

Annex 1: House of Commons Science and Technology Committee Inquiry into Peer Review Supplementary written evidence from the UK Research Integrity Office

May 2011

1. Introduction

- 1.1 The UK Research Integrity Office Ltd. (UKRIO) is an independent body which provides expert and confidential advice and guidance about the conduct of research, from ensuring good practice in research to help with specific cases of alleged misconduct. Since its creation in 2006, UKRIO has amassed considerable experience in helping employers, researchers and the public with issues of research conduct across all subject areas. No other organisation in the UK has comparable expertise in providing such support and we welcome enquiries from all disciplines of research.
- 1.2 Further information about UKRIO is available from its website: www.ukrio.org .
- 1.3 This document provides further information on UKRIO and its work. It describes:
 - a. The history of UKRIO, including how UKRIO has been funded in the past and how it is currently supported.
 - b. Our plans for the future.
 - c. UKRIO's views on the statutory regulation of the conduct of research.
 - d. Why we do not seek regulatory powers for our organisation.

2. The history and funding of UKRIO

- 2.1 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. UKRIO was set up in 2006 as a result of these discussions, to provide independent and expert support to the UK research community and to the public about the conduct of research, including the promotion of good practice and the prevention and investigation of fraud and misconduct.
- 2.2 The original proposal for UKRIO set out the intended model of support – an independent advisory body rather than a regulator – and the initial programme of work. The latter included: the creation of an advice and guidance service on issues of research conduct available to all in research; the publication of standards for good research practice and the investigation of alleged misconduct; and the provision of education and training, both direct and via input into institutional training programmes. The proposal also stated that UKRIO should be hosted by an existing organisation in its initial pilot phase. Accordingly, from 2006 to late 2010 UKRIO was an unincorporated association hosted by Universities UK (UUK).
- 2.3 Although hosted by an existing organisation in its initial phase, UKRIO has remained independent throughout. It has been directed by its own independent Board since its inception rather than by the Board of UUK and has never shared sensitive information regarding its work with UUK or any other third parties. Similarly, UKRIO is not responsible to any external body other than in accounting for the funding it receives in regular reports. Our

fundors do not determine whom we help or how we help them and any advice given is kept confidential within UKRIO.

- 2.4 Many UK organisations with interests in research came together to set up, fund and support UKRIO, including: the four UK Departments of Health, the four UK Higher Education Funding Councils, the Academy of Medical Sciences, the Association of the British Pharmaceutical Industry, the Association of UK University Hospitals, the Biotechnology and Biological Sciences Research Council, the Committee on Publication Ethics, the Medical Research Council, the Medical Schools Council, the Medicines and Healthcare products Regulatory Agency, Research Councils UK, the Royal College of Physicians, the Royal College of Physicians of Edinburgh, the Royal Society, Universities UK and research charities including the Wellcome Trust.
- 2.5 The Board of UKRIO is pleased with the progress that has been made during the past four years. It is evident that researchers, research organisations and the public, all of 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. The users of our services and publications have welcomed our focus on advice and guidance that is appropriate and proportionate, rather than burdensome and bureaucratic. Particular achievements include:
- a. The publication of our Code of Practice for Research and Procedure for the Investigation of Misconduct in Research. UKRIO's publications have been adopted and used by many research organisations and endorsed by research funders and professional bodies.
 - b. The establishment of a register of expert advisors on issues of research conduct.
 - c. The provision of confidential and independent support to researchers, members of the public, higher education institutions, NHS organisations and private sector and charitable bodies on a wide range of issues of research integrity and misconduct. In 2010 alone UKRIO helped with more than 60 cases and use of our services continues to grow exponentially year on year.
- 2.6 While UKRIO continues to fulfil its remit of supporting the UK life sciences research community, for some time it has assisted with cases which extend across all academic disciplines, including science and engineering, social sciences and the arts and humanities. We have found that the principles of research integrity are common to all disciplines, though we recognise that each discipline has its own technical considerations which cannot be transposed to other disciplines and provide specialist expertise whenever necessary. This approach has been welcomed by the many individuals and organisations who have sought our assistance with cases outside of health and biomedicine since the inception of UKRIO.
- 2.7 In late 2010, UKRIO transferred from Universities UK and became a company limited by guarantee, UK Research Integrity Office Ltd. There was no break in the continuity of UKRIO's services and we continue to provide independent and confidential advice to researchers, research organisations and the public. UKRIO's transition was in accordance with the original proposal for the organisation, which indicated that we should move towards a wider pool of funders and supporters after the initial stage of our development.
- 2.8 The majority of UKRIO's staff are experts who give their time to the organisation *pro bono*. Accordingly, we operate very cost-effectively, providing our services to all involved in research at a cost of approximately £90,000 per annum.
- 2.9 UKRIO was run at a surplus in its first phase and these funds are currently sustain the organisation. Our plans for securing further funding to guarantee the future of our organisation are discussed in section three, below.

3. The future of UKRIO

- 3.1 UKRIO has provided comprehensive guidance to research organisations, researchers and the public since 2006, with a focus on support that is appropriate and proportionate, rather than burdensome and bureaucratic. We have regularly responded to requests for assistance in all subject areas and types of research.
- 3.2 It has become clear since UKRIO was set up that many institutions and individuals value our confidential, independent and expert approach and the services that we offer to all involved in research. Some research organisations may feel that they have issues of research integrity well in hand; however, it has become clear that many more institutions value being able to seek advice from an external source. Researchers, organisations and the public have all been willing to come forward and seek guidance on difficult issues from UKRIO.
- 3.3 There are significant risks if such support is not available, risks to the quality and the reputation of UK research, to public funds and to the safety and wellbeing of members of the public who participate in research, as well as to the financial and legal well-being of research organisations.
- 3.4 UKRIO is therefore convinced that it must continue to supply and develop the support it currently provides to the UK research community and the public and is seeking funding for that purpose. The costs of providing UKRIO's services are minimal compared with the personal, institutional, financial, legal and reputational consequences of research misconduct.
- 3.5 Comprehensive and non-bureaucratic support for research integrity must continue. It is essential that the UK research community continues to have access to expert support from UKRIO to help maintain high standards of research, protect participants, and safeguard public funds.
- 3.6 We recognise that the current economic climate means that potential funders will be forced to make hard decisions concerning which expenditures can and cannot be considered. However, it should be noted that the sums involved in continuing the work of UKRIO are modest in comparison with the much more ambitious plans that some stakeholders have envisaged as necessary for a research integrity body and are minimal compared to the consequences of research misconduct. UKRIO operates very cheaply and cost-effectively, with a very small staff backed by a Board and a panel of expert advisers, both of which work *pro bono*.
- 3.7 UKRIO has always recognised that it will need to further evolve as the needs of the research community change. We also recognise that our previous funding base was designed to support us in the initial phase of our work and will need to change as well in order to support the project in the long-term. Accordingly, we are beginning a process to increase the stability of support for the project by broadening the existing pool of long-term funding bodies. As noted above, this is in accordance with the original proposal for UKRIO, which indicated that it should move towards a wider pool of funders and supporters after the initial stage of its development.
- 3.8 UKRIO was initially funded through a broad stakeholder group, including the UK Higher Education Funding Councils, the UK Departments of Health, the Research Councils, research charities and a variety of other organisations. UKRIO is now seeking a new model through which to fund its activities. We plan to implement a subscription model thus ensuring that, crucially, those who employ researchers and are the key users of the service, namely universities, the Department of Health and NHS organisations, other Government Departments and research organisations such as public and private sector research institutes, and industry continue to have the benefit of this vital function. This model has worked extremely well for the Committee on Publication Ethics (COPE) which our Vice-Chair, Michael Farthing, and a number of other editors started in 1997. COPE is now

funded directly through a large stakeholder group of the publishers of academic journals; many now regard being a funding signatory of COPE is an indicator of their aspiration to seek excellence in publication ethics and integrity in academic publications.

- 3.9 We plan to write to organisations who employ researchers and undertake research to invite them to become subscribers. We propose to ask individual institutions to contribute a modest annual fee and make a commitment for three years in the first instance. This will allow UKRIO to continue to work actively to develop its service model to continue to meet the increasing demands made of it. Although these are uncertain times for the funding of many organisations, UKRIO has clearly demonstrated that its services are both required and valued and that it fills a gap in the research community that is not currently provided by any other UK institution.
- 3.10 It should be noted that two aspects of UKRIO's model of support will not change regardless of the move to a subscription model of funding:
- a. Whistle blowers and other individuals will not be charged for our help. Individuals who need guidance and support from UKRIO - whether researchers, research participants, patients or the public – will continue to use all of our services free at the point of delivery.
 - b. Our funders and supporters will not determine whom we help or how we help them. Similarly, we will not share confidential information about cases or our other work with our subscribers or any other third parties.

4. Views on the statutory regulation of the conduct of research

- 4.1 There is currently no overall statutory regulation of research or of researchers in the UK. While there are regulators for certain types of research, such as human clinical trials or research involving animal subjects, and for certain types of researchers, such as (medical) doctors, these are exceptions rather than the rule. When issues of research conduct arise, if a field of research is not governed by statute, it normally devolves to the employer to investigate and, if necessary, take remedial action.
- 4.2 There has been considerable discussion by the research community, and also by Government and in the media, over whether there should be more statutory regulation of the research in the UK. Equally, there has been considerable discussion over whether there should be less regulation.
- 4.3 While some commentators feel that the introduction of statutory regulation of research conduct would be helpful, it appears that this is not the view of the majority and that there is little appetite for more regulation and bureaucracy. Even among those who feel that statutory regulation would be desirable, there is considerable disagreement over what form that regulation should take – its jurisdiction and powers – and also a recognition that its introduction would not be a cure-all. It seems that much of the research community does not want statutory regulation at this time or would not be accepting of it if it was introduced.
- 4.4 Research in the UK covers a wide variety of organisations and employers (universities, NHS bodies, private sector organisations, charities), subjects (from the arts and humanities to health and biomedicine) and funding sources (government, charities, private sector, etc.). It would be extremely challenging to establish a body which could regulate all aspects of the research enterprise. Given that there already exists a variety of bodies with legal responsibilities in this area, primary legislation would be required and Parliament has chosen not to act in this area to date.

- 4.5 If the introduction of a regulatory regime was felt to be desirable, it would be essential that there was considerable discussion and consultation regarding its remit, powers and method of operation. For example, it would be vital that any regulatory body: recognised and accounted for the particular nuances of the wide variety of research methodologies which would fall within its remit, which could range from the arts and humanities to health and biomedicine; ensured that mechanisms for the regulation and governance of research were clear, consistent and transparent; harmonised and streamlined existing regulation for research, retaining what works well out of current arrangements; and be risk-based and proportionate throughout its work.
- 4.6 Above all, it would be essential to carefully manage any process of introduction and consolidation of regulation to ensure that there was continuous and rigorous safeguarding of public funds and protection of the quality of UK research and, most importantly, the safety and wellbeing of patients and participants.
- 4.7 The implementation of statutory regulation of research should not be seen as a panacea. For example, regardless of whether all aspects of research conduct were subject to regulation or not, 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. A strength of a research regulator would be that it could take significant steps to alleviate such problems, for example, by simplifying and harmonising existing regulation; however, it should be recognised that statutory regulation of all research would not cure every problem with the system on its own.
- 4.8 The regulation and governance of research in the health and biomedical sciences was recently the subject of an independent review by the Academy of Medical Sciences (AMS). It is worth noting that the review did not recommend the expansion of regulation beyond its existing boundaries, for example to have jurisdiction over issues of research conduct currently addressed by employers. Rather, it felt that “there is evidence that UK health research activities are being seriously undermined by an overly complex regulatory and governance environment”. It concluded that there should be simplification and harmonisation of current regulation and that the application of this regulation should aim to be proportionate and symmetrical.
- 4.9 In our experience, we have found that employers of researchers, to whom it falls most often to resolve issues of poor practice and misconduct in research, do have the power to take action to determine what has occurred and apply appropriate corrective measures. Indeed, they have a responsibility to do so. In the past there have been questions about how keen employers have been to fulfil their responsibilities and whether they had sufficient expertise to do so in an effective manner. UKRIO was set up to help correct this situation.
- 4.10 When UKRIO was conceived, there were concerns about how research misconduct was being addressed. Some institutions appeared to lack formal mechanisms to investigate and address misconduct; others had formal mechanisms but it appeared that they were applied inconsistently. Matters have improved since then but institutional mechanisms can still vary a great deal, leading to a lack of parity. However, we have found that guidance from UKRIO, whether on specific cases via our advisory service or through use of our publications, has helped employers fulfil their responsibilities and avoid many common issues and pitfalls. The sharing of good practice in the promotion of good research conduct and the prevention and investigation of poor practice and misconduct is essential. UKRIO makes an important contribution in this area, as do existing regulatory agencies, bodies which fund research and other organisations. This method of support can help further improve the integrity of UK research without requiring the establishment of new regulatory powers.

- 4.11 We recognise that there are those who might feel frustrated at the state of research integrity in the UK. Virtually all of those involved with UKRIO Ltd are experts who give their time to the project *pro bono*. They represent a positive response to concerns expressed about research integrity, concerns which UKRIO has responded to and met a need which otherwise had gone unmet. Individuals and organisations with experience in addressing research misconduct are welcome to collaborate with UKRIO.

5. Why UKRIO does not seek regulatory powers for itself

- 5.1 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.
- 5.2 Since our inception, we have focused on advice and guidance that is appropriate and proportionate, not burdensome and bureaucratic. We recognise that research and researchers in the UK do not require micro-management or the imposition of more paperwork. Instead, organisations and individuals need guidance and support that is practical and useful, and which encourages research of the highest quality and ethical standards, rather than the creation of burdensome and restrictive systems.
- 5.3 Accordingly, our advice and standards draw upon existing good practice and our own unique and considerable experiences in promoting good research practice and addressing misconduct. They are designed to avoid creating additional bureaucracy and delays, causing problems for innovative and cross-disciplinary research or, when dealing with allegations of misconduct, being inflexible to the circumstances of individual cases
- 5.4 We recognise that there is no “one-size-fits-all” solution but we do believe there is room for common approaches to common situations and that good practice should be shared. Most issues of research integrity are not unique to any particular setting and nor are the solutions proposed. All disciplines have considered these issues, and how to respond to them, to a greater or lesser degree. It is UKRIO’s experience that there are many common themes that emerge, though we have always recognised that each discipline will have unique considerations and provide specialist expertise whenever necessary.
- 5.5 We also feel that our 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.
- 5.6 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.
- 5.7 There has been considerable use and uptake of our services since we began our work in 2006. Our status as an advisory body, rather than a regulator, has not been an impediment to this; in fact, it has helped it. We have found that we do not need statutory powers to get results. Our published guidance has been adopted and used by many institutions, while our advisory service dealt with more than 60 cases in 2010 alone. Whilst one might expect researchers, employers and the public to be hesitant about sharing problems with a non-regulatory body,

our experience has shown there is no such reluctance. Similarly, employers are more than willing to adopt and use our guidance on issues of research practice and addressing misconduct, despite its use being strictly voluntary.

5.8 Consequently UKRIO does not seek regulatory powers. In fact, we feel that to seek such powers would conflict with the core values and mission of UKRIO and the way in which we have successfully provided support to the research community and the public.

5.9 However, we have worked with existing regulators on matters of mutual interest and, if a statutory regime of regulation was ultimately regarded as desirable, we would be very keen to work with the body which was established to fulfil this function. If Parliament chose to act in this area, we feel very strongly that UKRIO's unique role could help an regulatory organisation minimise the burden of regulation and help maintain the UK's world-class reputation for conducting exceptional and innovative research. Meanwhile, UKRIO will continue to raise the profile of good practice in research and address misconduct.

6. Further information

6.1 For further information on UKRIO, please contact: James Parry, Acting Head, UK Research Integrity Office, tel. 020 7419 5498; email james.parry@ukrio.org .