



## **UK Research Integrity Office response to the Academy of Medical Sciences Review of the regulation and governance of medical research**

**June 2010**

### **Introduction**

The UK Research Integrity Office (UKRIO) is an independent body which offers confidential and expert advice and guidance to research organisations, individual researchers and members of the public about the conduct of research. UKRIO also publishes guidance on good research practice, provides education and training, supplies experts to participate as external members of institutional investigations of alleged research misconduct and operates a help line service where concerns can be reported in complete confidence.

Set up in the first instance to provide support to the health and biomedical science research community, we now offer guidance applicable to all fields of research carried out in universities, NHS Trusts and other research organisations.

As the only dedicated research integrity organisation in the UK, UKRIO has amassed significant expertise through its considerable experiences in helping employers and researchers address misconduct in research across all subject areas. No other organisation has comparable experience in providing such support to the UK research community.

UKRIO welcomes this opportunity to contribute to the Academy of Medical Sciences' review of the regulation and governance of medical research. We fully support attempts to improve research governance and reduce bureaucracy.

### **The role of UKRIO in the current regulatory environment**

Before commenting on current regulation and governance of medical research, it is worth clarifying the role that UKRIO plays in the current research environment.

UKRIO is not a regulatory body and has no formal legal powers. It was set up to provide independent and confidential support on issues of research conduct to research organisations, researchers and the public where there was none. Our services are provided *pro bono* and are applicable to all fields of research carried out in universities, NHS Trusts and other research organisations.

The advice that UKRIO gives in response to enquiries reflects best practice and the lessons learnt through its own, extensive experiences. Our guidance is voluntary, not mandatory, and does not attempt to micro-manage research. We recognise that, while there should be common approaches to common issues, organisations and researchers are best placed to determine the right way to put the promotion and support of good research practice into operation in their particular research environment. This approach has been welcomed by individuals and institutions alike.

Currently UKRIO receives about 30-40 formal requests for advice each year. We have provided assistance to individuals and institutions with concerns about research ranging from the health and biomedical sciences to

the arts and humanities. We have found that many issues of research conduct are common to all subject areas but provide specialist expertise when necessary. From the volume of cases that we deal with, it is evident that researchers and organisations, which might be expected to be hesitant about sharing problems with a non-regulatory body, are willing to come forward and seek guidance on difficult issues.

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.

Our remit is to provide guidance on available processes for dealing with concerns relating to the conduct of research. UKRIO does not have a case investigation role, though it can and does participate in investigations at the request of a regulator, employer or other appropriate body or person. While UKRIO has no formal legal powers, it has been able to successfully intervene directly in cases where existing mechanisms to resolve matters have been ineffective.

There is no overall statutory regulation of research or researchers in the UK and if a field of research is not governed by statute, it normally devolves to the employer to investigate allegations of research misconduct. Therefore, as well as providing support for researchers and members of the public, UKRIO was set up also to help employers to conduct such investigations to the highest possible standards. It does this through giving advice on specific cases, by publishing guidance on research conduct, and by providing experts to participate as external members of screening or investigation panels on request, to bring an external and skilled perspective to an enquiry and help reassure all involved that investigations will be thorough and fair.

Parliament may in the end decide that a statutory regime for regulating research is desirable but UKRIO does not seek the creation of such a regime. Instead, we are increasingly providing support to members of the public, researchers, universities and NHS Trusts, all of which recognise that research misconduct and questionable practices can tarnish the UK's well-earned reputation as a centre of excellence in research and look to UKRIO for help and advice.

UKRIO is funded and supported by many different organisations, including bodies which fund or regulate health and biomedical research, such as the Medicines and Healthcare products Regulatory Agency, the General Medical Council, the Medical Research Council and the Department of Health; however, it is not responsible to any external body other than in accounting for the funding it receives in regular reports. Additionally, UKRIO is governed by an independent Board, rather than by instructions from any of its funding bodies. None of the organisations which fund us have any role in determining which cases we may become involved with or the guidance and support that we might give and any advice and assistance given is kept confidential within UKRIO.

## **Responses to specific questions**

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

- 1.1 Robust governance is critical to help ensure the safety and wellbeing of research participants and good practice in the design, management, conduct and dissemination of research. It also has an important role to play in enabling the public to have confidence in research and trust in researchers.

- 1.2 Regarding ensuring the safety and wellbeing of participants, the principles of the Declaration of Helsinki are widely recognised and accepted. Principles relating to patient safety, wellbeing, dignity, rights, informed consent, confidentiality, respect and public trust need to be at the heart of the regulation and governance of medical research.
  - 1.3 Regulation and governance should also support organisations and researchers to produce and disseminate work of the highest quality and integrity. All involved in research need to be encouraged to consider the wider consequences of their work and to engage critically with the practical, ethical and intellectual challenges that are inherent in the conduct of high quality research, rather than treating legal, ethical or other requirements as just another process to be followed.
  - 1.4 Systems should also encourage researchers and organisations to anticipate what situations and problems might occur and agree jointly in advance how they might be addressed. A recurring theme from enquiries made to UKRIO is that many problems could be avoided or mitigated against if issues were considered in advance and a joint decision made on what action could be taken and then communicated to all concerned.
  - 1.5 It is recognised that there will always be tensions inherent in systems of governance and regulation and a balance will need to be struck between conflicting priorities. A more risk-based approach would be one way of ensuring that mechanisms are appropriate and proportionate, rather than burdensome and unbalanced; however, risk-based approaches depend on regulators, researchers and employers having a good understanding of the relevant risks.
  - 1.6 All involved in research must be educated to ensure that they have sufficient knowledge of the requirements of legal, ethical or other guidance and understand and appreciate their rationale. Organisations should provide appropriate training, resources and support to their researchers to ensure that they are aware of all relevant guidance and are able to comply with it. Similarly, regulators should work with organisations to help clarify how guidance should be implemented and to ensure that regulators do not underestimate the burden imposed by regulation and governance.
  - 1.7 Systems for the regulation and governance should be clear, consistent and transparent. They 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.
  - 1.8 Regulators and other bodies responsible for the regulation and governance of research should work together, to simplify and harmonise processes where possible and to reduce the bureaucratic burden associated with the design and conduct of research.
- 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 There are a significant number of regulatory and governance processes relating to medical research. While individual processes may not be particularly burdensome, many overlap and, when considered together, can represent a particular hindrance to the design and conduct of research.

- 2.2 The various regulation and governance procedures can have complex and difficult requirements. This has led to:
- a. other organisations, such as professional regulators and representative bodies, producing their own guidance to interpret regulations, many of which have differences of varying subtlety; and
  - b. variation in the interpretation and implementation of the requirements of regulation and governance at the local level.
- 2.3 UKRIO does not advocate the imposition of overly-rigid “one size fits all” mechanisms. We also fully recognise that professional bodies have the right to set standards for their members and that organisations and researchers are best placed to determine the right way to put the promotion and support of good research practice into operation in their particular research environment. We feel, however, that greater clarity and harmonisation of guidance would be particularly desirable.
- 2.4 The complex nature of current regulation and governance can also lead to slow and cumbersome systems for the approval and management of research projects. This can be exacerbated at the local level by:
- a. misinterpretation of current guidance by researchers and organisations alike, often leading to an overly-rigid application of systems;
  - b. a lack of transparency in systems and associated decision-making processes;
  - c. a lack of institutional support, training and sufficient time for R&D Offices to carry out their duties properly; and
  - d. poor communication between involved parties.
- 2.5 When cases of alleged poor practice or misconduct in research occur, 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.
- 2.6 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 to resolve, as it were slipping through the cracks between the various jurisdictions.

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

- 3.1 UKRIO recognises the need for a robust framework of regulation and governance for medical research and wishes it to work well.
- 3.2 In our experience, there can be considerable local variation in what processes are perceived to be working well. This appears to be related to locally introduced systems or other interpretations of national guidance.
- 3.3 A general view is that ethical processes for the conduct of research have improved in recent years, through the actions of bodies such as the Central Office for Research Ethics Committees, the Integrated Research Application System and the National Research Ethics Service (NRES). UKRIO would endorse this view.

- 3.4 We believe that NRES and the National Institute for Health Research (NIHR) are valuable sources of advice for all involved in research. Similarly, we welcome the guidance given by the Medicines and Healthcare products Regulatory Agency to research participants, researchers and organisations with concerns about the conduct of clinical trials.
- 3.5 The Department of Health's Research Governance Framework provides valuable guidance on the roles and responsibilities of individuals and organisations involved in research; however, interpretation of its guidance at the local level can and does vary.
- 3.6 We welcome the introduction of the NIHR Research Passport, although we recognise that there has been variable uptake of this initiative.

**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 instituted a "bureaucracy-busting initiative". As part of this, UKRIO is working with NIHR to provide a simple standard operating procedure (SOP) for researchers in the NHS to use when encountering suspected misconduct in research. The SOP will inform NHS managers in simple terms how to avoid making damaging mistakes at the outset when they have to handle an allegation or follow up a suspicion of misconduct in research. It will detail:
- a. who to inform – within a Trust, elsewhere within the NHS, and outside bodies, including statutory regulators;
  - b. where to find out more on each of the possibilities; and
  - c. where to get help if unsure.
- 4.2 We welcome the establishment of the NRES National Research Ethics Advisors' Panel and feel that it will be an excellent source of guidance and assistance for research ethics committees.
- 4.3 There are a number of organisations undertaking valuable work to streamline and harmonise guidance relating to the conduct of research in the international context. A key example is the guidance from the Organisation for Economic Cooperation and Development's Global Science Forum on *Investigating Research Misconduct Allegations in International Collaborative Projects*.
- 4.4 Other work is being undertaken by the European Science Foundation, the European Forum for Good Clinical Practice and the European Network of Research Integrity Offices, of which UKRIO is a founder member.
- 4.5 UKRIO finds that many issues arise relating to the publication and dissemination of research, in particular disputes over authorship. 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 NHS Trusts and universities to consider the adoption of such guidance.

**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 There is anecdotal evidence that systems, or certain elements of systems, in other countries are more efficient and/or less bureaucratic than those in the UK; however, there is also anecdotal evidence that other countries are experiencing similar problems regarding the regulation and governance of medical

research becoming burdensome and bureaucratic. More research is needed before a firm judgement can be made.

- 5.2 Countries with a greater level of statutory regulation of research or researchers than the UK still have issues with the conduct of research. While lessons can be learned from other countries and their approaches to promoting good practice in research and addressing poor practice and misconduct, the different models of regulation and governance each have their strengths and weaknesses and they should not be seen as a panacea.

**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 UKRIO recognises that patient safety and good research practice must be at the heart of regulation and governance of medical research; however, reduced bureaucracy, improved clarity and transparency, and a greater provision of training and resources would help make current processes less burdensome and more appropriate while still preserving integrity in research and the safety and wellbeing of patients.
- 6.2 Streamlining of processes would also be welcome. 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.
- 6.3 A more proportional, risk-based system would be welcomed, although, as noted above (1.5) all involved would need to have a proper understanding of the relevant risks.

**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 Ideally, the process will evolve into a more streamlined and harmonised system for the design, management, conduct and dissemination of research.
- 7.2 This should be accompanied by a greater level of training in the conduct of research of the highest quality and ethical standards, embedded in 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.
- 7.3 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.
- 7.4 Systems should encourage researchers and organisations to anticipate what situations and problems might occur and agree jointly in advance how they might be addressed.
- 7.5 As noted earlier, UKRIO does not seek the introduction of overall statutory regulation of research, medical or otherwise, or of researchers.

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

- 8.1 An approach based on the assessment of risks and on proportionality would be welcomed.
- 8.2 It has the potential to ensure that mechanisms for the regulation and governance of medical research are appropriate and proportionate, rather than burdensome and unbalanced.
- 8.3 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.
- 8.4 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.

### **Further information**

For further information on the views of UKRIO, please contact:

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