West Hertfordshire Hospitals NHS
NHS Trust

TRUST BOARD MEETING – 27 May 2010

Title of the Paper:	**Research and Development Briefing**
Agenda item:	**66/10**
Author:	**Colin Johnston, Medical Director**
Trust Objective:	**Patient Safety**

Key issues

Report on current arrangements for the delivery of research and development within the Trust

Purpose

To provide a briefing to the Board

Risk Implications for the Trust (*including any clinical and financial)*	**Mitigating Actions** *(Controls):*
Failure to deliver research and development in the expected manner will potential put the Trust at risk in terms of patient safety and reputation	The Trust has a research and development steering group to oversee the systems and processes and to advise the Medical Director

Level of Assurance that can be given to the Trust Board from the report [significant, sufficient, limited, none]:

Significant

Links to Key Line of Enquiry (KLOE 1 - 5)
N/A

Legal Implications:
None noted at this time

Recommendation to the Trust Board:
The Trust Board members are asked to:

- note this initial briefing on R&D related matters
- agree that reports will be made to future meetings of relevant and important issues affecting the Trust's R&D agenda including a new R&D Strategy for the Trust

West Hertfordshire Hospitals NHS
NHS Trust

Agenda No. 66/10

Public Board Meeting, 27 May 2010

Research & Development Briefing

Presented by: **Colin Johnston, Medical Director/Director of Patient Safety**

1. Purpose

This is the first time that the Trust Board has considered a paper on Research and Development activities in the Trust. The purpose of this paper is to provide a briefing on the national policy requirements in research and development and the development of research activities within the Trust.

Research and Development is seen as an important part of continual clinical improvement within the Trust. Participation in R&D studies enables the Trust to play a role in the way in which medical practice may change in the future and provides a platform for individuals with specific interest to further their clinical knowledge and practice.

2. National Context

In 2006, the Department of Health (DH) published a R&D Strategy 'Best Research for Best Health' which set the direction for NHS R&D to ensure a vibrant, world-class environment for conducting NHS health research. The Strategy set out the following strategic aims:

- To establish the NHS as an internationally recognised centre ofresearch excellence
- Attract, develop and retain the best research professionals toconduct people-based research
- Commission research focused on improving health and care
- Strengthen and streamline systems for research management and governance
- Act as sound custodians of public money for public good.

The profile of R&D has increased over the period since the publication of the Strategy. In 2009 the DH wrote to all Trust Chief Executives to remind them of their responsibilities as set out in recent policy statements. Specifically The NHS Constitution and associated Handbook confirms the commitment of the NHS to the promotion and conduct of research and states that the NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them. The NHS Operating Framework says that the NHS must play its full part in supporting health research and that all providers of NHS care

will need to increase their participation in research and should continue to increase their level of participation and performance in hosting research funded by non-commercial and commercial research funders. The national ambition is to double the number of patients taking part in clinical trials and other well-designed research studies within five years. As part of Quality Accounts, NHS providers should include the number of patients recruited to clinical research and SHAs are expected to ensure that NHS Trusts work with the National Institute for Health Research (NIHR) Comprehensive Clinical Research Network locally to contribute to this progressive increase

In May 2009 the Government published its Response to Review and Refresh of Bioscience 2015. In this document it said rather than asking each Trust to designate a Board member to take responsibility for research, the DH believes that it would be more effective for Trusts to set goals for research within their organisation and report on their achievement at least annually to the Board and in their annual report. It further indicated that it would be writing to Trusts in order that they set goals for research in their organisation, publish the average time taken for the local research approval process to be completed and ensure that they use the NIHR Coordinated System for gaining NHS permission and not to develop unnecessary additional activities or bureaucracies locally. To date the DH has not issued anything on the above, however, arrangements are being made within the Trust to comply with these requirements on the basis that they will be required to do so at some point in the future.

3. REGIONAL RESEARCH INFRASTRUCTURE

As part of the reorganisation of R&D infrastructure nationally local R&D networks were established in 2008. The NIHR Comprehensive Local Research Network (CLRN) consists of a number of locally managed CLRNs which support participation in the national portfolio of NIHR CRN studies. They have responsibility for:

- establishing and funding an excellent clinical research infrastructure to support a high quality portfolio
- facilitating patient participation
- providing the NHS service support costs which previously came through other NHS R&D funding streams
- providing and deploying resources for research management in order to ensure that the research portfolio is delivered to the highest standards of research governance.

The Trust is a member of the Essex and Hertfordshire CLRN (E&H CLRN) which has membership agreements in place with all the 17 NHS Trusts (acute, primary care, mental health) in Essex and Hertfordshire to ensure that research which has been adopted on to the NIHR CRN Portfolio is locally managed in accordance with the regulatory framework and national procedures issued by NIHR CRN. All of our R & D staff have both CLRN and Trust roles.

The CLRN Board has encouraged all Trust Boards to have regular reports to its public Board meetings in order that there is a greater understanding of the work of both the CLRN and local non CLRN R&D activities. Data is produced by the CLRN which it is hoped Trust Boards will consider and review. Within West Hertfordshire there is an R&D Steering Group which will, in addition to its current remit of overseeing the progress with and participation in R&D will also review data from the

CLRN and, through reports from the Medical Director, will report to the Trust Board any issues of importance requiring the Trust Board's attention.

4. RESEARCH AT WHHT

4.1 Structure

Across Hertfordshire the CLRN and Trust based R&D functions are managed as a single unit. The current arrangement is that the West Hertfordshire Trust R&D Manager also provides this function for East and North Hertfordshire Trust. She is supported by a small team who provide input across both Trusts.

4.2 Activity:

The Department of Health's R&D Strategy funds the support and governance of portfolio research. However, should Trusts wish to engage in non-portfolio research, the management and governance of such activity is outside the funded remit of the UKCRN and the CLRNs and is the responsibility of the NHS Trust.

Researchers at WHHT currently participate in 40 portfolio and 3 commercial research studies as well as a number of studies outside these two categories [e.g. student research, pilot studies].

Patient recruitment into UKCRN portfolio studies has risen dramatically over recent years:

2007/8	299
2008/9	371
2009/10	617 – well exceeding our target of 445

Researchers at WHHT maintain beneficial relationships with a number of universities, particularly the University of Hertfordshire

4.3 Funding

Support funding for our portfolio research via the CLRN is:

- Clinical/Non-clinical Delivery staff £154,628
- Service Support £274,000
- Research Management & Governance £ 70,433
- Training/Travel/Corporate Administration £ 25,861

Total funding: £524,922 paid in quarterly instalments

4.4 MHRA Inspection

The Medicines and Healthcare Products Regulatory Agency (MHRA) notified East and North Hertfordshire Trust of a routine GCP inspection in August. The inspection visit took place in December. The R & D systems are consistent across both Trusts and therefore the lessons learnt will apply equally to West Hertfordshire Trust. It is likely that West Hertfordshire will have an inspection any time within the next 2 years.

The inspection went well with no critical findings. Feedback from the inspectors was positive, particularly relating to research staff training. Formal feedback has been sent and we have responded.

The preparation for the inspection however has highlighted a number of issues throughout both Trusts that will require an action plan in addition to the MHRA response. These include:

- The need for better oversight of research teams
- More monitoring and audit of study documentation
- Documented audits of support departments [this was an MHRA finding]
- Documented logs of freezer contents, temperature logs, back up and alarm systems
- Equipment maintenance contracts and logs throughout all areas in the Trust
- Review and update of contracts and Service Level Agreements (SLAs)
- Some amendments to policies, Standing Operating Procedures (SOPs)s and standardisation of support department policies where possible

5. Action Required

The Board is asked to note this initial briefing on R&D related matters and to agree that reports will be made to future meetings of relevant and important issues affecting the Trust's R&D agenda including a new R&D Strategy for the Trust.

Colin Johnston
Medical Director
May 2010