



UK Research Integrity Office response to the Academy of Medical Sciences review of the regulation and governance of medical research: call for evidence on the function and scope of a proposed 'single research regulator'.

September 2010

General comments

The UK Research Integrity Office (UKRIO) welcomes this opportunity to use our unique experience to contribute to the Academy of Medical Sciences' review of the regulation and governance of medical research, in particular the proposal of placing responsibility for different aspects of medical research regulation within a 'single research regulator'. We fully support attempts to improve research governance and reduce bureaucracy.

Before responding to the specific questions posed in the second call for evidence of this Review, we wish to make it clear that UKRIO would not seek to become part of the proposed single research regulator, nor do we seek to acquire regulatory powers in our own right.

The need for independent support on matters relating to misconduct in research and the promotion of good conduct has been the subject of considerable discussion over many years and UKRIO was set up as a result of these discussions. We have provided confidential, independent, and expert guidance to research organisations, researchers and the public since 2006 and have regularly responded to requests for assistance in all subject areas and types of research.

UKRIO is not a regulatory body and has no formal legal powers. The advice and guidance it offers is not mandatory but reflects best practice in the conduct of research and addressing misconduct. We feel that this model of support - an independent advisory body offering confidential and expert support to institutions, researchers and the public - is particularly important given the Government's aims to help the sector to save money and further improve its international reputation. Our focus on support that is appropriate and proportionate, rather than burdensome and bureaucratic, is also in accordance with the Government's emphasis on relying on professional responsibility and reducing unnecessary bureaucracy.

One of UKRIO's strengths is that it is independent and offers enquirers total confidentiality, without having the responsibility or legal requirements of a statutory regulatory body. We do not seek to trespass on the remits of the various regulatory organisations but instead work with them as appropriate. In many ways, UKRIO was set up to fill in the gaps between the various jurisdictions, where no overall regulation might apply, and to direct researchers, organisations and the public to the regulators where their jurisdiction does apply.

As such, UKRIO would not seek to become part of the proposed single regulator for medical research. In fact, we feel that to seek regulatory authority would conflict with the core values and mission of UKRIO and the way that we have successfully provided support to the research community and the public.

However, we have worked with existing regulators on matters of mutual interest and would be very keen to work with the proposed single regulator for research in the same manner. We feel very strongly that UKRIO's

unique role can help organisations such as the proposed single regulator minimise the burden of regulation and help maintain the UK's world-class reputation for conducting exceptional and innovative research.

Since its inception in 2006, the number of requests for assistance received by UKRIO has risen year-on-year, demonstrating that organisations and individuals are willing to come forward and seek guidance on difficult issues from a non-regulatory body and value UKRIO's confidential support. The rate of enquiries has almost doubled over the last three years as a result of increasing awareness of UKRIO's effectiveness, with UKRIO currently addressing between 35 and 45 formal requests for assistance each year.

Potentially UKRIO could have a complementary role to the proposed regulator, a role which would not be judgemental but advisory and developmental, focussing on good practice and prevention of fraud and misconduct. We feel that our programme of work could supplement and support any regulator through proactive and preventative engagement with the research community: guidance on research conduct; provision of education and training; procedures for resolving issues of poor practice and misconduct; and advice on specific issues and situations.

Responses to specific questions

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 Simplification and harmonisation of existing processes would be welcomed and the creation of a single medical research regulator would have the great advantage of removing unnecessary duplication. It would be essential to carefully manage any process of consolidation to ensure the proposed single regulator remains rigorous in safeguarding public funds and protecting the quality of UK medical research and the safety and wellbeing of patients and participants.
 - 1.2 The current complexity of overlapping legislative requirements of different bodies can present 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. This 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 However, the current review needs to make clear what aspects of research and regulatory processes are being addressed. The emphasis of the review is on medical research, such as clinical trials, epidemiological studies and experimental medicine, and not necessarily on wider health research. As a result, there is a danger that non-medical research (meaning research that is not defined as above) will fall outside of the considerations of the review, and yet it is almost certain that the overarching architecture set in place by the proposed single regulator will undoubtedly become responsible for such research.
 - 1.4 It is essential that any regulatory body recognises and accounts for the particular nuances of the wide variety of research methodologies which would fall within its remit, such as research in health services or social care. This will require a number of subgroups or committees and access to sufficient expertise, at both the strategic and operational levels, in all aspects of research relevant to the body's functions.
 - 1.5 Consolidation of medical research regulation should not be seen as a panacea. For example, regardless of whether there are single or multiple sources of regulation, organisations such as professional regulators and representative bodies will produce their own guidance to interpret

regulations, many of which will have differences of varying subtlety. Similarly, there will be variation in the interpretation and implementation of the requirements of regulation and governance at the local level regardless of there being one or several regulators. One strength of the proposed body would be that it could take significant steps to alleviate such problems, for example, by simplifying and harmonising regulation; however, it should be recognised that amalgamation of medical research regulation will not cure every problem with the system on its own.

- 1.6 It is probable that new changes and systems will increase bureaucracy and delays in the short-to-medium term before long-term benefits materialise from the transition to a single regulator. Researchers and research administrators will require new training and it is likely that there will be delays to existing research projects.
- 1.7 The consolidation process would need to be carefully managed and monitored, with good communication between regulatory authorities and the research community throughout. This would hopefully minimise any disruption to current research projects and allow research organisations to anticipate changes to their systems for the governance and management of research.
- 1.8 Any process of amalgamation must ensure that aspects of existing regulatory bodies which work well are identified and transferred to any new organisation. Existing data, specialist expertise, mechanisms for communicating with researchers and the public, and mechanisms for researchers and the public to seek assistance must also be identified and transferred to any new single regulator.
- 1.9 The proposed single research regulator should take into account other initiatives, regulatory or otherwise, that have been put into practice to improve the quality of UK research.
- 1.10 It should be recognised that bodies regulating medical research, such as HFEA, can address issues which can be the subject of much public debate and concern. Care must be taken during any amalgamation of medical research regulation to reassure the public that the process will not result in a less rigorous regulatory regime. Similarly, the public must be reassured that a single medical research regulator would consider emotive or potentially controversial issues with the same depth and sensitivity as existing organisations.

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 UKRIO is not a regulatory body and has no formal legal powers. We do not seek to trespass on the remits of the various regulatory organisations but instead work with them as appropriate. As such, we do not think it would be appropriate for UKRIO to take a position on the future of the National Research Ethics Service and the research regulatory activities of the Human Fertilisation & Embryology Authority and Human Tissue Authority.
- 2.2 If it were decided to consolidate the research regulatory activities of NRES, HFEA and HTA into a single regulatory organisation, the possible advantages and challenges discussed in response to question one, above, should be borne in mind throughout, as should the following comments.
- 2.3 Any such consolidation process must ensure that those aspects of each regulator which work well are transferred to any new organisation.
- 2.4 It would be equally essential to identify and transfer the following from each existing arm's-length body to any new organisation:

- a. organisational data and expertise;
 - b. existing networks and other mechanisms for engaging with the research community and the public; and
 - c. existing mechanisms for research organisations, researchers and the public to seek assistance on matters within the remits of the existing arm's-length bodies.
- 2.5 If it was considered desirable to consolidate the research regulatory activities of NRES, HFEA and HTA into a single regulatory organisation, the regulation of patient-related data could also be consolidated into the proposed body.
- 2.6 Any amalgamation or streamlining of NRES, HFEA and HTA should take into account the initiatives which those organisations have put into practice to improve the quality of UK research, such as the NRES National Research Ethics Advisors' Panel, and ensure that such support for the research community and the public is maintained.
- 2.7 UKRIO would be very keen to work with a combined regulatory body on matters of mutual interest, as it has with existing regulators.
- 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 UKRIO agrees that the list of approvals listed in Annex II could be overseen by a single regulator provided that regulation is proportionate and appropriate and remains rigorous in protecting the quality of UK medical research and the safety and wellbeing of patients and participants.
- 3.2 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. Much focus for regulation has been on clinical trials and studies involving investigational medicinal products, 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 Local issues will still need to be considered by researchers and institutions; however the proposed regulator should play a strong role in ensuring consistency on how regulatory guidance is applied at a local and regional level. This would help reduce such phenomena as slightly different paperwork requirements between institutions, which often involve a significant investment in terms of time and effort and one which is frequently disproportionate to the risk of the research itself.
- 3.5 The proposed regulator could have the authority to establish governance arrangements, publish guidance, and issue approval for projects that do not involve direct patient contact. At present, legislation requires approval from each Trust, which can have unintended consequences, for example

it can be extremely difficult to undertake national studies of health professionals. There needs to be more trust in the system, so that approvals given in one place are recognised elsewhere.

3.6 On balance it is likely that a single regulator could provide most roles but that some local input would be required and also advantageous.

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 single regulator should develop a culture that is focused on facilitation rather than policing. The areas where most of the delays in initiating research projects generally occur should be identified and remedial action taken, to ensure that processes are proportionate while still protecting patients and public funds.

4.2 The proposed organisation could also support good practice by developing and maintaining a national repository of 'case law', so that examples of good practice in research governance and ethics committee decisions can inform future research design.

4.3 Streamlining of processes would be welcome as there can be considerable local variation in research governance processes, either because of locally introduced systems or particular interpretations of national guidance. For example, the introduction of common procedures and processes between NHS Trusts wherever possible would be greatly appreciated by researchers. Similarly, when the same data is required by multiple agencies, it would be helpful if it could be submitted to all in a broadly similar format.

4.4 A single regulator could champion an approach based on the assessment of risks and on proportionality. This has the potential to ensure that mechanisms for the regulation and governance of medical research are appropriate and proportionate, rather than burdensome and unbalanced. For example, a more risk-based and proportionate approach could help reduce unnecessary barriers to obtaining permission to undertake extremely low risk and non-intrusive research. Such barriers have led to many undergraduate research projects becoming entirely paper based. A single research regulator could aim for some consistency in risk perception and management across different locations.

4.5 It should be noted, however, that such a risk-based approach would depend on regulators, researchers and employers having a good understanding of the relevant risks and would require an appropriate level of oversight, especially while the new approach was being implemented. Suitable training and support would be needed, as well as clear information on where researchers and organisations could get further information or help if unsure.

4.6 Any risk-based approach must ensure that it is underpinned by principles relating to

- a. patient safety, wellbeing, dignity, rights, informed consent, confidentiality, respect and public trust; and
- b. good practice in the design, management, conduct and dissemination of research.

4.7 The proposed body could undertake an educational role to increase the willingness of both patients and administrators to participate in or support research.

- 4.8 If the proposed regulator were to have a number of different functions and powers and would therefore review or accredit various different aspects of research organisations, it would be important for the outcomes of such reviews to be distinguished. The failure of an organisation in one function should not necessarily imply that all of that organisation's research functions are judged to be weak or unreliable.
- 4.9 As noted in the above question, current regulatory organisations undertake a variety of activities relating to monitoring research projects and 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. It is imperative that existing functions of this nature which work well are identified and transferred to any new body, and further developed as necessary in response to:
- a. the changing needs of the research community and the public;
 - b. changes in legislation; and
 - c. developments in research practice and research ethics.
- 4.10 The proposed regulator should work with other organisations which play a role in improving standards of research practice, including the regulatory bodies for professions involved in research, other professional bodies, learned societies, and organisations as UKRIO.
- 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 Many of the current interfaces between organisations will become redundant if the proposed regulator takes on the responsibilities for complete oversight and decision-making associated with the lifecycle of research projects.
- 5.2 Key stakeholder relationships for the single research regulator would include:
- a. the Department of Health;
 - b. the Department for Business, Innovation and Skills;
 - c. the governments of the devolved nations of the UK;
 - d. other regulatory bodies with responsibilities for research;
 - e. the regulatory bodies for professions involved in research;
 - f. the NHS;
 - g. research sponsors and funders; and
 - h. research organisations in the higher education, NHS, charitable and private sectors, and their representative bodies such as Universities UK and the Association of the British Pharmaceutical Industry.
- 5.3 The single research regulator should also work with existing non-regulatory organisations with expertise in ensuring integrity in research, such as UKRIO.

- 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 research regulation across the scope of health related research would be welcomed; however, the potential problems observed in the response to question one, above, would apply to the amalgamation of medical research regulation from different ministries and could even be exacerbated.
- 6.2 As with the proposed changes to the research regulatory activities of NRES, HFEA and HTA, it is essential that any further consolidation recognises and accounts for the particular nuances of the wide variety of research methodologies which would fall within its remit. This will require access to sufficient expertise, at both the strategic and operational levels, in all aspects of research relevant to the body’s functions and suitable representation from researchers, organisations and the public.
- 6.3 In order to remain in accordance with the Government’s emphasis on relying on professional responsibility and reducing unnecessary bureaucracy, the consolidation process would need to be carefully designed, managed and monitored. This would also hopefully reduce bureaucracy and delays in the short-to-medium term before long-term benefits materialise from the transition to a single regulator.
- 6.4 Where government departments hold regulatory responsibilities for both health-related and other forms of research, particular consideration must be given to whether transferring health-related research permissions to the proposed single regulator would have a negative impact on their regulation of other research disciplines. Consolidating the regulation of one area of research must not adversely effect the regulation of other subjects and types of research.
- 6.5 It should also be recognised there would undoubtedly be concerns regarding whether a single research regulator with wider cross-government reach could do justice to such a broad range of regulatory responsibilities. This could potentially reduce the effectiveness of such an organisation and how it is engaged with by researchers, research institutions and the public.
- 7. What would be the optimal operational and governance arrangements for a ‘single research regulator’?**
- 7.1 The best operational and governance arrangements would remove unnecessary duplication in the system and ensure that mechanisms for the regulation and governance of research are clear, consistent and transparent. Arrangements put in place by current arm’s-length bodies which work well should be maintained within the new regulator.
- 7.2 Ideally, the process will evolve into a more streamlined and harmonised system for the design, management, conduct and dissemination of research.
- 7.3 Systems should clearly define the roles and responsibilities for researchers, sponsors and other bodies, and make it clear where further information and assistance can be sought. They should encourage researchers and organisations to anticipate what situations and problems might occur and agree jointly in advance how they might be addressed.

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 We believe it would be appropriate for the proposed single research regulator to have a UK-wide remit. 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 An additional benefit of a UK-wide remit is that it would enable the regulator to speak on behalf of the UK in international fora and negotiate on behalf of the UK within the European Union.
- 8.3 If awarded a UK-wide remit, the regulator should ensure that it has sufficient representation from the devolved nations as well as mechanisms to ensure effective two-way communication with researchers, research organisations and the public across the entire UK.

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 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, such as UKRIO and the Committee on Publication Ethics. The work of such organisations could supplement and support the proposed regulator through proactive and preventative engagement with the research community and in a way that is free of any conflict between developmental and judgemental imperatives.
- 9.2 It is likely that concerns will be brought to the attention of the proposed regulator which do not fall within its remit to address. Clear lines of communications must be established to quickly direct those raising concerns to organisations which can provide help, whether regulatory bodies or not. Similarly, other organisations which are commonly informed of alleged problems with the conduct of research must have mechanisms to direct those raising concerns to the proposed single regulator when those concerns would fall within its remit.
- 9.3 The proposed regulator should work with other bodies responsible for the regulation and governance of research to simplify and harmonise processes where possible and to reduce the bureaucratic burden associated with the design and conduct of research.
- 9.4 There must be effective lines of communication between the proposed regulator and those organisations which represent research organisations, researchers, and patients and research participants.
- 9.5 Regardless of whether there is one regulator for medical research or several, research organisations will remain corporate entities with: duties as employers of researchers; a responsibility for research conducted under their auspices; and a duty of care to participants in such research.
- 9.6 When poor practice or misconduct occurs in a field of research which is not governed by statute, it normally devolves to the employer to address. The proposed single regulator must work with other organisations to support employers in fulfilling their responsibilities and establish mechanisms to direct researchers, organisational representatives and the public to suitable assistance, such as that provided by UKRIO.

- 9.7 In cases of alleged poor practice or misconduct in research, there can be confusion about processes to investigate the allegation, determine the truth of the matter and take any necessary corrective actions. This is particularly the case where allegations involve collaborative or multi-disciplinary research or complex issues which require the involvement of multiple agencies, regulatory or otherwise. The single regulator should bear this in mind when devising or revising systems for the regulation and governance of research.
- 9.8 It is UKRIO's experience that, in some cases, issues relating to the conduct of research can still fall outside the remit of regulatory and other organisations, such as employers or funding bodies, to resolve, as it were slipping through the cracks between the various jurisdictions. Again, this should be borne in mind when devising or revising regulation and governance systems.
- 9.9 It would be helpful if the proposed regulator and other bodies, including non-regulatory organisations such as UKRIO, could work together to embed a greater level of training in the conduct of research of the highest quality and ethical standards into the career structure of researchers. It is the experience of UKRIO that many issues of good practice in research are not as self-evident as commonly thought and more attention needs to be paid to ensuring that organisations and researchers are aware of their responsibilities in this area. For example, the fundamentals of good practice in authorship and identifying and addressing conflicts of interest relating to research are thought to be widely known yet many problems can and do arise in relation to these issues.
- 9.10 UKRIO does not advocate the imposition of overly-rigid "one size fits all" mechanisms for education and training but feels it would be valuable to promote common approaches to common situations, as we have done in our own education and training activities. Research organisations need to be encouraged to support researchers to carry out safe, ethical and high quality research, while researchers need to be encouraged to seek assistance and guidance rather than give into pressure to cut corners.
- 9.11 UKRIO finds that many issues arise in relation to the publication and dissemination of research. We welcome guidance on these issues published by bodies such as the Committee on Publication Ethics, the Council of Science Editors, the International Committee of Medical Journal Editors and the World Association of Medical Editors. We would urge any single regulator to encourage research organisations to adopt and promote such guidance.

Further information

For further information on the views of UKRIO, please contact: James Parry, Acting Head, UK Research Integrity Office, tel. 020 7419 5498; email info@ukrio.org.

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