



***National Institute for
Health Research***

Dismantling the barriers to clinical research

30th April 2009, The Wellcome Trust, London

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Summary

74 senior researchers, funders, regulators, NHS and University leaders and managers and representatives of NIHR and the Department of Health worked together to:

- Identify the current barriers to clinical research
- Review the work being done to reduce barriers and
- Suggest the agenda for action needed now.

There was broad agreement on a number of themes:

- The frustrations caused by the often lengthy and costly processes of obtaining approvals for clinical research and the damaging impact on studies and on the appetite of clinicians and others to undertake research
- In many cases, the significant delay and cost related to inconsistent and excessively risk-averse interpretation of policies and rules by R&D offices
- The delays and costs associated with complying with particular research governance vary widely from one study and institution to another
- The absence in many parts of the NHS of adequate professional research management to support researchers in overcoming obstacles
- The significant progress that has been made in streamlining the process for ethical approvals - though inconsistencies in application remain
- The promise represented by the Coordinated System for gaining NHS Permissions ('CSP') and by the Comprehensive Local Research Networks – though some of the benefit of these developments has yet to feed through fully at the local level
- The need for MHRA and others to adapt the regulatory approach to take more account of the level of risk of different studies
- The need to provide incentives for senior NHS managers to support research
- The need for more standardized costs of treatment and research

Agenda for action

The workshop identified the following points:

Action	Responsibility	Next step and timing
1. Rename and reconfigure R&D offices to be "Research Services Support Units" providing the necessary professionalized support for researchers		
2. Develop a programme of education and training for research support managers and staff to equip them to provide strong support to researchers		
3. Set national standards and processes for research support		
4. Develop national accreditation of Research Services Support Units		
5. Develop the coordinated system for gaining NHS permissions ('CSP') and the Comprehensive Local Networks research governance support		
6. Work with NHS management to see how to involve senior managers in supporting research		
7. MHRA to develop risk based approach and tailor inspections to the level of risk		
8. HTA to agree guidelines on national datasets		
9. Encourage the Royal Colleges to increase the research element in clinicians' training and development		

Workshop participants will be approached to support these actions.

The intention is to meet again in one year to review progress and identify priorities for further action.

Principal problems identified by small groups

Problem	Number of groups who focussed on the problem
<ul style="list-style-type: none"> • Trust R&D Offices – Long delays, inconsistencies, lack of leadership, staff, training and standard operating procedures; lack of professionalism; inconsistent interpretation of legislation 	11
<ul style="list-style-type: none"> • Regulators - Inappropriate “one size suits all” approach, regardless of risk and complexity of trial 	6
<ul style="list-style-type: none"> • Ethics - Inconsistency of approach in handling applications. “RECs are generally much improved ... but still some inconsistencies .. and need clear guidelines to avoid over-restrictive interpretation.” 	6
<ul style="list-style-type: none"> • Treatment and research costs - Lack of standardised costings; excess Trust costs 	4
<ul style="list-style-type: none"> • MHRA – “heavy handed, not helpful, threatening <u>but</u> do have a duty to the patient”; “uncertainty regarding the fear of inspection leading to disproportionate Trust reactions.” “Trials office and inspection not joined up.” 	4
<ul style="list-style-type: none"> • Standardised approach - Lack of central access to a common set of paperwork and data 	3
<ul style="list-style-type: none"> • Morale - The demotivating impact of time-consuming and complex approval procedures on current and potential future researchers 	2
<ul style="list-style-type: none"> • Research culture - Lack of support among Trust chief executives and senior managers 	2
<ul style="list-style-type: none"> • Human Tissue Authority – “very conservative, risk-averse procedures”; “broadly proportionate.. but is there need for a national memorandum of understanding?” 	2
<ul style="list-style-type: none"> • NHS R&D offices - risk averse and not facilitating research 	1
<ul style="list-style-type: none"> • Indemnification – lack of guidance; over- 	1

interpretation	
<ul style="list-style-type: none"> • CLRNs acting differently; “some way to go with local operations” of CLRNs 	1
<ul style="list-style-type: none"> • “Research passports not working; not national” 	1
<ul style="list-style-type: none"> • PCTs – “no understanding of R&D”; “unrealistic and unnecessary reporting requirements” 	1

Priorities for action now, as identified by small groups, with suggested approach

- **Risk Assessment and classification**

- Agree simple, common classification of risk
- Consider structured risk assessment approach which enables key risks to be addressed as early as feasible in study life cycle..."
- "MHRA should convene meeting in June 2009"

- **Professionalisation of R&D offices**

- "Move towards consistent interpretation of regulatory frameworks by Trusts" – build up links, networking across organisations
- "Need staff who understand how system fits together"
- "Training service is needed"
- Draw on existing good practice

- **Research Services Units**

- "Re-badge" R&D Departments as "Research Support Services"
- Set up discussions between these units and other stakeholders
- Foster local public debate about the value of research
- Include research admin. and recruitment as quality indicators
- Make CLRN funding dependent on minimum local standards
- NIHR to coordinate development of suite of SOPs for Research Services Units, including costs templates and indemnity;
- Ensure Trusts know what is required in terms of research support and administration

- **Accreditation approach to R&D support**

- Provide for accreditation over 12 months
- Involve users
- High level support and lead
- Set principles that can guide behaviour change

- Link to proper training
- **Education and training of R&D support staff**
 - “Need a road map (see MRC example) of uniform national training”
 - Identify career pathway needs
 - NIHR to develop a national accredited training programme
 - DH to limit funding to Trusts with accredited staff
- **Education and training of researchers and clinicians**
 - Research Science Support to provide training to PIs and CIs
 - Royal Colleges to incorporate research understanding and awareness into clinician training
- **Incentivisation of trusts, CEOs and Research Directors**
 - Change the local ethos – to develop commitment to research
 - Look at the experience of “good and bad” Trusts [supportive or not of research]
 - Meet with CEOs; see how to influence
- **Standardised costing**
 - Devise simple model
 - Use Activity Based Funding
 - Ensure transparency of portfolio administration
- **Access to data and restrictions by NIGB**
 - Ensure data is expected to be used for research
 - Avoid legal misinterpretation
- **Material Transfer Agreements**
 - Need to be standardised; simplified (2 signatures not 6)

- General MTA to signed at time of approval of trial, rather than by each Trust
- Annual report to Ethics Committee accessible to R&D offices

- **MHRA Risk Assessment**

- MHRA and Ethics Committees to consult with the research community to decide how they regulate different levels of risk and make actions proportionate to the risk
- Less confrontational style from MHRA Inspectors; more pre and post inspection support

- **PCTs**

- Consider whether PCTs need to have any research governance function. Could these functions be taken over by PCLRNs?

Summary of objectives and agenda of the workshop

Purpose

To identify the specific barriers to clinical research in England and the work that needs to be done now, and by whom, to dismantle them.

Outcomes sought

For researchers, regulators, NHS and university managers and funders to:

- Develop more of a shared understanding of the specific problems that exist
- Understand and learn from the efforts that have been made to overcome the problems
- Identify the priority topics that need to be addressed now
- Agree who will take responsibility for each topic and what the next steps are.

Led by:

Professor Dame Sally C Davies, Director General of Research and Development,
Department of Health

Professor Paul Stewart, Director of Research and Knowledge Transfer, University
of Birmingham

Sir Mark Walport , Director, The Wellcome Trust

Agenda

Part 1 – What are the problems?

Four stories of the current problems:

1. Dr Jeremy Tomlinson, University of Birmingham
2. Dr Simon Gibbs. Hammersmith Hospital
3. Professor Morris J Brown, University of Cambridge
4. Professor Ian Roberts, London School of Hygiene and Tropical Medicine

Table groups consider the priority problems in their experience.

Part 2 – What has been done to reduce the barriers?

Summary of the work done and under way:

- IRAS (Integrated Research Application System) – Janet Wisely
- CSP (Coordinated system for gaining NHS approvals), Research Passports and other Network developments – John Sitzia.
- MHRA – Martyn Ward

Part 3 – What is the agenda for action needed now?

Each table group identifies not more than 3 priority topics.

Part 4 - What work is needed next and who should lead it?

Table groups take one of the priority topics and suggest a way forward for that topic.

Closing comments – Professors Paul Stewart and Sally Davies