Summary of major points in the Academy of Medical Sciences Review - A new pathway for the regulation and governance of health research (Jan 2011)

The report's main recommendation is that the government establishes a new independent Health Research Agency, to coordinate the way health research is regulated and governed. The proposed body would have two major functions:

- to rapidly approve NHS research proposals via a new National Research Governance Service
- to unify the system for ethical approvals

The Academy also recommends changes to the EU Clinical Trials Directive (EUCTD); the way patient data is used in research; and to the culture in the NHS, to better embed research in the way it works.

What criticisms did the Academy make of the current system?

- Slow, unnecessary and risk-averse governance arrangements within NHS Trusts are the single greatest barrier to health research
- There are too many bodies with overlapping responsibilities involved in approvals and permissions often giving conflicting advice on the same research
- We're not taking advantage of the NHS' position as the largest public health service to use recorded patient data for research. This is because of an uncertain legal framework
- NHS managers don't have enough incentives (as they do to deliver immediate healthcare targets) to support health research
- The MHRA's strict interpretation of the EUCTD is hampering clinical trials
- The regulatory and governance environment creates delay, increased cost and low patient recruitment – without enhancing the safety or well-being of patients and the public
- Researchers are partly responsible for delays, not always aware of the regulatory and governance requirements
- Multi-site studies are particularly hampered by NHS Trusts, especially in terms of lengthy negotiation of contracts, duplication of checks and no clear mechanism for an overall agreement to begin the multisite study. Although the Comprehensive Local Research Networks (CLRNs) are meant to undertake global checks just once (for NIHR portfolio studies) the evidence suggests this is not happening and checks are being repeated locally

- Uncertainty about what constitutes a research cost, an excess treatment cost and service support cost continues to delay progress
- The National Research Ethics Service (NRES) has made good progress in streamlining ethics approvals, but ethics guidance is needed for researchers prior to application, and there is potentially unnecessary overlap with other bodies who do ethics assessments e.g. the Human tissue Authority

What will the new Health Research Agency (HRA) do?

- Provide a single point of entry and exit for applications to undertake health research in the UK
- Bring together NIHR and non-NIHR portfolio studies and work with the current IRAS single application system
- Oversee all R&D and ethics assessment and provide a single point of contact for advice on issues arising during the assessment process
- To be created as a new Non-Departmental Public Body

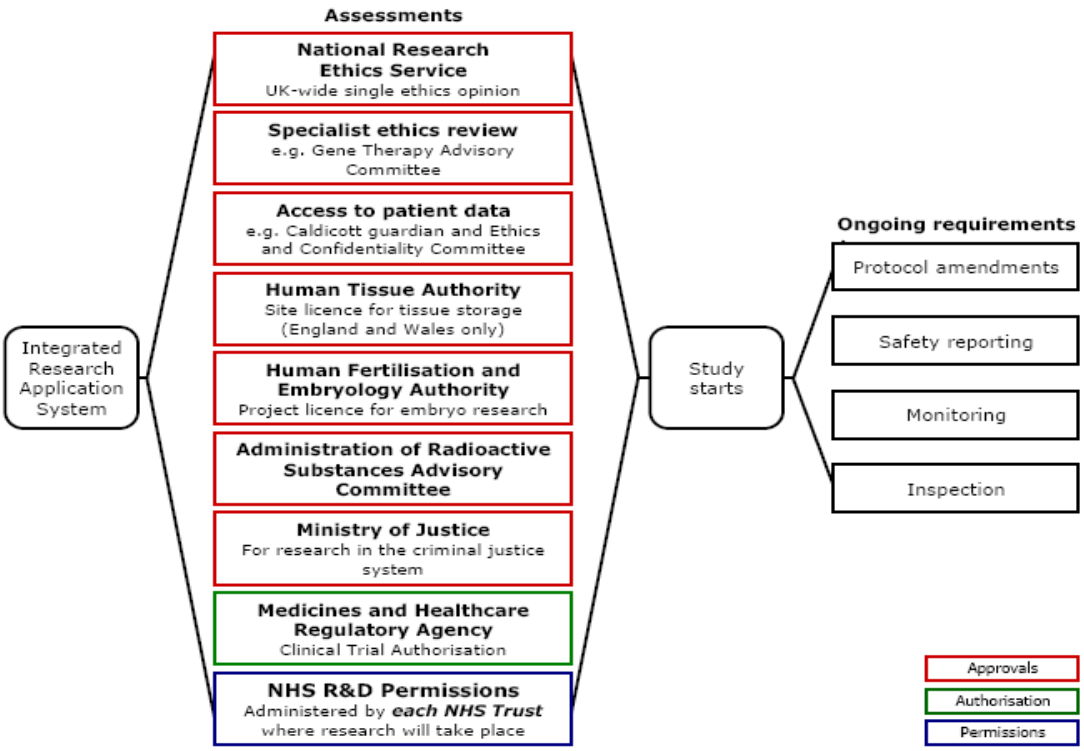
(a) National Research Governance Service (NRGS)

- Will be a new service and key component of the HRA
- Perform all study-wide R&D checks once and recommend studies as suitable for the NHS. NHS Trust R&D offices will be expected to then assess local feasibility and capacity and confirm willingness to participate in the study within 20 days
- Provide model agreements and agreed costing structures for the study – particularly beneficial for non-commercial studies where the main challenges lie
- Provide this service for both NIHR portfolio and non-portfolio studies

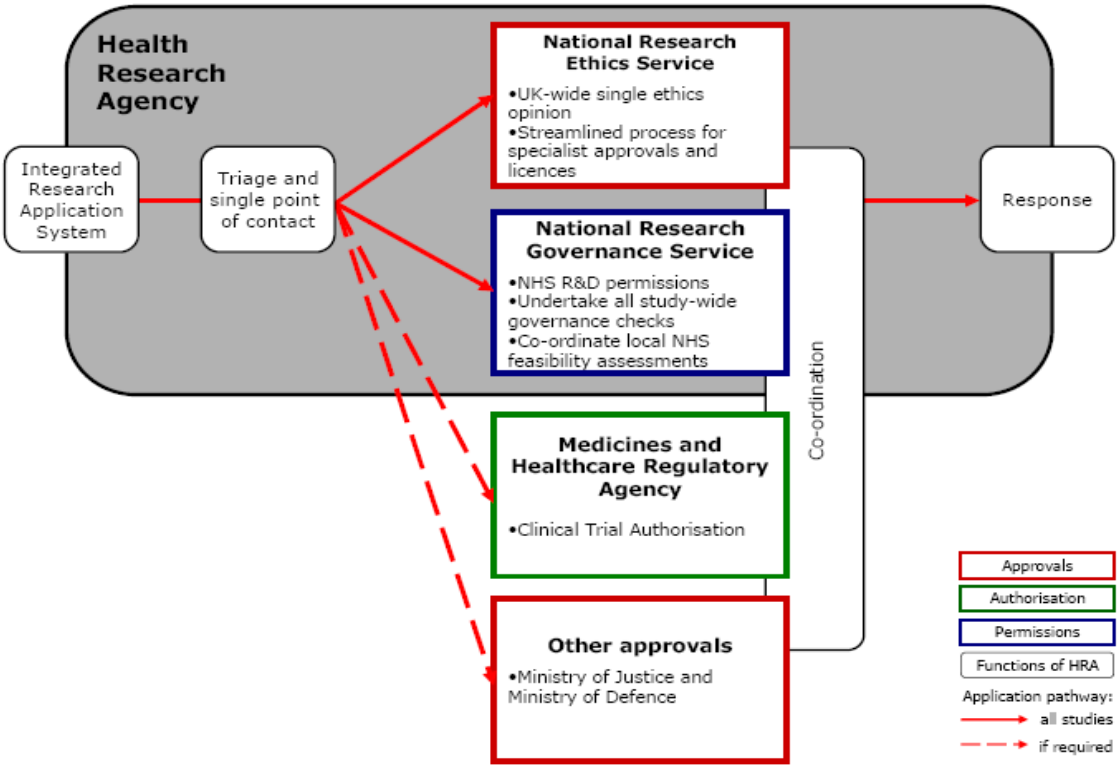
(b) Unified ethical approvals

- NRES will be a key component of the HRA and will continue its existing coordinating function
- The HRA will incorporate the specialist ethical approvals functions which are currently held by other bodies
- The HRA will provide a single ethics opinion on studies

The current pathway



The new pathway



What recommendations are made on the EUCTD?

- The Government and the MHRA should influence the European Commission to revise the EUCTD to ensure that approval and monitoring requirements are more proportionate to risk and simply the requirements to report adverse events
- Before this happens the MHRA should itself adopt a more proportionate approach to regulation, especially when it comes to inspecting Good Clinical Practice in studies (which comes under a lot of criticism for how it is handled)

What recommendations are made on patient data?

- More progress is needed following the Data Sharing Review in 2008
- The Ministry of Justice should produce clear guidance on the interpretation of the Data Protection Act for health research
- In addition a system is needed to allow approved researchers to work with healthcare providers to identify potential patients to be contacted about research studies in which they might wish to participate (the initial contact with the patient would be made by the clinical care team)

What recommendations are made on improving the NHS culture for research?

- More and better information for patients and the public about the role and benefits of health research
- Metrics and indicators of NHS Trust research activity should be developed and included in the NHS Operating Framework
- Each NHS Trust should have an Executive Director responsible for promoting and reporting on research activity
- HCP training should include education on clinical studies

Next Steps

The recommendations have been fully supported by the AMRC, CRUK and the MRC.

Andrew Lansley has welcomed the report and has committed to considering how to implement the recommendations.

The full report is available here http://www.acmedsci.ac.uk/index.php?pid=47&prid=88