UK Research Integrity Office

Position statement:

Statutory regulation of research integrity

Updated November 2016

Introduction: research integrity in the UK

1. Structures for supporting and safeguarding research integrity have been debated for decades. Ultimately, all countries and jurisdictions rely on self-regulation by researchers. What varies are the structures set up to support and oversee this self-regulation and to ensure that action is taken when needed. Some countries take a regulatory approach. Others, such as the UK, have a policy of minimising regulation and relying more on professional practice.
2. 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.
3. When issues of research conduct arise, if a field of research is not governed by statute, it normally devolves to the relevant employer – such as a university, NHS body or private sector organisation - to investigate and, if necessary, take remedial action (issues of research conduct involving research students would be addressed by the relevant university). In turn, research funding bodies, via contractual mechanisms, help ensure that employers fulfil their responsibilities.

4. As stated in *The Concordat to Support Research Integrity*[1], UK research organisations are also responsible for taking positive steps to ensure that research is carried out in accordance with accepted professional standards. This includes '…collaborating to maintain a research environment that develops good research practice and nurtures a culture of research integrity… [and] supporting researchers to understand and act according to expected standards, values and behaviours'. Again, funding bodies help ensure that employers fulfil their responsibilities in this area.

The role of the UK Research Integrity Office

5. The UK Research Integrity Office (UKRIO) is an independent charity, offering support to the public, researchers and organisations to further good practice in academic, scientific and medical research. We welcome enquiries on any issues relating to the conduct of research, whether promoting good research practice, seeking help with a particular research project or investigating cases of alleged fraud and misconduct.

6. Since 2006, UKRIO has provided independent, expert and confidential support across all disciplines of research, from the arts and humanities to the life sciences. We cover all research sectors: higher education, the NHS, private sector organisations and charities. No other organisation in the UK has comparable expertise in providing such support in the field of research integrity.

7. UKRIO is an advisory body, not a regulator. Our advice and guidance are not mandatory; instead, they reflect and reinforce existing good practice. We have no interest in micro-managing researchers or telling them what they 'must' do. Our intent is to provide practical and proportionate advice, which the public and the research community may find useful.

8. Reflecting confidence in our approach to issues of research integrity and the services that we provide to the research community, today more than 50 UK universities subscribe to UKRIO[2], including most of the Russell Group of universities. Most recently, universities from outside the UK have also discovered the benefits of a UKRIO subscription.

9. Recognition of the value of our work extends beyond higher education: *The Consensus Statement on Research Misconduct in the UK*[3] strongly endorsed our work, urging those who have not done so to join, and the Royal Society and the British Academy subscribe to UKRIO, along with a number of independent research institutes. *The Concordat to Support Research Integrity* was developed with the assistance of UKRIO and it recognises us as a key source of support for research institutions and researchers. In a 2016 progress report on The Concordat[4], the essential work of our charity was noted by many of the organisations who contributed to the report.

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[1] Universities UK et al., 2012. *The Concordat to Support Research Integrity* [online]. Available from: http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf

[2] http://ukrio.org/our-subscribers/

[3] British Medical Journal and Committee on Publication Ethics, 2012. *A consensus statement on research misconduct in the UK*. *BMJ*2012;344doi: http://dx.doi.org/10.1136/bmj.e1111 [online]. Available from: http://www.bmj.com/content/344/bmj.e1111

[4] Universities UK et al., 2016. *The Concordat to Support Research Integrity: A Progress Report* [online]. Available from: http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2016/concordat-research-integrity-progress-report.pdf

Views on the statutory regulation of the conduct of research

10. 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.

11. 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.

12. 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.

13. If the introduction of a regulatory regime was felt to be desirable, it would 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.

14. 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.

15. 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.

16. The regulation and governance of research in the health and biomedical sciences was the subject of an independent review by the Academy of Medical Sciences in 2011[5]. 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.

17. In July 2011, the House of Commons Science and Technology Committee published its report *Peer Review in Scientific Publications*[6]. One of the conclusions of this report was '...that there should be an external regulator overseeing research integrity.' The Government responded to the report in September 2011[7]. It declined the call to legislate on this issue, stating:

> '…the Government does not agree that there is a case for setting up an external regulator to oversee the employers. There are already a number of regulatory and licensing bodies in key areas of research, and therefore any new regulatory body would increase regulatory burden on employers, and risks causing unnecessary overlap and uncertainty. Through the Research Integrity Concordat the Government will expect employers of researchers to deal with research integrity in an open and transparent manner."

18. Subsequently, a stakeholder group including the Government, UUK and the major UK research funding bodies published *The Concordat to Support Research Integrity* in 2012. This set out a non-regulatory approach to safeguarding research integrity, with a strong emphasis on culture and leadership. A 2016 progress report[8] found that, while there was no room for complacency, the Concordat approach:

> '…is seen as an appropriate, proportionate and effective mechanism and there has been considerable investment by research organisations and their staff in ensuring that systems and processes are fit for purpose.'

19. The report[9] also stated that:

> 'Overall, support for the concordat approach was strong across institutional representatives, research managers and administrators, and funders. Recognition of the autonomy of employers is seen to be important, and the flexibility of the concordat approach is highly valued. The approach continues to be favoured by practitioners over alternatives such as direct regulation.'

20. 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

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[5] Academy of Medical Sciences, 2011. *A new pathway for the regulation and governance of health research* [online]. Available from: http://www.acmedsci.ac.uk/download.php?file=/images/project/130734957423.pdf

[6] House of Commons Science and Technology Select Committee, 2011. *Peer review in scientific publications* [online]. Available from: http://www.publications.parliament.uk/pa/cm201012/cmselect/cmsctech/856/856.pdf

[7] UK Government, 2012. *Memorandum in response to 'Peer review in scientific publications'* [online]. Available from: http://www.publications.parliament.uk/pa/cm201012/cmselect/cmsctech/1535/1535.pdf

[8] Universities UK et al., 2016.

[9] Universities UK et al., 2016.

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.

21. 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[10] or through use of our publications[11], 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.

22. 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 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 promoting research integrity or addressing research misconduct are welcome to collaborate with UKRIO.

Why UKRIO does not seek regulatory powers for itself

23. 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[12].

24. 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.

25. 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.

[10] http://ukrio.org/get-advice-from-ukrio/

[11] http://ukrio.org/publications/

[12] UK Research Integrity Office, 2014. *Guidelines for Seeking Advice* [online]. Available from: http://ukrio.org/get-advice-from-ukrio/

26. 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.

27. 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.

28. 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.

29. 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. We received over 100 formal requests for our help in 2016, as well as many informal ones. Our publications[13] have been endorsed by funding bodies and learned societies, and are used by many leading research organisations including over 50 universities.

30. The 2016 progress report[14] on *The Concordat to Support Research Integrity* recognised the 'excellent support and leadership from the UK Research Integrity Office' on research integrity. This was echoed by comments from [15]many of the organisations who contributed to the report:

> '…the most oft-cited resources that institutional leads on research integrity drew on were those provided by the UK Research Integrity Office, with both the 'hard' guidance available through UKRIO (such as model policies and processes) and the 'soft' support (such as informal advice and the annual conference) being highly valued.'

31. 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.

32. 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

[13] http://ukrio.org/publications/

[14] Universities UK et al., 2016.

support to the research community and the public. 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.

33. If Parliament chose to act in this area, we feel very strongly that UKRIO's unique role could help a 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.

Further information

34. For further information, please contact UKRIO on +44 (0)20 3828 1325 or infor@ukrio.org .

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