



UKRIO submission to 'Shaping an effective national role for the HRA'

March 2012

1. Introduction

- 1.1 The UK Research Integrity Office (UKRIO) welcomes this opportunity to contribute to the consultation on the role of the Health Research Authority (HRA). We fully support its aim to improve research governance processes. Reducing bureaucracy will clarify responsibilities for protecting patients and the public, and enhancing the quality and ethical standards of research, as well as reduce burdens on researchers and others.
- 1.2 This submission draws upon the views of: the staff of UKRIO; members of its Board of Directors; members of its Advisory Board; and members of UKRIO's Register of Advisers, the experts who assist UKRIO in responding to questions and concerns about the conduct of research.
- 1.3 In addition, our submission draws upon UKRIO's extensive experience in the promotion of good research practice and addressing poor practice and misconduct. As the only dedicated research integrity body in the UK, UKRIO has amassed considerable expertise in these issues, particularly in relation to research in health and biomedicine.
- 1.4 In the event of any queries about this submission, please contact James Parry, Chief Executive, UKRIO on 01273 234 697 or at james.parry@ukrio.org.

2. About the UK Research Integrity Office

- 2.1 The need for independent support in handling misconduct in research and promoting good conduct has been the subject of considerable discussion over decades. UKRIO was set up to support good research practice and assist with the prevention and investigation of questionable practices and misconduct. Since 2006, UKRIO has provided independent and expert support on a wide range of issues across all disciplines of research. We help all involved in research: members of the public, individual researchers and research organisations including universities, NHS bodies, private sector organisations and charities. No other organisation in the UK has comparable expertise in providing such support in the field of research integrity.
- 2.2 UKRIO offers support that is appropriate, practical and proportionate, not burdensome or bureaucratic. The guidance we offer is not mandatory. It reflects best practice. We promote good research practice and robust and fair methods to address poor practice and misconduct, as well as providing expert guidance in response to specific requests for assistance. Our support extends across all academic disciplines. We promote common approaches to common situations, and provide subject-specific expertise whenever necessary.
- 2.3 This approach has been welcomed. Use of our services has continued to grow year on year. UKRIO received more than 60 formal requests for assistance in both 2010 and 2011. Many leading research organisations,

UK Research Integrity Office

including over 50 universities, use our published guidance ¹, which is endorsed by funding and professional bodies. It has become clear since UKRIO was set up that employers and individuals value our confidential, independent and expert service and are willing to come forward and seek guidance from UKRIO. We would not be approached if we were not needed.

- 2.4 We do not seek to trespass on the responsibilities of regulatory organisations but instead work with them as appropriate. UKRIO fills gaps between jurisdictions, where the scope of regulation may seem unclear, and helps to direct researchers, organisations and the public to the right regulators where their jurisdiction does apply. UKRIO helps institutions achieve high standards when they have to manage challenges to research integrity, and it advises individuals faced with bad practice. Our advice and guidance emphasises the good practice that runs across all research disciplines and all regulatory remits. In this way our role complements that of regulators such as the Health Research Authority and supports the work of Government and research funders.

Our programme of work

UKRIO provides a comprehensive programme in support of research integrity. Key elements include:

- **UKRIO's Code of Practice** for Research and **Procedure for the Investigation of Misconduct** in Research. UKRIO is publishing supplementary guidance on particular aspects of research practice and notable issues and pitfalls.
- **UKRIO's advisory service**, which provides independent, expert and confidential advice on the conduct of research, whether promoting good practice or addressing poor practice and misconduct. The service is open to all involved in research and covers all disciplines. We welcome enquiries on general issues as well as specific projects and cases.
- **UKRIO's Register of Advisors** - experts who are available to serve as external members on panels investigating or adjudicating upon claims of research misconduct.
- **Illustrative case studies** of issues of research practice, including addressing poor practice and misconduct.
- **Expert assistance** to research organisations devising, implementing or revising systems to ensure good practice in research and address misconduct.
- **In-depth and long-term support** to help improve standards of research practice in an institution.
- **Advice and support** in developing and delivering training programmes on issues of research integrity, such as:
 - courses for *new researchers* in the responsible conduct of research; and
 - instruction for *senior managers* in the process of investigating allegations of research misconduct.
- **Implementation of national initiatives** such as the *Consensus Statement on Research Misconduct in the UK* and the forthcoming *Concordat to Support Research Integrity*. The introduction of new policies can lead to a 'tick box' mentality unless provided with comprehensive and long-term support. UKRIO has considerable experience in helping organisations put into operation the principles and standards of new research guidance.
- **Informing the development of new UK and international initiatives**, using UKRIO's unique experience, expertise and data.

¹ UK Research Integrity Office: *Procedure for the Investigation of Misconduct in Research* (2008) and *Code of Practice for Research: promoting good practice and preventing misconduct* (2009). Both available from www.ukrio.org

3. Responses to specific questions

3.1 The role you (or your organisation) play in research within the NHS

3.2 UKRIO has supported research in the NHS since its creation, providing advice and support to institutions, researchers and patients with queries about good research conduct or concerns about questionable practices or misconduct. Our guidance publications have been used by NHS bodies and researchers.

3.3 UKRIO was set up to provide support to the health and biomedical sciences community on issues of research integrity. While we now address enquiries from other research disciplines, the majority of requests for our assistance still relate to the life sciences and UKRIO is well aware of the importance of supporting good practice in health and biomedical research: to retain the public's trust; to help ensure the wellbeing of research participants; to enhance this country's international reputation in the research on which the national economy depends; and, not least, to secure the best return on public funds.

3.4 Accordingly, while UKRIO continues to respond to enquiries from other disciplines, we pay particular attention to issues of good research practice and misconduct in health and biomedicine. UKRIO continues to fulfil its remit of supporting the UK life sciences research community, working with other organisations with interests in research integrity to ensure clear and unified guidance and reduce duplication of effort and bureaucracy. We provide expert advice in response to requests for assistance but we are also proactive in promoting and supporting good research practice and robust and fair methods to address poor practice and misconduct.

3.5 UKRIO provides support which crosses the boundaries of regulatory remits and the sectors involved in health and social care research. We advise and support:

- a. all researchers;
- b. all employers of researchers; and
- c. research participants and patients.

3.6 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.

3.7 It should be noted that the issues which come to UKRIO tend not to be ones that fall within the remit of regulators. These are wider issues of research practice, which will need to be taken into consideration regardless of changes to regulation and governance.

3.8 In our view, Government policy encourages a role for UKRIO which complements that of the HRA:

- a. UKRIO is an independent source of confidential support to institutions, researchers and patients. It helps organisations to achieve high standards in managing challenges to research integrity, and advises individuals faced with bad practice.
- b. UKRIO emphasises the good practice that runs across all research disciplines, though, again, we take account of the differing technical considerations and norms of research of each.
- c. It does not compete with the HRA in setting standards for compliance with health research regulation.

UK Research Integrity Office

3.9 **The criteria you use (or that should be used) when assessing the quality or risk of research in the NHS / Your views on what constitutes good quality ethical research**

- 3.10 Good research practice – that research should be safe, accurate, honest, ethical and legal - is commonly thought to be self-evident. Nonetheless, there is a growing body of evidence which suggests research misconduct is not rare. A 2009 meta-analysis by Danielle Fanelli of the University of Edinburgh² reported that just under 2% of scientists admitted to have fabricated, falsified or modified data or results at least once. Just over a third admitted to ‘questionable research practices’ – bias in reporting short of outright falsification or similar misconduct that violates basic standards of research. Evidence suggests that, due to their frequency, such questionable practices have as great an impact on the integrity of research as major misconduct if not more so. It seems that pressures, whether internal or external, can drive researchers to cut corners or worse.
- 3.11 Replication of experiments and peer review play an important part in discovering fraud before it can have an impact. But there is evidence these mechanisms are not as strong as they should be. Most research is not directly replicated. Misconduct may be detected only long after publication - and by readers rather than colleagues, supervisors, editors or reviewers. Colleagues can be afraid to speak out. We encourage the HRA to focus on the relationships by which research employers, sponsors and study sites support one another in ensuring that each has played its own part in preventing or detecting poor practice.
- 3.12 It is increasingly recognised that poor practice, unethical behaviour, fraud and other forms of misconduct can cause significant harm to research. Such practices damage the quality of UK research and its international reputation and represent a breach of trust with the public, which supports research through charities, other funding bodies and taxes. They can put participants at risk or cause actual harm, cause considerable financial and reputational damage to research institutions, and jeopardise public funds.
- 3.13 In our experience, UK science is by no means a disaster zone, but there is no reason for complacency. The UK’s mechanisms for demonstrating good research practice are complex and not especially transparent: justice may be done but is not often seen to be done. More consistent and complete structures would support good professional practice and encourage research of the highest quality and ethical standards. Confusion about managing unethical behaviour and research misconduct is risky for the UK, which could and should be an example to the rest of the world.
- 3.14 **Your views on how good quality ethical research can be delivered in the NHS more efficiently**
- 3.15 Professional responsibility means taking steps to minimise predictable harm. Guidance for researchers and organisations should encourage the strong professional ethos which, thankfully, drives most research here. 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.
- 3.16 The HRA 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. The work of such organisations could supplement and support the work of the HRA through proactive and preventative engagement with the research community.

² Fanelli, D., 2009. *How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data*. PLoS ONE 4(5): e5738. doi:10.1371/journal.pone.0005738

UK Research Integrity Office

- 3.17 We see UKRIO's role as two-fold, to:
- a. Promote good research practice amongst researchers and employers, and assist with addressing misconduct and questionable practices
 - b. Feedback to regulators such as the HRA, anonymously and in confidence, regarding what we hear about what works well and what perhaps might need revision
- 3.18 A benefit of UKRIO is that we can pass on anonymised lessons learned and wider implications from our extensive experiences. These already inform our programme of work and we are keen to use our expertise to inform the work of others.
- 3.19 **The standards, guidance or policies that determine approaches organisations take to review, fund, approve, manage, monitor and/or disseminate research**
- 3.20 UKRIO is not an originator of standards for compliance with regulation and has no ambition to become one. UKRIO does not try to set those standards but it does help with the good practice that reassures regulators they are dealing with a competent institution. Our published guidance, such as our Code of Practice for Research, complements and enhances, rather than replaces, standards and policies from the HRA and other bodies.
- 3.21 Regulators are expected to look for evidence of professional practice and to focus effort where on higher risk places and activities. In this sense UKRIO can complement regulators like HRA.
- 3.22 **Your suggestions for improvement**
- 3.23 In our view, UK research does not require more bureaucracy or statutory regulation, nor do UK researchers need to be micro-managed or encumbered with more paperwork. Instead, organisations and individuals need guidance and support that is practical and useful, and which encourages research of the highest quality, ethical standards and professional practice. However, it is widely felt that there is unhelpful confusion about the way that the general standards should be interpreted in particular settings.
- 3.24 The HRA was created as part of wider efforts to streamline the regulation and governance of health research, and clarify how individuals and organisations can comply. UKRIO has always supported straightforward research guidance with a risk-based approach. We promote the adoption of practices that are easy for everyone to understand and which focus on managing challenges to research integrity. We would be happy to take part in discussions of the most efficient way for the relevant bodies to demonstrate good practice and effective risk management. Inspection is an area where responsibilities appear both to overlap and to leave gaps.
- 3.25 UKRIO welcomes efforts to streamline and harmonise regulatory procedures, with clear and proportionate guidance for the research community avoiding duplication of effort. We stand ready to co-operate with HRA and other bodies that are trying to produce a joined-up picture for researchers and use our unique experience, expertise and data to inform this process.
- 3.26 **What you think the HRA's key priority should be**
- 3.27 A more systematic and visible effort to promote integrity and high ethical standards in UK research, with a focus on support that is appropriate, practical and proportionate. This should be accompanied by simplification and harmonisation of existing processes and information requirements to reduce burdens and bureaucracy and minimise barriers to innovative or cross-disciplinary research.

UK Research Integrity Office

- 3.28 It will be essential to carefully manage any process of consolidation to ensure rigor in safeguarding public funds and protecting the quality of UK medical research and the safety and wellbeing of patients and participants.
- 3.29 Local issues will still need to be considered by researchers and institutions; however the HRA should play a strong role in ensuring consistency on how regulatory guidance is applied at a local and regional level.
- 3.30 It would be helpful if the HRA and other bodies, including UKRIO, could work together to embed a greater level of training in the conduct and management of research into the career structure of researchers and staff who support research. 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 know how to interpret and apply their responsibilities. 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.
- 3.31 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 across research disciplines, 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.