Ashford and St. Peter's Hospitals NHS
NHS Foundation Trust

TRUST BOARD
27th January 2011

TITLE	**Terms of Authorisation:** **Research & Development Department- Quality Assurance**
EXECUTIVE SUMMARY	As part of the Terms of Authorisation the Board needs to confirm to Monitor that there is sufficient capacity to carry out research in the connection with the provision of healthcare. The Trust has well established Research Management and Governance (RM&G) System in place. The Research & Development Department (R&D) uses the National Institute for Health Research Coordinated System for gaining NHS Permission for approving research studies. The Trust's R&D Team is led by high profile researchers and clinicians. The Trust is a member of the Surrey and Sussex Comprehensive Local Research Network and has the second highest recruitment of patients into clinical studies.
BOARD ASSURANCE (RISK)/ IMPLICATIONS	Robust management of research is important as this is a formal requirement of the Trust's Terms of Authorisation.
STAKEHOLDER/ PATIENT IMPACT AND VIEWS	There is a patient representative as well as representatives from the University of Surrey and Royal Holloway University of London on the Trust R&D Committee
EQUALITY AND DIVERSITY ISSUES	None known
LEGAL ISSUES	None known
The Trust Board is asked to:	Confirm the arrangements for research and development and agree that a formal letter is submitted to Monitor requesting authorisation for the continuation.
Submitted by:	Prof Jeremy Wright, Director R&D Clinical Director Obs & Gyn, Dr Isaac John, R&D Manager, Dr Martha Wrigley, Clinical Trials Manager On behalf of Dr Mike Baxter, Medical Director
Date:	10 January 2011
Decision:	For Approving

Ashford and St. Peter's Hospitals NHS
NHS Foundation Trust

TRUST BOARD
27th January 2011

Research & Development Department- Quality Assurance

1 BACKGROUND

As part of the Terms of Authorisation , the Trust Board is required to provide written confirmation to Monitor that the Board has confidence that:-

- The Trust has the capacity and capability to carry our research in connection with the provision of healthcare;
- That all relevant authorisations with respect to carrying out said research have been secured;
- That the said research will be carried out in accordance with generally accepted ethical standards; and
- That the said research will not inhibit the provision by the Trust of the mandatory goods and services referred to in schedule 2 of the Authorisation.

2 RESEARCH AND DEVELOPMENT AT ASHFORD AND ST PETER'S HOSPITALS NHS FOUNDATION TRUST.

The mission of the department is to establish a research culture in the Trust which supports all our staff who participate in national and international clinical trials, and conduct high quality research in areas of local and national importance.

3 Research Management and Governance (RM&G) System:

The Trust has a well developed Research Management and Governance System in operation. The Research and Development (R&D) Department is using National Institute for Health Research Coordinated System for gaining NHS Permission (NIHR CSP – see attached leaflet) for approving commercial and NHS funded trials.

All local research proposals are scrutinised by the Trust R&D Committee and given conditional approval. The major role of this Committee is to provide expert advice to improve the quality of research proposals. The Investigators are asked to take on board the R&D committee's comments and to revise their research proposals accordingly. Revised proposals are then submitted to the NHS Research Ethics Committees (REC) for ethics approval.

After ethics approval, all REC approved documents are collected and governance checks are carried out before granting final approval to the Investigators. The Trust has e-database (ReDA) for logging all research studies.

4 Research Projects:

The Trust has generally 3 kinds of research projects:

1. **Commercial Trials:** Drug and Devices trials funded by

pharmaceutical and devices manufacturers

2. **UKCRN Trials** – Trials adopted by the UK Clinical Research Network
3. **Student & Local Research Projects:** Research carried out by Trust staff and visiting researchers for education and service improvement

5 R&D Department:

Dr Mike Baxter, Medical Director, is the Executive Director responsible for R&D in the Trust. Profiles of the top R&D Team are given below which clearly demonstrate that the Trust has very capable and high profile staff providing leadership in this area.

Prof Jeremy Wright MD FRCOG, Director R&D:

Professor Jeremy Wright MD FRCOG is Director of Research and Development at ASPH NHS FT, a position he has held since this became an NHS requirement. He has held a consultant appointment at ASPH (formerly St Peter's Hospital) since 1985. At the Trust he has served on various committees and is now Clinical Director for Women's Health for a third term.

He has a track record of research leading to publication in peer review journals and holds a visiting chair in the Postgraduate Medical School, University of Surrey where he is the clinical director of the MSc in Advanced Gynaecological Endoscopy. He has lectured and published widely on endometriosis a gynaecological condition in which there is ectopic endometrium like tissue scattered through the pelvis. He has been awarded both the Bair-Bell lectureship (RCOG) and the Alec Turnbull lectureship (BSGE).

Nationally he has served as an officer of the medico-legal society, the British Society for Gynaecological Endoscopy (President 2007-9) and as section president Royal Society of Medicine

Dr Isaac John PhD, R&D Manager

Dr John is R&D Manager at Ashford and St Peter's Hospitals NHS Foundation Trust and Honorary Lecturer at Royal Holloway, University of London. Dr John has more than 10 years of teaching and research experience in molecular genetics at the Nottingham University, UK and the University of Michigan, USA. He was full-time lecturer at Exeter University. He has 15 publications in peer-reviewed journals, 2 book chapters and 3 patents with the University of Nottingham. Dr John worked in R&D at the Department of Health and he was member of a team responsible for launching Genetics Knowledge Parks, Genetics Reference Laboratories and the UK Bio-bank project. Dr John has recently developed web-based Good Clinical Practice (GCP) course (www.gcptraining.org.uk) for clinical trial investigators.

Dr Martha J Wrigley PhD RN, Clinical Trials Manager

Dr Wrigley is Clinical Trials Manager at Ashford and St Peter's Hospitals NHS Foundation Trust, and is currently seconded, part-time, to the Surrey & Sussex Comprehensive Local Research Network as Senior Lead Research Nurse. She is an Honorary Research Fellow at the University of Surrey and a Visiting Fellow at the University of Brighton. She has over ten years experience of clinical trials, witnessing and being a part of the many changes which have

occurred during the last decade. Her PhD looked at primary prevention for heart disease, and the development of health promotion clinics for people at high risk of developing cardiovascular disease. She has 8 publications in peer reviewed journals and is currently working on two, research for patient benefit applications, with the University of Surrey. She is an accredited GCP trainer, facilitating on the NIHR, highly acclaimed, GCP course.

6 Research and Development Strategy

The Trust has a Research and Development Strategy which was agreed by the Trust Executive Committee in September 2009. This includes 7 strategic goals.

Goal 1: Restructure Research and Development Department

Goal 2: Establish an R&D Research Fund, pooling income generated from all research activities

Goal 3: Develop profit sharing system from commercial trials among stake holders

Goal 4: Strengthen and develop research capacity across specialities

Goal 5: Enhance public engagement and increase two to three fold participation in research

Goal 6: Strengthen links

Goal 7: Increase two to three fold income from commercial and non-commercial sources

The Trust Board received a presentation from the Research and Development team in July 2010 which highlighted progress against these objectives.
Good progress was demonstrated on all aspects.

7 Assurance

The Research and Development Committee forms part of the Trust's overall governance structure and reports to the Clinical Governance Committee. Further assurance is then given to the Integrated Governance and Assurance Committee via the annual report from the Clinical Governance Committee.

8 Impact on NHS Services

All research investigators have to fill out Site Specific Information (SSI) on Integrated Research Application System (IRAS) which is reviewed by the R&D to assess capacity issues and impact on services in the Trust. Reviewed and modified SSI is then signed off by the relevant Divisional Director to make sure that care of NHS patients is not compromised.

9 SUMMARY

The Trust has robust arrangements in place underpinning its approach to research

UKCRN
UK Clinical Research Network

NHS
National Institute for Health Research

Network Coordinating Centre

Introducing a new system which will provide a consistent and streamlined process for gaining R&D permission in the NHS in England

National Institute for Health Research Coordinated System for gaining NHS Permission (NIHR CSP)

The **National Institute for Health Research Coordinated System for gaining NHS Permission (NIHR CSP)** is a system for gaining permission from NHS organisations to undertake clinical research, which will initially be available to studies that fall within the NIHR Clinical Research Network Portfolio.

What will the new system do?

- **Reduce the duplication** in the NHS review process
- **Provide a single point** to which sponsors and investigators need to apply for NHS permission to start multi-site and single site studies
- **Ensure clarity regarding the roles and responsibilities** of sponsors, investigators, Clinical Research Networks and NHS Trusts

What are the benefits of NIHR CSP?

NIHR CSP will bring significant benefits. These will include:

- A **single national system** that fully satisfies all governance and regulatory requirements
- A **single point of entry** for approvals
- A **standardised process** by which investigators will gain NHS permission
- **Reduced bureaucratic burden** particularly for multi-site studies
- **Reduced time to gain approvals** which fully satisfy all governance and regulatory requirements
- A **high quality process** coordinated nationally through the NIHR CSP Unit and locally through Comprehensive Local Research Networks

How will NIHR CSP work?

NIHR CSP:

- Builds on best governance practice being used in the NHS R&D management community
- Establishes time targets for key stages
- Defines and carries out checks that only need to be done once
- Minimises the administrative burden placed on researchers
- Ensures that researchers obtain all the necessary approvals prior to commencement of their study
- Will be accessed by investigators through the Integrated Research Application System (IRAS) to provide a single point of application

NIHR CSP will be conducted in accordance with national Operating Procedures that clearly define which governance checks are global (undertaken once only per study), which are local (undertaken at every participating site) and who is responsible for carrying them out.

Who is leading the development of NIHR CSP?

The NIHR Clinical Research Network Coordinating Centre is leading on the development of NIHR CSP on behalf of the National Institute for Health Research (NIHR) and in collaboration with key partners such as the UK Clinical Research Collaboration, the National Research Ethics Service, the NHS R&D Forum, the Association of the British Pharmaceutical Industry and researchers.

What are the timescales for implementation?

NIHR CSP will be implemented during 2008. It will initially be available to studies that fall within the NIHR Clinical Research Network Portfolio and will be compatible with similar systems being developed in Northern Ireland, Scotland and Wales.

How can I find out more?

Further information is available on the UKCRN website at **http://csp.ukcrn.org.uk**

or by emailing **csp@ukcrn.org.uk**

For more information about related developments, such as the Integrated Research Application System (IRAS), visit the UKCRC website at **www.ukcrc.org**

or the NIHR website at **www.nihr.ac.uk**

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