Medical Schools Council

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September 2010

Medical Schools Council response to the
Review of the Regulation and Governance of Medical Research – Second call for evidence from the Academy of Medical Sciences on proposals for 'a single research regulator'

The Medical Schools Council represents the interests and ambitions of UK Medical Schools as they relate to the generation of national health, wealth and knowledge through biomedical research and the profession of medicine.

The Medical Schools Council welcomes this second call for evidence as an opportunity to contribute to the Academy of Medical Sciences review of the regulation and governance of medical research. Further to our submission of evidence in June, the Medical Schools Council remains fully supportive of efforts to improve research governance and reduce bureaucracy. Whilst the NHS provides an optimal framework for clinical research, which should provide the UK with a strong competitive advantage, this is currently eroded by the burden of regulation from a multiplicity of regulatory organisations.

The Medical Schools Council is broadly supportive of the principle to create a single research regulator, provided that any streamlining is both risk-based and proportionate. The second call for evidence specifically recognises that "[i]n 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". If it is created, the proposed single research regulator should take into account other initiatives that have been put into practice to improve the quality and integrity of UK research. Any simplification and harmonisation must be carefully managed to ensure the proposed single regulator remains rigorous in safeguarding public funds, continues to protect the quality of UK medical research and ensures the safety and wellbeing of patients and participants.

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

   1.1 The Medical Schools Council is broadly supportive of the principle to create a single research regulator, incorporating the existing work of the NRES, HTA and HFEA. The proposed single research regulator should take into account other initiatives that have been put into practice to improve the quality of UK research. It is important that the proposed ALB adopts a culture of facilitation, with a smaller focus on regulation and policing, and operates to tight timescales.

   1.2 The creation of a single medical research regulator would have the great advantage of removing unnecessary duplication. This would support the Government's aims to help the sector to improve efficiency, save money and further strengthen its international reputation for research. The current complexity of overlapping legislative requirements of different agencies represents a major impediment to research. A single reference point, with a single set of processes, would simplify and speed up the process of carrying out medical research. The creation of a single medical research regulator would enable research staff to know where to access all relevant legislation and documentation, and it would enable training to be focused, for the benefit of interpretation at local and regional level.

1.3 Some of the major challenges relate to the transitional period of creating a single regulator, with new changes and systems likely to increase administrative burden in the short-to-medium term, requiring new training and disrupting current research. The transition would need to be carefully managed in a way which doesn't create an additional layer of administration, and this would need to be introduced over time to ensure that there is no interregnum which paralysed research. It would be essential to identify and transfer the aspects of each regulator that currently work well, and to ensure that organisational knowledge is not lost. Good communication between the regulator and the research community would help to ensure a smooth and transparent transition for procedures.

2. In light of the stated aims in the ALB report, what should be the future of the National Research Ethics Service and the research regulatory activities of the Human Fertilisation & Embryology Authority and Human Tissue Authority?

2.1 The research regulatory functions of the NRES, HFEA and HTA could be merged into a single ALB. It would be advantageous to include the regulation of patient-related data within the same ALB.

3. Research involving human participants, their tissues or data currently involves multiple approvals and regulatory bodies (e.g. granting ethical approval, access to tissue or patient data, and local NHS R&D approval). A schematic representation of some of the approvals involved is provided in Annex II. Which approvals or 'permissions' should be within the remit of a 'single research regulator' to maximise its effectiveness and impact?

3.1 Any streamlining will need to be risk-based and proportionate, such that low risk research can be progressed rapidly without excessive documentation either prior to or during a project. This would be in accordance with the Government's emphasis on professional responsibility and reducing unnecessary bureaucracy.

3.2 Much focus for regulation has been on clinical trials and studies involving investigational medicinal products, and growth in regulatory requirements has inflicted a disproportionate burden on investigator-initiated studies. Not only does this add to the complexity of the project, but also to the costs. The risk is that innovative 'blue-sky' research will not be progressed because of the lengthy and excessive processes for gaining approvals.

3.3 Much research in health services uses qualitative methods such as focus groups, database analysis and research using linked electronic patient records. Whilst ensuring high regulatory standards, each of these methods has particular nuances which are different from standard clinical trials. It is essential that any regulatory body recognises and accounts for this.

3.4 The need to obtain separate R&D approvals from Trusts, which have slightly different paperwork requirements, requires a significant investment in terms of time and effort, which is frequently disproportionate to the risk of the research itself. Furthermore it would be beneficial for a national research regulator to be empowered to issue guidance, establish governance arrangements and issue approval for projects that do not involve direct patient contact. At present, legislation requires approval from each Trust – which makes it virtually impossible to undertake national studies of health professionals, as one example. There needs to be more trust in the system, so that approvals given in one place are recognised elsewhere. The Research Passport is intended to overcome this problem.

3.5 It should be recognised that not all clinical research involves the NHS. If a study involves volunteers from HEI staff only, then NHS R&D approval would not be necessary, although the university would need to have appropriate governance arrangements in place.

3.6 There would still be a need to i) ensure that local costs are estimated to allow the costs to a Trust of research in the NHS to be assessed, and ii) there would still need to be some mechanism to oversee compliance with

approved study protocols. On balance it is likely that a single regulator could provide most roles but that some more limited local input would be required – and would be beneficial.

3.7 Assuming that regulation is proportionate, the Medical Schools Council agrees that the list of approvals listed in Annex II can be overseen by a single regulator. NHS R&D approvals, and approvals from institutional sponsors, will still need to be obtained as local issues will need to be considered.

4. 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'?

4.1 The Medical Schools Council believes that the value of a single research regulator is derived from oversight of the entire regulatory process and lifecycle, including decision-making functions. The second call for evidence specifically recognises that "[i]n 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". If it is created, the proposed single research regulator should take into account other initiatives that have been put into practice to improve the quality of UK research and work with existing non-regulatory organisations with expertise in ensuring integrity in research, including the UK Research Integrity Office.

4.2 Barriers to separately obtaining research ethics and research governance approval to undertake low-risk, non-intrusive research, have led to many undergraduate research projects becoming entirely paper based. A single research regulator with an educational role could, in principle, achieve much by way of increasing the participation in, and support for, research at an undergraduate level.

4.3 It will be important to reorganise the process of granting NHS R&D approval, where most of the delays in initiating research projects generally occur.

5. 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?

5.1 Assuming that the single research regulator assumes complete oversight and decision-making responsibilities associated with the lifecycle of a research project, many existing interfaces between organisations will become redundant. Key stakeholder relationships will include the Department of Health, the Department for Business, Innovation and Skills, the NHS, research sponsors (e.g. Research Councils) and research organisations (e.g. Higher Education Institutions).

5.2 Given the ongoing remit and legal responsibility of the MHRA for the regulation of drugs and devices, we query whether separate approvals and permissions would still need to be sought from both the MHRA and the new single research regulator. Streamlining this process would be welcomed.

6. 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?

6.1 Consolidation and simplification of the process of research regulation across the scope of health related research would be welcomed. Given that the single research regulator will have the relevant knowledge and expertise, it

would make sense to extend the scope of regulation to include other areas of research affecting health outcomes and public health.

6.2 The AMS Review needs to be clear about its scope and remit. There is a danger that non-medical research – i.e. studies that are not clinical trials, experimental medicine or epidemiological trials – will fall outside of the considerations of this review, yet the overarching architecture of the single ALB will undoubtedly become responsible for wider areas of research affecting health outcomes and public health.

7. What would be the optimal operational and governance arrangements for a 'single research regulator'?

7.1 Optimal operational and governance arrangements should eliminate current duplications in the system. Where there are existing and effective systems that function well, these should be adopted within the new ALB.

7.2 There is a great danger that we are professionalising research so much that practising clinicians are reluctant to support clinical research, or that they feel they not have the skills to be able to do so. The strengths of a single research regulator should develop a culture that is focused on facilitation above regulation or policing.

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

8.1 The Medical Schools Council believes that there should be a UK-wide remit for a single research regulator. The current situation in which systems for some approvals differ from country to country within the UK causes delays and confusion in the context of studies that are being conducted across UK internal boundaries.

8.2 In the future, the EU may consider common requirements for research, and the UK should have a united voice on these issues in the EU parliament.

9. 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.

9.1 An overhaul of legislation, which brings together the important components of current legislation in a clear and concise way, which removes unnecessary duplication and which emphasises the principle that policies and procedures should be appropriate to the degree of risk, would be extremely beneficial.

9.2 Impediments to research are both the underpinning regulation, and its implementation at regional and local level. Guidance and support for researchers is complex, with many organisations producing their own guidance. A single research regulator would be a positive step in the right direction.

9.3 Greater streamlining of processes for peer review of studies, and communication of the outcomes of that peer review process, from funding bodies to regulatory authorities is desirable. There is a lack of clarity and consistency, particularly with respect to the individual 'project' elements of fellowship and programme grant applications.

9.4 There would be merit in the regulator developing training for research organisations and managers to include a standardised approach to risk assessment, and to ensure consistency on how regulatory guidance is applied at a local and regional level.

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