Medical Schools Council

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**Medical Schools Council response to the Academy of Medical Sciences Review of the regulation and governance of medical research**

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 consultation as an opportunity to contribute to the Academy of Medical Sciences' review of the regulation and governance of medical research, and fully supports attempts 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 eroded by the burden of regulation from a multiplicity of regulatory organisations.

Almost all research organisations now employ staff to assist with the complexities of the approvals process. The increasing costs of gaining regulatory approval could be significantly reduced if the process were proportional and streamlined. The Medical Schools Council calls for an overhaul of legislation to create a single 'Medical Research Act' which:

i) Brings together the important components of current legislation in a simple, clear, concise way
ii) Removes unnecessary duplication and excessive regulation
iii) Emphasises the principle that policies and procedures should be appropriate to the degree of risk.

## 1 What are the principles that should underpin the regulation and governance of medical research?

1.1. Safeguards to ensure patient and public safety, consent, confidentiality, respect and public trust – and processes through which to raise questions or concerns - are fundamental for the public to have confidence in medical research and respect for clinical researchers. Regulation has an important role to play in promoting quality control, standardisation of research, and validity of findings, and in creating recognition that clinical trials are necessary for the development or improvement of treatment modalities.

1.2. Governance arrangements need to be clear, transparent and consistent, setting out clear responsibilities for the sponsor and the researcher. They should enable full engagement and commitment from all relevant partners and stakeholders, and aim to reduce the bureaucratic burden associated with the initiation and implementation of research.

1.3. It is essential that issues of risk and proportionality should underpin the regulatory process.



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**2 What are the most significant regulatory and governance impediments to medical research in the UK? In each case, is the impediment caused by: the underpinning regulation (or absence of regulation); its implementation at national or local level; the guidance and support provided for researchers (or lack of it)?**

2.1. Much of the governance process is valid and necessary, but there is a disproportionate requirement and/ or interpretation of the requirements by some R&D Offices to carry out excessive levels of policing which are not necessary in relation to the actual risk.

2.2. There is a large number of overlapping regulations and governance procedures concerning medical research which may not, in themselves, be a barrier to research. However when considered together they represent a major impediment to research.

2.3. The complex and difficult requirements of regulation and governance have led to many organisations producing their own guidance documentation. For example the Academy of Medical Sciences, the General Medical Council and the Royal Colleges all have slightly different documents which provide links to other documentation including the EU Trials Directive, MHRA and the HTA. Greater clarity on a single source of guidance would be helpful.

2.4. The variable interpretation and implementation of regulation and governance at local and national levels adds further levels of complexities and burden for organisations and individual researchers. In some cases, the requirements for compliance has led to an over-reaction in organisations, for example requiring individual researchers to comply to HTA frameworks for all human material, whether or not they are relevant to the HTA.

2.5. The governance process has resulted in a culture of policing rather one of facilitating research, with often a long time lag in initiating and facilitating research projects. The complexities of regulatory processes require a high level of organisational investment and inevitably cause delays, which make the UK less competitive to external investors.

2.6. The punitive powers of some organisations, for example the HTA and the MHRA, are clear yet the benefits are often opaque. In a risk-averse culture it can be very difficult to obtain the multitude of signatures required to initiate and progress clinical research.

2.7. R&D approvals are also holding back UK Research[1]. Although not an issue in all NHS Trusts, many continue to enforce internal policies and requests for supplementary documentation. Co-sponsorship contracts vary across the NHS. A reluctance on the part of both NHS Trusts and Universities to assume sponsorship of students is jeopardising the UK research capability.

2.8. The 'one size fits all' model of regulation and governance inhibits progress in low-risk or no-risk research, for example questionnaire studies or case note reviews.

2.9. Considerably more responsibility is now places on R&D offices and sponsors of research, without always having appropriate training, guidance or review of their capacity in this regards. Junior staff are reluctant to take decisions, and this in turn induces delays. Trust

[1] http://www.icr-global.org/crfocus/2009/20-10/managing-clinical-research-in-the-uk/)



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Chief Executive Officers need to show an active interest in the efficient running of their research office.

2.10. In addition to resource requirements in obtaining approval for a study, once the clinical trial is underway, there is a further burden in ensuring adequate oversight of the research, which is often difficult to achieve without dedicated trial support staff, for example the requirements of the MHRA Good Clinical Practice and Research Governance Framework.

**3 Which parts of the regulatory and governance framework are working well and why?**

3.1 The changes instigated by the NIHR Research Networks are working particularly well. The system for ethical approval has been streamlined (MRES) although the documentation and regional discussions regarding even relatively straightforward decisions remain complex.

3.2 The Integrated Research Application System (IRAS) has been a great advance in the application process combining, as it does, several of the applications that currently have to be made, although it may be further streamlined.

3.3 The National Research Ethics Services (NRES) works well for multi-centre research trials.

3.4 There are considerable advantages in the implementation of the Co-ordinated System for gaining NHS Permission (CSP) but further streamlining will be necessary to reduce the burden on staff time. The CSP has the potential to become a standardised process.

3.5 There is variable uptake of the NIHR Research Passport across the UK, but it has been particularly beneficial in reducing the burden of multiple CRB and Occupational Health checks.

3.6 The DH Research Governance Framework (RGF) is clear in its definitions and allocation of responsibilities, and ensures that there is a clear distinction between the roles of all who are involved in research. However, flexibility within this framework has led to variable interpretation of the RGF. A more standardised approach would be helpful.

**4 What initiatives to reduce the burden of the regulatory and governance framework are currently in progress, both here and abroad?**

4.1 NIHR has initiated a bureaucracy-busting initiative, the outcomes of which are highly anticipated but as yet unknown.

4.2 The Scottish R&D system shows that a streamlined process can be implemented and effective.

4.3 A number of universities and Trusts are working together to try to reduce bureaucracy and streamline processes. In some universities, 'low risk' procedures have been introduced to fast-track the approval of some types of research deemed to be lower risk, for example organisational research, by having a single ethics reviewer.

**5 What can we learn from the regulatory and governance framework in the different nations of the UK and from outside the UK?**

5.1 Whilst we recognise that practice is variable between – and even within – institutions, there is scope to learn from good practice within the UK, with some R&D offices already operating a



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system of proportionality, or accepting paperwork prepared for other institutions. Some sites set up very quickly, whereas others take a lot longer. This indicates that some of the 'burden of regulation' arises from local management issues.

5.2 Finland has a much more straightforward system of regulation underpinned by trust.

5.3 Italy is subject to the same European legislation as the UK, but patients are entered into trials rapidly in all hospitals. The regulations in the UK make our position as a country in which medical research can survive, less competitive

5.4 In the United States, Institutional Review Boards (IRBs), similar to UK research ethics committees, are more quickly responsive and, being institution based, they have a positive interest in research.

**6 What changes to the regulatory and governance framework would provide the greatest improvement to the progress of medical research, without putting patients at unnecessary risk?**

6.1 Dramatic changes are urgently required to the regulatory and governance framework. Attention needs to be given to ensure that low risk research is progressed rapidly without excessive documentation either prior or during the project. Whereas much of the focus for regulation been on clinical trials and studies involving investigational medicinal products, an increase in the regulations has inflicted a disproportionate level of burden on investigator initiated studies. The risk here is that truly original, blue sky ideas will not be investigated because of the lengthy and excessive processes for gaining approvals.

6.2 A single ethical approval process, particularly for multi-centre studies between universities, research network infrastructural support and NHS Trusts, would dramatically improve the timeliness of research. There needs to be a dramatic reduction in the regulatory processes, and an acceptance of paperwork (for example CRB checks) from other research centres. Networks should improve consistency of approach (for example, design) and facilitate collaboration.

6.3 A change in the stance of regulatory documentation would contribute to a system which facilitates, rather than polices, research. At present the language used gives the impression that researchers cannot be trusted, and the public perception of medical research is not enhanced by an overuse of terminology such as 'putting patients at risk', 'protection' or 'safeguards'.

6.4 To enable BRCs, AHSCs and Clusters with their collaborative research agenda, a system of internal central sign off for collaborative projects should be implemented. This is already used at some AHSCs and could be extended more widely. Collaborative research will be increasingly undertaken, and this approach to shared sign-off should be facilitated.

6.5 There is a need for further guidance around consent, with a lack of clarity amongst researchers about what exactly constitutes sufficiently informed yet usefully generic consent. A single consent process should be considered for multiple studies conducted on the same patient's samples.



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6.6 Governance staff must receive robust, accredited training in research management and appropriate risk assessment.

**7 How might the medical research process evolve in the future? Does this raise any additional issues for the regulatory and governance framework?**

7.1 It is clear that a gradual evolution of the current research process would be far too slow and cumbersome. There would need to be a rapid and dramatic change initiated by a relatively small group of stakeholders who have the ability to influence the processes.

7.2 Regulatory systems will need to be flexible to address a number of developments in medical research, for example increased use of bio-banks for biomarkers, stem cell and genetics research, bio-manipulation. The focus of health services research may well become more oriented to economic analysis.

7.3 The advent of drug trials targeted to a specific patient population (often genetically defined) will mean more trials involving small numbers of patients across multiple sites. This will mean that rapid, national approval for studies in the NHS will have even greater importance.

7.4 There should be an expectation amongst patients and the general public that they will contribute to the research effort for the benefit of the NHS and patient care. Patients and the public as stakeholders should be informed of its success to be able to share the pride in the exceptional performance of UK biomedical research. In the long-term, one goal would be to for the public to be sufficiently well-informed about the value of de-identified surplus tissue for ethically approved medical research that presumed consent could be introduced.

**8 Is there a need for a more risk-based approach to medical regulation and how might this be developed and adopted?**

8.1 The Medical Schools Council calls for an overhaul of legislation to create a single 'Medical Research Act' which:

- 8.1.1 Brings together the important components of current legislation in a simple, clear, concise way
- 8.1.2 Removes unnecessary duplication and excessive regulation
- 8.1.3 Emphasises the principle that policies and procedures should be appropriate to the degree of risk.

8.2 A single Medical Research Act would send a clear message to Trusts and Universities that change is necessary in the regulatory and governance framework if UK research is to flourish. It would also ensure that research staff know where to access all relevant legislation and would enable training to be focused.

8.3 As with all forms of regulation, there are inevitably tensions, and a balance will need to be reached between accountability and proportionality. Risk assessment of all projects would be the preferred means of ensuring proportionality of approach.

8.4 Consideration would need to be given as to who undertakes the risk assessment – whether self-assessed, which brings issues of acceptability, or a more centralised approach, which brings issues of improving knowledge of the research, organisation and appropriate levels of risk for that context.



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8.5 Approaches to risk-based regulation already in existence should be explored in the first instance. Any changes should be fully piloted and lessons learnt.

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