Academy of Medical Sciences: Call for evidence on the function and scope of a proposed 'single research regulator'

Response by the Wellcome Trust September 2010

Introduction

1. The Wellcome Trust is a global charity dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.

2. The UK bioscience sector has become increasingly concerned over recent years that regulatory burdens are unnecessarily delaying research and damaging the UK's reputation as a world leader in biomedical research and development. The Trust therefore welcomes the Academy of Medical Sciences' (AMS) call for evidence on a 'single research regulator' as proposed by the Department of Health in '*Liberating the NHS: Report of the arms' length bodies review'* and is pleased to be able to respond to the consultation.

3. **Single Research Regulator:** The key drivers for proposing a 'single research regulator' should stretch beyond reducing administrative costs and reducing the number of NHS bodies. We must also ensure that the UK position as a world leader in medical research is safeguarded. Minimising the number of regulatory burdens and associated costs, whilst maintaining public confidence in the regulatory system, will be key. The Trust therefore supports the principle of a 'single research regulator' if it can deliver the following advantages to the current system:
    - simplified, streamlined approvals system for all medical research involving human participants, their tissue and data;
    - significant opportunity and financial cost savings for researchers, with longer term, ongoing, financial savings for Government;
    - consistency and transparency in decision making, with clear lines of accountability; and
    - a single regulator to champion medical research issues, undertake coordinated horizon scanning and strategic development across medical research.
4. The Trust would not support a 'single research regulator' model which does not achieve the advantages set out above, or address the regulatory burdens to medical research. A single regulator which does not address these issues is liable to have no impact or potentially make worse the regulatory burden on medical research. Therefore our support for a single regulator is limited to a model which encapsulates the elements we have set out in paragraph 5 onwards.
5. **Key Principles for a Single Research Regulator:** We have identified a number of key principles that a single research regulator would need to operate under in order to benefit the medical research environment in the UK:

- **Principles of better regulation**: Any new regulator must take a proportionate, risk based and transparent approach to regulation. It should aim to enable the safe conduct of research, maintain an appropriate degree of checks and balances, meet the highest ethical standards but without introducing additional bureaucracy, while maintaining public confidence.
- **Facilitating research:** Facilitating research to improve human health should be a core aim of any regulator of research. There needs to be a symmetry of regulator and regulated: a regulator should be held accountable for unnecessarily delaying research which could benefit patient safety and improve human health, in the same way that researchers must be held accountable for breaches of confidentiality or causing unnecessary harm to a research participant.
- **Appropriate remit and scope**: A single regulator, comprising the research regulatory functions of existing separate organisations – we estimate at least seven - should have oversight of all of the approvals required for medical research using human participants, their tissue or data to allow a streamlined approach. However, the single regulator does not necessarily need direct involvement in all approvals. It will also be important to clarify its remit in relation to social science-based research, and to ensure a single 'medical research' regulator does not lead to unintended consequences for the regulation of social science research related to health and well-being.
- **Consistent approach**: A single regulator should focus on providing consistent advice, decisions, training and guidance to researchers and ethics committees regarding regulatory requirements and approvals.
- **Minimise the regulatory cost of research:** Formation of a single regulator should provide both opportunity and financial cost savings for researchers. A single streamlined regulatory process for research will minimise both the time and cost associated with approving research so that funds allocated to research can be spent on research itself and not on regulatory processes. A streamlined system should also reduce the opportunity costs associated with the delay to, or failure to undertake, a piece of research. The rationalisation of multiple layers of bureaucracy, approvals processes and reporting requirements should also result in cost savings for Government in the longer term.
- **Effective governance structure:** Any new regulator must have an appropriate governance structure and membership, incorporating an appropriate range of expertise, including from the research community, and also lay person representation.

Proposed model for a single research regulator

6. We have considered a number of possible models for a single research regulator that could encapsulate the principles set out above and also tackle the major barriers to medical research to effectively streamline research regulation and governance. In our response to the AMS first call for evidence[1], we identified the biggest barrier to medical research as being NHS Research & Development Offices (NHS R & D), followed by the need for a more risk based approach to regulation, specifically with regard to the implementation of the European Clinical Trials Directive. The proposed model also addresses these barriers, by including the governance checks undertaken in NHS R & D and clinical trial authorisation administered by the Medicines and Healthcare products Regulatory Agency (MHRA) within the scope of the single regulator.

7. ***Single research regulator with devolved activities:*** Our ideal model for a single research regulator is one constituted of a central body with an advisory and monitoring function, which

[1] http://www.wellcome.ac.uk/About-us/Policy/Consultation-responses/index.htm

grants all approvals and licences, with straightforward approvals devolved to local offices - similar to the current Research Ethics Committees (RECs). These local committees must be wholly accountable to - and monitored by - the central body. The key elements of the single regulatory entity are listed below.

- **Scope:** The single research regulator would cover all regulatory aspects of research involving human participants, their tissue and data in order to effectively streamline regulation. This should include the research remits of the following:
    - Human Tissue Authority (HTA);
    - Human Fertilisation and Embryology Authority (HFEA);
    - National Research Ethics Service (NRES);
    - Administration of Radioactive Substances Advisory Committee (ARSAC);
    - Gene Therapy Advisory Committee (GTAC);
    - The Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care;
    - Medicines and Healthcare Products Regulatory Agency (MHRA); and
    - NHS R & D Offices.

- **Key functions** of a single research regulator should be as follows:
    - approval/licensing of all research involving human participants, their tissue and patient data – either by a local office for straightforward decisions or the central body itself for more complex decisions;
    - development and review of guidance and codes of practice, specific to the remits of the organisations covered above for both researchers and local RECs to ensure consistency;
    - training for researchers and local committees;
    - an appeals function for decisions taken by local RECs;
    - consideration and advice relating to new technologies and novel ethical issues, to be provided to the Department of Health, local RECs and the research community;
    - issue site licences for storage of human tissue;
    - inspection and monitoring of sites holding licences to undertake research;
    - media and communications function to ensure transparency (see paragraph 13); and
    - management and development of the Integrated Research Application System (IRAS).

- **Governance:** The single regulator will report to the Secretary of State for Health. Each local REC will be accountable to the central body, to which it will report periodically. The central body will train and monitor the local RECs to ensure consistency of decision making and monitoring of emerging issues that might need greater scrutiny by the central body. Scientific and ethical expertise will be covered centrally, by expert advisory committees, and will need to encompass the areas of expertise currently covered by the different authorities.

- **Process:**
    - Applications will be received through the Integrated Research Application System (IRAS) as they are currently;

- The central body undertakes triage process similar to the current Central Allocation System of National Research Ethics Service (NRES) and allocates project applications to a local REC[2] or the central body;
- Decisions for project approvals are devolved to local RECs where only 'straightforward' ethical issues need to be addressed;
- For studies involving the use of embryos, gene therapy, stem cell therapy or additional exposure to radiation, and new and emerging technologies where necessary, approvals will be administered through a mechanism in the central body;
- Clinical Trial Authorisations will also be administered within the central body;
- The role of the secretariat for the RECs will be expanded to also cover NHS R & D governance checks where checks are currently duplicated in the approvals process. This should leave the NHS Trust with only its own risk assessment and feasibility study to undertake.

- **Implementation:** This proposed model is substantially based upon the existing IRAS application processes and local REC structures so should not require major upheaval. Expansion to include the NHS R&D governance checks in order to reduce duplication and reduce inconsistencies would require some change, and the local REC secretariat may need additional training and staff.

- **Changes to legislation:** To best capitalise on this opportunity, primary legislation should be reviewed with the aim of 'delayering' and rationalising regulations so that every regulatory procedure has a clearly identifiable purpose and to enable a fully streamlined process.

8. **Inclusion of NHS R & D governance checks:** We recognise that the autonomous nature of NHS Trusts contributes to the difficulties in obtaining approvals for multisite trials. Autonomy must not lead to inefficiencies, and it is therefore essential that a solution is found to ensure NHS Trusts do not duplicate checks, or refuse to accept approvals that are undertaken centrally for the sake of autonomy.

9. **Inclusion of MHRA Clinical Trials Approvals:** The Department of Health Review concluded the MHRA should be retained in its current form, with its two fold functions: it is responsible for ensuring medical products and devices are safe through licensing, and also oversees the implementation of the Medicines for Human Use (Clinical Trials) Regulations. However, in the Trust's response to the first AMS call for evidence, we noted that the MHRA is seen to be risk averse, in not differentiating between academic clinical trials and trials for licensing of medicinal products and devices, and inconsistent in its approach to inspections.

10. We suggest that the clinical trials authorisation process should also be brought under the remit of a single regulator, ensuring a single streamlined process for both industry and academia. Incorporating these approvals within a single research regulator designed to facilitate research and with a good understanding of both academic and commercial research, should provide an excellent environment in which concerns about the lack of a risk-based approach around clinical trial authorisation can be addressed. The positive aspects of MHRA's research function, such as adherence to agreed timescales, must also be maintained. The research community has been very positive about the HTA and the HFEA as regulators. It would be ideal if such regulatory culture could be retained in the new body and applied to clinical trials regulation.

[2] To streamline processes, we would envisage that either the central body would give a single approval for multi-site trials, or one single REC is delegated the authority to approve the trial for all sites, as is currently the process for ethics approval of multi-site trials through the main Research Ethics Committees

11. Two alternative models for a single research regulator are a fully centralised body which undertakes all regulatory functions or a fully devolved system where local institutions self-regulate. However, we do not consider that either model is able to fulfil the principles or efficiencies set out above. The advantages and disadvantages of the other two models are detailed in Annex A.

Additional Issues to be addressed *(full AMS questions in italics)*

What are the possible advantages and challenges of 'placing the responsibilities for different aspects of medical research regulation within one arm's-length body'?

12. *Advantages*: The advantages of a single regulator, if modelled as detailed above are as follows:

    - simplified, streamlined approvals system for all medical research involving human participants and their tissue;
    - significant opportunity and financial cost savings researchers, with longer term, ongoing, financial savings for Government;
    - consistency in decision making, with clear lines of accountability;
    - a single regulator to champion medical research issues, undertake coordinated horizon scanning and strategic development across medical research.

13. *Challenges:* The key challenges in the creation of one single regulator for research will be ensuring the following:

    - that the new body meets the key principles identified above;
    - regulatory procedures are rationalised, so that the regulatory burden upon researchers is reduced and achieves real cost savings and benefits;
    - the new body complements and works closely with the new Public Health Service, Care Quality Commission, Health and Social Care Information Centre and remaining functions of MHRA;
    - the new body is staffed with a high calibre expert advisory board which includes some lay person representation;
    - that current expertise and positive aspects of the existing arms length bodies are not lost;
    - existing bodies that would form part of the single research regulator currently operate on different financial models, for example MHRA operates on full cost recovery basis, whilst NRES is funded by the Department of Health. The funding model for a single research regulator must ensure that its costs are proportionate and affordable for those it regulates;
    - the significant scope of the new body means that there is a risk that it will become a "monster" which must be closely monitored and evaluated.

In addition to granting permissions for research, a range of other functions and powers are currently distributed across several bodies. These related roles include monitoring research projects, inspecting research sites and facilities, public engagement, exploring and preparing for novel ethical issues raised by research, and an 'educational' role in improving the regulatory process and professional standards of research practice. What should be the key functions of a 'single research regulator'?

14. We have set out the functions of the single research regulator above. In terms of any public engagement function, the organisation will need a sufficient communications and media

capacity to ensure that the regulator is transparent; equipped to deal with media and public enquiries; and to maintain public confidence in the regulatory framework. We recommend that the HTA and HFEA are used as models since they have been very effective in dealing with these issues.

How would a 'single research regulator' best fit into the wider regulatory and governance framework? The broad regulatory environment includes, for example, authorities that have a legal duty to approve specific subsets of research, organisations which look to promote best practice in information and research governance, and other bodies that grant permission for research to be undertaken on NHS patients. How might a 'single research regulator' interface with other bodies or approvals to create an efficient and effective environment for public and private sector research?

15. To streamline the approval process for research, we have suggested the incorporation of all the research approval functions from bodies such as the MHRA, the NHS R&D offices and the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board for Health and Social Care within a single research regulator. Such a body could then promote best practice and more efficiently and effectively interface with other bodies such as the Care Quality Commission and Public Health Service. It would also serve to remove the confusion and lack of consistency that can arise when multiple agencies are tasked with regulating a single sector.

The ALB report states there is potential for a single research regulator to have 'wider cross-government reach'. Should the scope of the 'single research regulator' encompass health-related research permissions currently outside the remit of the Department of Health (e.g. Ministry of Defence, Ministry of Justice) or other areas of research affecting health outcomes and public health?

16. Ideally, a new single research regulator would have delegated authority from the Ministry of Justice and the Ministry of Defence to approve research using participants who fall under their remit. Again, this would simplify and streamline the approvals process for researchers, reduce duplication and save money.

Should a new 'single research regulator' have a UK-wide remit and how would this fit with current structures in the devolved nations?

17. The new single research regulator should have a UK wide remit, but it will need careful consideration to ensure the new system works with existing structures in the devolved nations. The existing National Research Ethics Service does not have a UK-wide remit, but has an arrangement with its counterparts in Scotland, Wales and Northern Ireland that means that this is not a barrier. Similarly, Scotland has its own human tissue regulation, however it has delegated the regulatory responsibility to the UK Human Tissue Authority and so a similar approach might work well.

In isolation, the creation of a 'single research regulator' will not deliver an effective regulation and governance system that facilitates advances in medical research and ensures the safety of research participants and the public; what other significant measures are needed to improve the regulation and governance framework for medical research? If relevant, respondents may want to cross-refer to an earlier submission to the AMS review.

18. As noted, a single research regulator which encompasses the HTA, HEFA and ethics committees, as proposed by the Department of Health review, does not address the existing key barriers to undertaking medical research in the UK. For this reason we have suggested including the NHS R&D functions and the research component of the MHRA in our proposed model of a single research regulator.

19. The formation of a single research regulator in isolation will not provide the accountability that would introduce a symmetry between the regulator and those it regulates. Therefore mechanisms must also be put in place to ensure that the regulator is held accountable for unnecessarily delaying research which could benefit patient safety and improve human health.

20. The remaining issue that the Trust identified in its previous submission which is not directly addressed by the provision of a single research regulator is the clarification of processes to facilitate access to patient data. We therefore suggest the single regulator also take on the functions of the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care as they relate to the use of identifiable patient data for research purposes. In doing so, there needs to be much greater clarity about the use of patient data for research, and in particular the processes required for the use of pseudonmyised data and the linking of datasets, and for access to identifiable information to identify people to take part in a trial. Once these processes have been agreed – which should include implementing the recommendations of the Data Sharing Review – the single regulator should, in many cases, be able to devolve authority to local RECs to process straightforward applications, but could still have a role in considering more complex applications for the use of identifiable information where appropriate.

ANNEX A: Alternative models

Fully centralised:

- Responsible for all stages of approvals process for all research applications (i.e. local RECs abolished);
- Would provide advice on issues relating to embryos, tissue, gene therapy, radiation etc.;
- Issue site licences for storage of human tissue (currently required by the Human Tissue Act), and undertake monitoring / inspection required by other legislation;
- A fully centralised model could improve consistency;
- The body would be dealing with a very large number of applications, including those that raise only limited ethical questions which may introduce additional delays;
- Having a single body managing approvals would mean that researchers who want to attend a relevant committee meeting may have to travel a long distance to do so, imposing a significant time burden on these researchers;
- A centralised body would lose any local knowledge in decision making; and
- The model does not address barriers of NHS R&D offices.

Fully devolved:

- All research applications would be devolved to institutions, which would self-regulate, for example through a local committee;
- A central body would be created, but its main functions would be to issue licences for storage of human tissue and to undertake monitoring / inspection required by other legislation;
- The central body would have no role in project approvals, which could lead to a lack of consistency in decision-making;
- Approval of a broad range of issues at a local level would require sufficient expertise in complex issues – for example embryo research and gene therapy - on every committee which may be unfeasible;
- Some researchers have called for more self-regulation. However, this system could lead to difficulties and delays obtaining approvals for multisite studies; and
- Some recognised ethics committees would still be required to fulfil requirements set by current legislation.