth Hospitals Trust is committed to a fully integrated clinical research strategy, for which every staff member is responsible.

• This strategy document aims to make explicit our strategic intentions for the development of clinical research in Portsmouth and our Vision for the future.

• This document sets out our Vision, Mission and five Strategic Goals with associated objectives, to ensure we can meet our aims.

Our Goals are:

• Goal 1: To Embed Research
  Integrate a comprehensive research strategy into Trust culture, policies and practice

• Goal 2: To Increase Opportunity, Participation and Performance
  Maximise patient participation in high quality, funded, NHS-focused research

• Goal 3: To Develop Capability, Capacity and Infrastructure.
  Develop an expert workforce and clinical research infrastructure

• Goal 4: To Improve Standards
  Establish effective Research Management & Governance (RM&G) Systems to ensure quality, safety and regulatory compliance

• Goal 5: To Maximise Benefits
  Maximise the clinical and economic benefits of research and research innovations.
Introduction

The purpose of this strategy document

The purpose of this document is to state explicitly the Trust’s commitment to Clinical Research over the next five years, and to set out our Vision of excellence for the future. This document also outlines how we expect to achieve our specific goals and become a thriving research active organisation by April 2014.

How this strategy has been developed

This strategy has been developed in response to national reforms for health research (1), and our local desire for a clear way forward to drive and embed research into our Trust’s culture.

This strategy takes into account national directives and aims to reflect these; whilst considering the local landscape and addressing our challenges, priorities and needs. In January 2008 an away day was held with key stakeholders to identify our Strengths, Challenges, Opportunities and Threats, and from this our strategic plans were formulated.

This revised document is an updated presentation of this original work. Our primary key initiatives for delivery shall be identified and documented separately, on an annual basis, via the Trust's business planning process.

About Portsmouth Hospitals NHS Trust

Portsmouth Hospital NHS Trust is one of the largest acute hospital trusts in the country. We provide a full range of emergency and other care services to more than half a million people.

The Trust employs over 6,000 people, provides specialist and tertiary services and, following completion of a new hospital build, some of the best hospital facilities in the South. Our teams have a good track record in innovation and we are an organisation firmly committed to high quality care and excellence for our patients.

Adapted from p.4 PHT Annual Report 2009-2010 (2)
Why should Portsmouth Hospitals be involved in Clinical Research?

We believe that high quality research is fundamental to our interests as an NHS care organisation; that we have a duty to contribute; and that our patients, staff and trainees should be given every opportunity to participate wherever possible. This reflects our core values and is an aim of the National Institute for Health Research (NIHR)

“The NIHR is committed to working with clinicians and managers in NHS Trusts to make sure that patients are aware of opportunities to take part in research relevant to them, and have the necessary information to make informed choices on whether to participate.” (3)

Participating in Clinical Research reflects our key values as a Trust and is important to us because:

- It is the generation of new Knowledge. This knowledge informs our decision-making around the best care options for our patients, and helps us to find answers to everyday clinical questions.

- It builds local expertise and informs our clinical teams about their patients, as well as how new interventions, techniques and innovations work early on in their development.

- It motivates both our staff and our patients. It promotes a commitment to excellence and a drive to do well. Patients who engage in the research process often have a greater sense of purpose; and a quality research culture attracts high quality staff (4)

- It encourages reflective practice and challenges how we do things; promoting collaboration, partnerships and the transfer of knowledge across organisations and professional groups

- It is income generating and sustainable; contributing to the provision of cutting-edge facilities, and to the improvement of our clinical capacity.
Patient & Public Benefit

UK scientists and health professionals are “responsible for a wide range of medical advances, including discovering antibiotics, laying the foundations of molecular biology, inventing CT scanning, and pioneering mammalian cloning.”

Our knowledge and understanding of the causes of ill health and what works best to prevent and treat it can only be advanced through the investment of our time and resources in research. Clinical research is the means by which evidence is generated to inform and change our clinical practices, and is the foundation upon which great progress has been made with respect to health improvement. There is also some emerging evidence that patients do well simply by taking part in a clinical research study.

Patient and public benefit is therefore the greatest reason to support research delivery in Portsmouth Hospitals NHS Trust.

‘60 years of research in the NHS benefiting patients’

1948–1958
Lung cancer and smoking
The dangers of bed rest

1959–1968
Hip replacement
Palliative care and the modern hospice movement

1969–1978
The Glasgow Coma Scale (GCS)
The world’s first IVF baby

1979–1988
Detecting osteoporosis using ultrasound
A genetically engineered vaccine for hepatitis B

1989–1998
Preventing recurrent miscarriage
Joining up the dots to save premature babies

1999–2008
Bioengineering heart valves
**The NHS Constitution**

A Trust’s commitment to high quality clinical research delivery is “a driver for improving the quality of care and the patient experience.” (8) And is clearly documented in both the NHS Constitution (Jan 2009) (9) and NHS Operating Frameworks (Dec 2009) (10)

These policy and operational requirements to support research have been explicitly outlined in a letter from The Director General of Research & Development to all Chief Executives in July 2009, and are summarised in the table below. In her letter (11), Dame Professor Sally Davies reiterates the policy statements and urges Trust’s to set goals for their research, against which annual progress and performance should be reported to Trust Boards. Trusts must also measure and report key performance indicators annually in their Quality Accounts, and our first report can be seen in Appendix E

---

**Research and Innovation in the NHS**

| The NHS | NHS Constitution  
NHS commitment to the promotion and conduct of research  
NHS Operating Framework  
NHS must play its full part in supporting research; National ambition to double the number of patients in clinical research |
| --- | --- |
| Strategic Health Authorities | NHS Operating Framework  
SHAs to ensure that NHS trusts work with NIHR Clinical Research Network locally to contribute to the increased numbers of patients in clinical research |
| Primary Care Trusts | Duty to Promote Innovation  
SHAs to support NIHR Clinical Research Networks locally; SHAs to develop the capacity of the NHS to support research |
| NHS Providers | NHS Operating Framework  
All providers to increase their participation in research  
Quality Accounts  
All providers to report on the number of patients in clinical research |
| NHS Patients | Handbook to NHS Constitution  
The NHS will do all it can to ensure that patients are made aware of research that is of particular relevance to them |

Economic Gains

Despite the current downturn in our economic climate we are assured that clinical research delivery continues to be supported by the new coalition Government. But perhaps it is precisely because of this climate that we should be focussing our efforts on maximising the benefits from a fully integrated clinical research strategy and improving our ability to compete and perform well.

“The coalition Government’s White Paper, Equity and excellence: Liberating the NHS, provides strong support...The White Paper also makes timely reference to the importance of research in times of constrained resources: ‘Research is even more important when resources are under pressure – it identifies new ways of preventing, diagnosing and treating disease. It is essential if we are to increase the quality and productivity of the NHS and to support growth in the economy’ (Equity and excellence, July 2010, p.24).”

A paper entitled “Medical Research: what's it worth?“, presents the findings of research aiming to quantify this financial gain using investments in Cardiovascular Disease (CVD) and Mental Health Research as a starting point. The results are striking:

“Bringing the various strands of the study together, and accounting for sensitivity analyses around the different estimates, the team’s best estimate for the total health and GDP returns from public and charitable CVD research, for the period 1975–92, is around 39%.

In other words, a £1 investment in public/charitable CVD research produced a stream of benefits thereafter equivalent to earning £0.39 per year in perpetuity. The best estimate for the combined health and GDP gains from mental health research is 37%.”

Our participation in clinical research should therefore not only have a positive impact on the health of the public and our patients, but it should also have an impact on the wealth of our country and, from a local perspective, on our Hospital services.

Who should be involved in delivering Clinical Research in Portsmouth Hospitals NHS Trust?

We believe that contributing to research is core business for Portsmouth Hospitals NHS Trust and that every Clinical Service Centre and Department should be involved in delivering our Vision.

Whilst there are individuals who may not lead research, there should be support from all staff members towards the national and local effort. This may mean undertaking specific research roles and responsibilities, or simply providing support for colleagues who are engaged in the research process; it is nevertheless our intention to ensure Trust-wide participation.

“Increasingly, it is recognised that research is not just something that should concern clinicians and that evidence-based practice should extend to management and policy making.”

Research Strategy
FINAL Version 1.0, January 28th 2011
What sort of Clinical Research should we be undertaking at Portsmouth Hospitals NHS Trust?

**Patient and People-Based Research**

The generation of new knowledge sits firmly within a complex and inter-related framework of innovation, translation, development, evaluation and implementation.

The pathway below is taken from the NIHR website to show the sorts of knowledge-based activities that are directly funded by the Institute and its partner organisations. However, if we take the NIHR to represent research for the NHS, this pathway also highlights how the NHS is primarily concerned with taking basic science and translating it into tangible benefits for patients; using experimental and other methods to bring innovations “from the bench to the bedside and back again”

The Trust is therefore interested above all, in more applied, “Patient and People based” clinical research which will make a difference to the way that we do things in Portsmouth.

http://www.nihr.ac.uk/research/Pages/default.aspx
Where we are now

Portsmouth Hospitals NHS Trust is primarily a large care organisation but one that has shown considerable past commitment to research (13). Since the introduction of the NIHR and ring-fenced funding for research delivery, we have increased activity, capacity and workforce significantly.

Research currently sits within the Corporate Division as a Clinical Standard, and is part of the Medical Director’s Executive portfolio. The Director of Research is responsible for the strategic direction and governance of all research activities, with accountability for core research office staff, and the performance management of those Trust employees who are working on research. Reports are provided to the Governance and Quality Committee, every six months.

The Trust works in close collaboration with the Hampshire and Isle of Wight Comprehensive Local Research Network (HIOW CLRN) and local Topic Specific Research Networks, which form part of the National Clinical Research Network for England, whose aim is to: “ensure that patients and Health Care Professionals, from all parts of the country, are able to participate in and benefit from clinical research” (14).

Over the past two years a number of successful awards have been secured from the Hampshire and Isle of Wight Comprehensive Local Research Network (HIOW CLRN), to fund key front-line posts across the Trust, which has increased our capacity to recruit patients into studies that are adopted onto the National Institute for Health Research (NIHR) Portfolio. This is in addition to an annualised activity-based budget, which has grown by 500%.

Please refer to Appendices A-E for more summaries of where we are now:

- Appendix A: An Organisational Chart;
- Appendix B: A Summary of all Trust Posts currently supported with NIHR Funding;
- Appendix C: PHT Research Permission Times against Target;
- Appendix D: PHT Research Activity Summary 2009-2010
- Appendix E: PHT 2009 Quality Accounts

Number of Patients Recruited into NIHR Portfolio Studies

<table>
<thead>
<tr>
<th></th>
<th>2008-2009</th>
<th>2009-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>901</td>
<td>4018</td>
</tr>
</tbody>
</table>

NIHR/CLRN Income to Portsmouth Hospitals NHS Trust*

<table>
<thead>
<tr>
<th></th>
<th>2008-2009</th>
<th>2009-2010</th>
<th>2010-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income</td>
<td>£388,000</td>
<td>£950,000</td>
<td>£1,976,000</td>
</tr>
</tbody>
</table>

*Excludes grant awards and commercial income
Where we want to be & how we are going to get there

Our Vision

Our Vision is to be a nationally recognised centre of clinical research excellence, which will improve the health and wealth of our patients in Portsmouth.

Our Mission

Our mission is to innovate, translate, collaborate and participate; embracing quality research that matters to the needs of our patients and the public, and providing sustainable and effective research services.

Our Plan

We plan to create a thriving quality research culture and operational research capability, which ensures in 5 years time:

- That we are a provider of choice for research sponsors and funders
- That we can bring increased opportunities to our patients and our staff

The following document sets out 5 strategic goals with plans for how we intend to achieve them over the next 5 years.
## Our Goals

<table>
<thead>
<tr>
<th>GOAL 1: To Embed Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrate a Comprehensive Research Strategy into Trust Culture, Policies and Practice</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GOAL 2: To Increase Opportunity, Participation &amp; Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximise and Sustain Patient Participation in High Quality, Funded, NHS-Focused Research</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GOAL 3: To Develop Capability and Capacity &amp; Infrastructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop an Expert Workforce and Clinical Research Infrastructure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GOAL 4: To Improve Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish Effective Research Management and Governance (RM&amp;G) Systems to Ensure Quality, Safety and Regulatory Compliance.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GOAL 5: To Maximise Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximise the Clinical and Economic Benefits of Research and Research Innovations</td>
</tr>
</tbody>
</table>
GOAL 1: Embed Research

Integrate a Comprehensive Research Strategy into Trust Culture, Policies and Practice

To achieve this goal, we will:

1.1 Create effective and clearly defined lines of accountability to the Trust Board for research; its management, governance, delivery and performance.

1.2 Create accountability for the strategy within Clinical Service Centres, departments and across professional groups; performance managing their commitment to research, and key strategic initiatives against specified targets.

1.3 Ensure that Research is represented at appropriate committees and working groups across the Trust.

1.4 Have visible and accessible core Research Services.

1.5 Develop a comprehensive communications strategy for Research in Portsmouth Hospitals NHS Trust and ensure that any improvements made towards our strategic goals are widely promoted across the Trust.

1.6 Actively engage Service Users, Patients and the Public to contribute to the Trust’s research delivery, ensuring that improved involvement is reported and performance is managed at Clinical Service Centre level.

1.7 Ensure that clinical research activities feed and support the Trust’s strategies for innovation, development and evaluation; i.e. that new innovations are researched appropriately and effectively; that innovations from research are developed and maximised; and that new knowledge is generated, which has an impact on clinical practice.
In 5 years time, we will:

- Have all staff “thinking research”, when considering their patient’s care pathway.
- Have all departments and specialties engaged in the research process and making a Trust-wide contribution to the research effort.
- Have all professional groups participating in research; for example more Nurses, Allied Health Professionals and Managers.
- Have more Trust policies, which are aligned to the national research plan.
- Have improved Patient and Public involvement in research projects, strategies, policies and processes.
- Have improved staff satisfaction through contributions to a research active organisation.
- Have clinical research fully aligned with the Trust’s innovation, development and evaluation strategies.
GOAL 2: Increase Opportunity, Participation, & Performance

Maximise and Sustain Patient Participation in High Quality, Funded, NHS-focused Research

To achieve this goal, we will:

2.1 Identify, target and support Trust staff and Clinical Departments with the skills and capabilities to secure external funding from recognised NIHR portfolio partners.

2.2 Create Clinical Research Leads within specialty groups / departments with responsibility for the promotion, development and delivery of clinical research activity.

2.3 Prioritise and focus our efforts and resources on areas where there is existing capability, expertise, local need and potential performance.

2.4 Improve study set-up, opening more UKCRN portfolio and other high-quality studies quickly and efficiently.

2.5 Ensure study permission times meet nationally agreed targets.

2.6 Capture, monitor and performance manage participant recruitment at all levels (monitoring against a specified target).

2.7 Identify any blocks to recruitment and facilitate their resolution.

2.8 Promote Trust facilities and expertise as a Research Service.

2.9 Utilise the expertise and support of key partners in creating opportunities and driving performance. Key partners include: the NIHR Research Design Service; Clinical Research Networks; Clinical Trials Units; Biomedical Research Units; Academic, Commercial and Charitable Collaborators; Local NHS Organisations; Patients and the Public.

2.10 Translate local basic science expertise into clinical research opportunities and outcomes for the Trust.
2.11 Ensure that the resource and cost implication of “other” non-portfolio, non-commercial research activity ¹ is financially justified and in line with national priorities, and/or those local needs identified in the Trusts Clinical Service Centre strategies.

In 5 years time, we will:

- Have more patients, across specialty areas, being given the opportunity to take part in NIHR Portfolio studies, and improve the numbers of patients participating in them.
- Have more clinical departments and specialties participating in NIHR portfolio studies.
- Have more ‘own-account’ Portsmouth studies adopted onto the national NIHR portfolio.
- Have more NIHR portfolio studies open to recruitment.
- Have more collaboration with industry partners.
- Have more collaborative formalised, visible programmes of research with (academic) partners.
- Have at least 50% of our studies, which are open to recruitment, delivering to their recruitment and timeline targets.
- Have more research opportunities translated from the basic sciences.
- Have more individuals citing research opportunities as a reason for their wanting to work at Portsmouth Hospitals NHS Trust.

¹ “Other” research might include un-funded projects as part of training posts or programmes (e.g. SpR, PhD/MD and post/undergraduates), or projects funded by non-portfolio sources, for example internal charitable funds.
GOAL 3: Develop Capability, Capacity & Infrastructure

Develop an Expert Workforce and Clinical Research Infrastructure

To achieve this goal, we will:

3.1 Define and increase our operational research capability.

3.2 Apply for funding to support the creation of new research jobs and facilities within the Trust.

3.3 Utilise income (NIHR Flexibility and Sustainability Funding / Activity-based funding and income generation) to support emerging research, clinical researchers and research infrastructure.

3.4 Create Clinical Research Leads within professional groups and specialities that have responsibility for the support, promotion, development, and delivery of clinical research activity amongst their peers.

3.5 Work closely with academic partners to create opportunities for new clinical academic posts and research fellowships.

3.6 Formalise and structure all research roles and responsibilities across the Trust defining job descriptions / plans for those staff directly engaged in delivering high quality clinical research.

3.7 Reward and recognise those staff involved in high quality clinical research and research innovations.

3.8 Develop and manage the competencies of staff engaged in the research process, providing training opportunities at all levels.

3.9 Ensure that all research staff appraisals include input from individuals with appropriate research expertise.

3.10 Promote the NIHR research careers pathway \(^{15}\), supporting individuals who show commitment, expertise and potential.

3.11 Develop work-based learning opportunities for all healthcare professionals engaged in research.

3.12 Develop capacity and capability within support departments, such as Pharmacy, Radiology, Pathology and Cardiology.
3.13 Ensure that research experience and expertise is considered as part of the Trust's HR selection processes.

3.14 Centrally co-ordinate Trust research facilities and expertise to ensure they are fit for purpose and to identify and resolve any blocks to research.

**In 5 years time, we will:**

- Have a published Operational Capability Statement for research, which demonstrates quality co-coordinated, and competitive research services.

- Have more staff with protected time for funded research duties as part of their job role or their job plan.

- Have more Principal Investigators from across professional groups.

- Have more members of the NIHR faculty (Senior Investigators, investigators and associates).

- Have more NIHR research awards.

- Have more staff trained and demonstrably competent to deliver research.

- Have improved, “fit for purpose”, and dedicated research facilities.

- Have better, cutting-edge resources for research and innovation.

- Have more Research Leaders / Chief Investigators and more research grant awards.
GOAL 4: Improve Standards

Establish Effective Research Management and Governance (RM&G) Systems to Ensure Quality, Safety and Regulatory Compliance

To achieve this goal, we will:

4.1 Identify and address any weaknesses in the Trust’s Research Management and Governance systems, which may prevent compliance with UK regulations or recognised standards of quality and safety.

4.2 Set out clearly the standards and procedures for good practice in research, making them accessible to all staff and research teams.

4.3 Ensure that all policies and procedures are monitored, peer-reviewed and kept up-to-date on an annual basis.

4.4 Develop clinical research training opportunities to ensure that all staff and research teams are able to conduct research in accordance with Trust policies and procedures and SOP’s, and that this training is recorded.

4.5 Develop systems for the monitoring and audit of research activities; ensuring that corrective action is taken where necessary and those lessons are learned.

4.6 Ensure all RM&G systems are as effective and efficient as possible, and proportionate to risk.

4.7 Ensure that NHS permission times meet nationally agreed targets.

4.8 Ensure that core research services are transparent, visible, accessible and facilitative.
In 5 years time, we will:

- Have evidence of improved standards of good practice in clinical research across the Trust.
- Have systems in place which will ensure that the Trust is compliant with current UK legislation governing clinical research activity for both sponsored and hosted research activities.
- Have improved patient experience of clinical research in Portsmouth.
- Have improved confidence amongst patients, staff, research funders and sponsors with regards to the standards of clinical research in Portsmouth Hospitals NHS Trust.
- Have minimised the likelihood of clinical incidents related to research.
- Have no critical findings from an MHRA inspection.
- Have minimised the likelihood of Serious Breaches related to Clinical Trials of Investigational Medicinal Products (CTIMPS).
- Have increased the numbers of staff trained in Good Clinical Practice (GCP) in research.
GOAL 5: Maximise Benefits

Maximise the Clinical and Economic Benefits of Research and Research Innovations

To achieve this goal, we will:

5.1 Ensure that our research is primarily focused on the priorities and needs of our patients and clinical services.

5.2 Prioritise and support research, which clearly sets out its potential for a tangible impact on patient care.

5.3 Monitor how our research findings have improved knowledge and affected service delivery.

5.4 Support innovation, ensuring that developments are captured, researched, and further developed to bring tangible improvements to our patients.

5.5 Translate the results of our research activities into practice developments and clinical gains.

5.6 Ensure that all of our research activity is published and thus contributing to the knowledge base.

5.7 Ensure that all research innovations are protected and effectively managed and exploited.

5.8 Ensure that all income from research and research innovations is managed within a comprehensive financial and intellectual property management framework.

5.9 Ensure that any surplus income generated through research and research innovations is used to sustain, support and expand priority driven clinical research activity and infrastructure.
In 5 years time, we will:

- Have increased the tangible impacts of our clinical research and research innovations, on patient care.
- Have increased knowledge transfer and numbers of publications in high-impact, peer reviewed journals.
- Have an effective financial management framework for research and research innovations.
- Have more income from research and research innovations.
- Have more research, innovation and clinical initiatives realised through the investment of income generation.
References

(1) National Institute for Health Research (NIHR); Accessed November 2010: http://www.nihr.ac.uk/Pages/default.aspx


(4) SDO Network Briefing Paper: Being a Good Research Partner: The Virtues and Rewards. NIHR. Oct 2010

(5) Mckinsey Report. Clinical Research in the UK: *Towards a single system that reliably delivers distinctive quality and rapid access at reasonable cost.* August 2005

(6) Sumit R. Majumdar, MD, MPH; Matthew T. Roe, MD MHD; Eric D. Peterson, MD MPH; Anita Y. Chen, MS; W. Brian Gibler, MD; Paul W Armstrong, MD (2008) ‘Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials’ *Arch Intern Med*, 168 (6), p657-662.

(7) 60 years of research in the NHS benefitting patients, NIHR. June 2008


(14) NIHR Clinical Research Network Coordinating Centre, Accessed November 2010 http://www.crncc.nihr.ac.uk/

(15) Research Training and Career Development. Version 1, NIHR. August 2010
http://www.nihr.ac.uk/files/pdfs/Briefing%20documents/2.2%20Research%20Training%20and%20Career%20Development.pdf
Glossary

ABF Activity Based Funding
Accrual Participants Recruited (Number)
CEO Chief Executive Officer
CLRN Comprehensive Local Research Network
CTIMP Clinical Trial of an Investigational Medicinal Product
CRN Clinical Research Network
CSP Co-ordinated System for Gaining NHS Permissions
CTUs Clinical Trials Units
DeNDRoN Dementia & Degenerative Diseases Network
DH Department of Health
FsF Flexibility & Sustainability Funding
GCP Good Clinical Practice (Research)
HIOW CRLN Hampshire & Isle of Wight Comprehensive Local Research Network
MHRA Medicines & Healthcare Products Regulatory Agency
NIHR National Institute for Health Research
PA Programmed Activity
PHT Portsmouth Hospitals NHS Trust
Portfolio Portfolio Research Eligible for Support from the NIHR
R&D Research & Development
RDS Research Design Service
RfPB Research for Patient Benefit Research Programme
RM&G Research Management & Governance
SDO Service Development & Organisation
SHA Strategic Health Authority
SOPS Standard Operating Procedures
SPR Specialist Registrar
Sponsor Organisation responsible for the Governance of a piece of Research
UKCRC UK Clinical Research Collaboration
UKCRN UK Clinical Research Network
WTE Whole Time Equivalent
Appendix A:

Organisational Chart (Jan 2011)
Research Strategy

FINAL Version 1.0, January 28th 2011
## Appendix B:

**Numbers of PHT Posts with NIHR Funded Research Time (by Specialty)**

<table>
<thead>
<tr>
<th>Professional Group</th>
<th>Specialty Area</th>
<th>Numbers (WTE or PA)</th>
<th>2008-2009</th>
<th>2010-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Scientists</td>
<td>Radiology</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical Physics</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic/Radiology</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Research Technician</td>
<td>Respiratory</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td>Pharmacists</td>
<td>Cancer</td>
<td></td>
<td>0.5 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic (TBA)</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>Generic (TBA)</td>
<td></td>
<td>1.0 WTE</td>
<td>1.0 WTE</td>
</tr>
<tr>
<td>Pharmacy Clerk</td>
<td>Generic (TBA)</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td>Research Dietician</td>
<td>Renal</td>
<td></td>
<td>0.2 WTE</td>
<td></td>
</tr>
<tr>
<td>Research Midwife</td>
<td>Reproductive Health &amp; Childbirth (TBA)</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td>Nurse Researchers</td>
<td>Age &amp; Ageing</td>
<td></td>
<td>0.2 (WTE)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Musculoskeletal</td>
<td></td>
<td>0.2 (WTE)</td>
<td></td>
</tr>
<tr>
<td>Research Nurse Manager</td>
<td>Generic</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td>Research Nurses</td>
<td>Cancer</td>
<td></td>
<td>4.4 WTE</td>
<td>6.55 WTE</td>
</tr>
<tr>
<td></td>
<td>Gastro</td>
<td></td>
<td>0.5 WTE</td>
<td>1.0 WTE</td>
</tr>
<tr>
<td></td>
<td>Cardiology</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Critical Care</td>
<td></td>
<td>1.9 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dementia &amp; Neurodegenerative Diseases</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Emergency Medicine</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td></td>
<td>1.4 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Musculoskeletal</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Neonates</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ophthalmology</td>
<td></td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renal</td>
<td></td>
<td>1.2 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reproductive Health (GUM)</td>
<td></td>
<td>1.5 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Respiratory</td>
<td></td>
<td>0.2 WTE</td>
<td>1.0 WTE</td>
</tr>
<tr>
<td></td>
<td>Stroke</td>
<td></td>
<td>0.5 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medicines for Children</td>
<td></td>
<td>0.5 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gynaecology</td>
<td></td>
<td>0.5 WTE</td>
<td></td>
</tr>
<tr>
<td>Professional Group</td>
<td>Specialty Area</td>
<td>Numbers (WTE or PA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td>----------------</td>
<td>---------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2008-2009</td>
<td>2010-2011</td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>Cancer</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cardiovascular</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Critical Care</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dermatology</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(TBC)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ear Nose and Throat</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(TBC)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gastroenterology</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic/Health Services research (GUM)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infectious Diseases</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medicines for Children</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Musculoskeletal</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nervous System Disorders</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(TBC)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ophthalmology</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reproductive Health (GUM)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Respiratory</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stroke</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Surgery</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Specialty Area Leads (Medical)</td>
<td>Diabetes</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renal</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DENDRON (DMOP)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Research Director</td>
<td>Generic</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Research Facilitator</td>
<td>Diabetes</td>
<td>1.0 WTE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic</td>
<td>1.0 WTE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Manager</td>
<td>Cancer</td>
<td>1.0 WTE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Administrator</td>
<td>Generic</td>
<td>0.5 WTE</td>
<td>1.0 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Musculo-Skeletal</td>
<td>0.5 WTE</td>
<td>0.6 WTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Critical Care</td>
<td>0.6 WTE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Governance Officer</td>
<td>Generic</td>
<td>2.0 WTE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Manager</td>
<td>Generic</td>
<td>1.7 WTE</td>
<td>1.2 WTE</td>
<td></td>
</tr>
</tbody>
</table>

**NB:** This table excludes other research staff funded by research grant awards, charitable funds or commercial income.
Appendix C:

NHS Permissions: Approval Timelines against Target

A chart to show PHT median study approval times (from SSIF to study permissions letter) for projects submitted through CSP (Co-ordinated System for NHS Permissions). Taken from the HIOW CLRN Organisational Recruitment Report, November 2010

![Chart showing NHS Permissions Approval Timelines against Target]

Chart 5 illustrates the percentage of studies that have taken 40 days or less (goal) from SSIF to NHS Permissions Letter issued as at (06/12/2010). Data from 2009/10 is compared to quarter 1 and 2 for 2010/11 to monitor improvement.
### Appendix D:

**Research Activity Summary: Reported In the PHT Quality Account 2009-2010**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>New Projects Submitted to PHT R&amp;D</td>
<td>76</td>
<td>114</td>
<td>50%</td>
<td>Unknown</td>
<td>69 (61%)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Total Projects Approved to Start</td>
<td>41</td>
<td>74</td>
<td>80%</td>
<td>20</td>
<td>49 (66%)</td>
<td>145%</td>
</tr>
<tr>
<td>Total Projects Ongoing</td>
<td>207</td>
<td>243</td>
<td>17%</td>
<td>104</td>
<td>142 (57%)</td>
<td>37%</td>
</tr>
<tr>
<td>Active/Open to Recruitment</td>
<td>112</td>
<td>179</td>
<td>60%</td>
<td>52</td>
<td>98 (55%)</td>
<td>88%</td>
</tr>
<tr>
<td>In Active Follow-Up</td>
<td>50</td>
<td>49</td>
<td>-2%</td>
<td>45</td>
<td>44 (90%)</td>
<td>-2%</td>
</tr>
<tr>
<td>Completed</td>
<td>45</td>
<td>15</td>
<td>-67%</td>
<td>9</td>
<td>1 (7%)</td>
<td>-89%</td>
</tr>
<tr>
<td>Accrual Target</td>
<td>Unknown</td>
<td>1281</td>
<td>Unknown</td>
<td>Unknown</td>
<td>1081 (84%)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Actual Accruals</td>
<td>Unknown</td>
<td>3268</td>
<td>Unknown</td>
<td>901</td>
<td>3136 (96%)</td>
<td>248%</td>
</tr>
</tbody>
</table>

**Ongoing Projects by Funding Category**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial not for Commercial Gain</td>
<td>21</td>
<td>20</td>
<td>-5%</td>
<td>14</td>
<td>14 (70%)</td>
<td>0%</td>
</tr>
<tr>
<td>Commercial Contract</td>
<td>23</td>
<td>32</td>
<td>39%</td>
<td>0</td>
<td>8 (25%)</td>
<td></td>
</tr>
<tr>
<td>Charity</td>
<td>63</td>
<td>79</td>
<td>25%</td>
<td>48</td>
<td>67 (85%)</td>
<td>40%</td>
</tr>
<tr>
<td>DH</td>
<td>28</td>
<td>37</td>
<td>32%</td>
<td>14</td>
<td>25 (68%)</td>
<td>79%</td>
</tr>
<tr>
<td>Other Government</td>
<td>2</td>
<td>1</td>
<td>-50%</td>
<td>1</td>
<td>1 (100%)</td>
<td>0%</td>
</tr>
<tr>
<td>Research Council</td>
<td>21</td>
<td>21</td>
<td>0%</td>
<td>19</td>
<td>21 (100%)</td>
<td>5%</td>
</tr>
<tr>
<td>Unfunded/Student Work</td>
<td>19</td>
<td>20</td>
<td>5%</td>
<td>0</td>
<td>0 (0%)</td>
<td>0%</td>
</tr>
<tr>
<td>University Funded</td>
<td>9</td>
<td>10</td>
<td>11%</td>
<td>3</td>
<td>3 (30%)</td>
<td>0%</td>
</tr>
<tr>
<td>Unfunded</td>
<td>8</td>
<td>10</td>
<td>255</td>
<td>0</td>
<td>0 (0%)</td>
<td>0%</td>
</tr>
<tr>
<td>Other Funding</td>
<td>13</td>
<td>13</td>
<td>0%</td>
<td>5</td>
<td>3 (23%)</td>
<td>-40%</td>
</tr>
</tbody>
</table>

**NB:** Since this data was published the total PHT accruals have been reported as actually **4018**
Appendix E:

Trust Quality Accounts 2009-2010 (Research)

The number of patients receiving NHS services provided or sub contracted by Portsmouth Hospitals NHS Trust in 2009/2010, that were recruited during that period to participate in research approved by a research ethics committee, was 3268. Of these, 3136 were recruited into 142 studies adopted onto the National NIHR Portfolio; compared with 901 patients from 104 Portfolio studies ongoing in the previous year (an increase in accruals of 248%). 100 were recruited into non-Portfolio studies (NB: it should be noted that systems for recording non-portfolio activity are under-developed and that the accuracy of non-Portfolio accrual data will improve over time).

There has been a general increase in research activity in Portsmouth Hospitals NHS Trust during 2009/2010, and the Research Department has seen a 50% rise in applications submitted; an 80% increase in the numbers of projects approved; a 60% increase in the numbers of projects open to recruitment during the year and an 88% rise in NIHR Portfolio studies open and in the active phase. In total Portsmouth Hospitals NHS Trust has participated in 243 ongoing research projects during 2009-2010, showing a steady 17% improvement on April-March 2008-2009.

This increasing level of participation in clinical research demonstrates Portsmouth Hospitals NHS Trusts’ commitment to improving the quality of care we offer and to making our contribution to wider health improvement. Our research activity spans across all of the clinical divisions and there is commitment from the Trust Board, Research department, clinical specialities and professional groups, that patient participation in high quality research must be supported. Active promotions of the NIHR Portfolio database and improvements in research capacity and infrastructure have been key strategic objectives, which have been successfully under-pinned with external funding from Hampshire and Isle of Wight Comprehensive Local Research Network (HIOW CLRN). In addition Portsmouth Hospitals is lead organisation for 16 studies ongoing within 2009-2010; has secured 2 NIHR ‘Research for Patient Benefit’ grants; and is a co-applicant on a large prestigious grant award from the Medical Research Council.

Portsmouth Hospitals NHS Trust has used national systems in the research governance and management of studies in proportion to risk; which includes governance checks using NIHR standard operating procedures; national model template agreements; national costing templates for industry sponsored Portfolio research; and national guidance for the (HR) management of external researchers and use of the NHS research passport.