

# House of Commons Science and Technology Committee: Research integrity inquiry

## Written submission from the UK Research Integrity Office

February 2017

### Executive Summary

- Integrity in research is essential: to safeguard high standards in research; to retain the public's trust; to enhance the UK's international reputation; and to ensure the safety and wellbeing of research participants.
- The UK's approach to supporting and enhancing research integrity is non-regulatory, with a strong emphasis on culture and leadership. This approach has received positive feedback but there is no room for complacency.
- Data on research integrity is piecemeal. Additional research needs to be carried out to more accurately assess research integrity and research culture, in the UK and elsewhere. UKRIO will be developing a programme to conduct and/or fund further research on research integrity in the UK.
- Institutions have moved towards greater openness and transparency regarding research integrity, and we would urge them to continue their work in this area. Similarly, funders can build on existing data on research integrity by pooling and publishing anonymised summary data.
- Concerns about the negative influence of certain aspects of 'research culture' need to be addressed by long-term and collective action by the research community, supported by funders and publishers.
- Expanded regulation of research integrity would not address the majority of current concerns and would instead add new burdens and bureaucracy. UKRIO therefore remains opposed to new or expanded statutory regulation, except, consistent with current practice, in those areas where it is determined there are sensitive ethical issues or safety/ national security considerations.
- UKRIO does not seek regulatory powers for itself, as this would conflict with both our remit and the way in which we have successfully provided support to the research community and the public.

- 1 The UK Research Integrity Office<sup>1</sup> (UKRIO) is an independent charity, supported by subscriptions from research organisations<sup>2</sup>, offering support to the public, researchers and organisations to further good practice in academic, scientific and medical research. We promote integrity and high ethical standards in research, as well as robust and fair methods to address poor practice and misconduct, through publications on research practice<sup>3</sup>, support and services to organisations<sup>4</sup>, education and training activities<sup>5</sup>, and by providing expert guidance in response to requests for assistance<sup>6</sup>.
- 2 Since 2006, UKRIO has provided support across all disciplines of research, from the arts and humanities to the life sciences. Our work covers 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.

## The extent of the research integrity problem / Causes and drivers of recent trends

- 3 There is growing scrutiny and discussion of issues of 'research integrity', 'scientific integrity', 'research practice', 'good research conduct' and 'research misconduct'. A key issue is what standards – regulatory or otherwise- there are for the conduct of research and if these standards are being adhered to.
- 4 Breaches of these standards range from honest but avoidable errors<sup>7</sup> ('sloppiness') and the inability to replicate research findings<sup>8</sup>; through minor but deliberate transgressions ('questionable research practices')<sup>9</sup>; to serious, intentional breaches of research practice ('scientific fraud', 'research misconduct')<sup>10</sup>.
- 5 Issues of research integrity have been examined by Government<sup>11</sup>, Parliament<sup>12</sup>, research funders<sup>13</sup>, learned societies<sup>14</sup>, academic journals<sup>15</sup> and international organisations<sup>16 17 18 19</sup>. This has led to new guidance for the conduct of research<sup>20</sup> or changes in structures for research governance<sup>21</sup>. To date Government has declined calls to legislate on these issues, such as creating statutory oversight or investigatory bodies<sup>22</sup>.
- 6 Research integrity has been examined in the mainstream<sup>23</sup> and academic<sup>24 25</sup> media. There has been thoughtful discussion but often the focus can be on 'scandals', whether the term might be applicable<sup>26</sup> or not<sup>27</sup>. There has also been increased interest from the public and blogs that discuss unacceptable practices in research can attract a large readership<sup>28 29</sup>.
- 7 Data on research integrity are piecemeal. As noted in the recent POSTnote<sup>30</sup>, information about the frequency of poor practice and deliberate misconduct is limited and often approximate, with much of the research focussing on international biomedical sciences. Studies have examined the frequency of fraud and questionable practices<sup>31</sup>, the influence of career and other pressures<sup>32</sup>, and retractions of academic papers<sup>33</sup>. Universities have begun publishing annual statements on research integrity, including anonymised summary data on misconduct cases; however uptake has been slow and more universities need to adopt this culture of openness<sup>34</sup>.
- 8 Research Councils UK (RCUK) publishes similar information in its annual research integrity statement gathered from audits of grant-holding organisations<sup>35</sup>. As more organisations undergo the audit process<sup>36</sup>, this data will become more robust.
- 9 It would be useful if other funders who collect similar information from grant holders could pool anonymised summary data with that of RCUK and make this data publicly available. Not only would this increase the robustness of research integrity data in the UK, it would also encourage research organisations and others to be more open. Such data should not focus solely on misconduct but also include activity to enhance good research practice.
- 10 **Causes and drivers of recent trends:** there is some evidence of an increase in problems, in journal retractions, and in requests for advice to UKRIO. It is unclear whether this is due to increased frequency of research misconduct or to improved detection, increased awareness by researchers, and greater openness by research organisations and journals. In addition, UKRIO's Advisory Service covers how to achieve good practice in research and does not focus solely on poor practice and misconduct.

- 11 Much discussion has taken place on what influence ‘research culture’ may have on the quality and ethical standards of research. This includes, for example: assessment of research proposals; how research outputs are disseminated and assessed; research governance and integrity; career development, progression and workload; and leadership of research teams and research organisations. It also takes into account the aims of the Equality Challenge Unit (e.g. the Race Equality Charter<sup>37</sup> and the Athena SWAN Charter<sup>38</sup>) and the Leadership Foundation for Higher Education (e.g. the Aurora programme<sup>39</sup>).
- 12 A 2014 report by The Nuffield Council on Bioethics<sup>40</sup> found that scientists generally have high expectations of themselves and others, aspiring to do rigorous, ethical work and valuing the influence of guidelines such as *The Concordat to Support Research Integrity*<sup>41</sup> (*‘The Concordat’*). However, the inquiry also reported major concerns about pressures to focus on and report positive results, and also perverse incentives to fabricate, alter, omit or manipulate data, including ‘cherry picking’ results.
- 13 Aspects of research culture, such as competition, “are believed both to bring out the best in people and to create incentives for poor quality research practices”<sup>42</sup>. Some argue that problems are caused by existing initiatives and practices; others that initiatives and practices are sound but have been communicated poorly by stakeholders and misunderstood by researchers. UKRIO’s view is that both arguments have some merit.
- 14 The Nuffield Council’s report<sup>43</sup> focuses on science in the UK. Anecdotally, similar issues have been reported in other disciplines, as well as in other countries. This suggests that problems with research culture are limited neither to the sciences nor to the UK.
- 15 Additional research needs to be carried out to more accurately assess research integrity and research culture, in the UK and elsewhere. To that end, in 2017 UKRIO will be developing a programme to conduct and/or fund further research on research integrity in the UK, complementing existing work such as the Horizon 2020-funded Promoting Integrity as an Integral Dimension of Excellence in Research (PRINTEGER)<sup>44</sup>.

### **The effectiveness of controls/regulation (formal and informal), and what further measures if any are needed**

- 16 Structures for safeguarding research integrity have been debated for decades. Ultimately, all countries and jurisdictions rely on self-regulation by researchers<sup>45</sup>. 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<sup>46</sup>.
- 17 **Initiatives for supporting research integrity in the UK** have evolved over some years. Key milestones include the creation of UKRIO in 2006; the creation of the Health Research Authority in 2011; and the publication of *The Concordat* in 2012 and its adoption as a condition of funding by major research funders and the Higher Education Funding Council for England<sup>47</sup>. The Committee on Publication Ethics, which now has an international remit, was established in 1997 by a group of journal editors in the UK<sup>48</sup>.

- 18** There is currently no overall statutory regulation of research conduct in the UK. Regulators – such as those for certain types of research (e.g. human clinical trials or research involving animal subjects) or for certain types of researchers (e.g. medical doctors) - are exceptions rather than the rule.
- 19** When issues of research conduct arise, unless the type of research is governed by statute, it normally devolves to the relevant employer to investigate and take any remedial actions. Research funders, via contractual mechanisms, help ensure that employers fulfil their responsibilities<sup>49</sup>.
- 20** As stated in *The Concordat*<sup>50</sup>, UK research employers are also responsible for taking positive steps to ensure that their research meets accepted standards: ‘...collaborating to maintain a research environment that develops good research practice and nurtures a culture of research integrity... supporting researchers to understand and act according to expected standards, values and behaviours’. Again, funders help ensure that employers fulfil these responsibilities<sup>51</sup>.
- 21** This work by employers and funders is supported by the activities of UKRIO, learned societies, professional bodies and other networks. UKRIO’s work draws on the expertise of the UK research community and, like the activities of the NHS R&D Forum<sup>52</sup> and the Association of Research Managers and Administrators (ARMA)<sup>53</sup>, facilitates the sharing of good practice by organisations and researchers. UKRIO also acts as a conduit to provide anonymous feedback on whether initiatives are working well and or might require adjustment. UKRIO will continue to collaborate with partner organisations, for example on the further development of a framework of policies and procedures for university research ethics committees with ARMA
- 22** Safeguarding and enhancing research integrity in the UK can therefore be said to have a tripartite structure:
- a. research organisations supporting and overseeing their researchers;
  - b. funding bodies monitoring research organisations; and
  - c. UKRIO and others supporting the first two groups.
- 23** At the core is self-regulation by researchers but this is not taken for granted, as demonstrated by the roles and activities of the three groups.
- 24** **The role of UKRIO:** UKRIO is an advisory body. Our advice and guidance are not mandatory but reflect and reinforce existing good practice<sup>54</sup>. We have no interest in micro-managing researchers; our intent is to provide practical, proportionate and useful advice.
- 25** Reflecting confidence in our ethos and services, more than 60 UK universities and other research organisations subscribe to UKRIO<sup>55</sup>, including most of the Russell Group of universities. Organisations from outside the UK have also discovered the benefits of a UKRIO subscription.
- 26** Support for UKRIO extends beyond higher education: *The Consensus Statement on Research Misconduct in the UK*<sup>56</sup> strongly endorsed our work and the Royal Society and the British Academy subscribe to UKRIO. *The Concordat* was developed with our assistance and it recognises us as a key source of support. In a 2016 progress report on *The Concordat*<sup>57</sup>, the essential work of our charity was noted by many organisations.

**27 Effectiveness and next steps:** *The Concordat* codified the UK's approach to safeguarding and enhancing research integrity: non-regulatory, with a strong emphasis on culture and leadership. The 2016 progress report<sup>58</sup> 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.'

**28** The report<sup>59</sup> also stated that:

'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.'

**29** We have found that employers do have the power to investigate concerns about research and apply appropriate corrective measures. Indeed, they have a responsibility to do so. In the past there have been questions about how keen employers were to fulfil their responsibilities and whether they had sufficient expertise to do so effectively. UKRIO and subsequent initiatives were set up to correct this situation. Employers should continue to investigate concerns about research thoroughly, fairly and in a timely manner. To ensure objectivity and transparency, and to help reassure involved parties that the process will be fair, UKRIO has recommended for some time that investigation panels include an external member<sup>60</sup>; we also assist organisations in locating such experts.

**30** In our experience, guidance from UKRIO, whether advice on specific cases<sup>61</sup> or via our publications<sup>62</sup>, can help employers fulfil their responsibilities and avoid many common pitfalls. More needs to be done and increased openness and sharing of good practice is essential. UKRIO makes an important contribution in this area, as do existing regulatory agencies, funders and others. This method of support can help further improve the integrity of UK research without requiring the establishment of new regulatory powers.

**31** Anecdotally, employers can feel limited on what information they can legitimately disclose at the conclusion of a research misconduct investigation - for example, if an allegation was upheld and the researcher concerned then moved to another institution but without requesting a reference from his/her previous employer. It would be helpful for regulatory bodies, funders and professional bodies to explore how they might address these situations when they occur.

**32** The evidence from The Nuffield Council on Bioethics<sup>63</sup> confirms the view of UKRIO and others that research institutions must continue to provide strong leadership to build a research environment that supports researchers throughout their careers in striving for robust scientific design and high ethical standards. Equally, funders, journals and publishers must explore how they can better support researchers and organisations to achieve this. We look forward to exploring with the research community and other stakeholders how this might be done.

**33** Effecting cultural change is long-term work. However, many of the issues identified are familiar and much work already is being done to address them, including in universities (e.g. establishing research integrity 'champions' to further support good practice<sup>64</sup>) and across the research community as a whole -

for example, the San Francisco *Declaration on Research Assessment* (DORA)<sup>65</sup> and the growing uptake of ORCID digital IDs by researchers<sup>66</sup> and publishers<sup>67</sup>. Such proactive measures and increased openness should be encouraged. To avoid duplication of effort, the research community can also learn from existing initiatives, such as Athena SWAN, and build on them.

### **What matters should be for the research/academic community to deal with, and which for Government?**

*UKRIO's views on these issues, including why the charity does not seek regulatory powers, are described in further detail in our [Position Statement on the Statutory Regulation of Research Integrity](#)<sup>68</sup> (2016) and we would draw the attention of the Committee to this document.*

- 34** Regulation of research, as of any other activity, can take various forms, ranging from regulation via statute, through regulation by independent bodies, to self-regulation.
- 35** There has been considerable discussion over whether there should be more statutory regulation of research in the UK. Equally, there has been considerable discussion over whether there should be *less* regulation.
- 36** Some feel that statutory regulation would be helpful. However, it appears that most of the research community does not want statutory regulation and increased bureaucracy, or would not be accepting of it if it was introduced. Within the minority who feel that statutory regulation would be desirable, there is considerable disagreement over what its jurisdiction and powers should be. They also recognise that it would not be a cure-all.
- 37** Research in the UK covers a wide variety of organisations, subjects and funding sources. It would be extremely challenging to establish a body to regulate all aspects of the research enterprise. As there are already various bodies with legal responsibilities in this area, primary legislation would be required and no Government has chosen to act in this area to date.
- 38** If statutory regulation was felt to be desirable, considerable discussion and consultation on its remit, powers and method of operation would be essential. Any regulatory body must: account for the particular nuances of the wide variety of research methodologies which would fall within its remit; ensure that mechanisms for regulation were clear, consistent and transparent; harmonise existing regulation, retaining what works well; and, above all, be risk-based and proportionate.
- 39** It would be essential to carefully manage any introduction of regulation to ensure that there was continuous, rigorous safeguarding of public funds and protection of research quality and, most importantly, the safety of patients and participants.
- 40** The statutory regulation of research would not be a panacea. Whether more aspects of research conduct were subject to regulation or not, professional and representative bodies will produce their own guidance to interpret regulations, many of which will have differences of varying subtlety. Similarly, variation in the interpretation and implementation of the requirements of regulation would exist at the local level.

- 41** It is unclear whether regulation would be an effective tool to address many of the existing concerns about research integrity. For example, the issues of culture and leadership identified by the Nuffield Council on Bioethics<sup>69</sup> and others require long-term work by the research community as a whole to address. It is hard to see how a regulatory body, whether statutory or otherwise, could address these issues.
- 42** As noted earlier, we have recently published an updated position statement on regulatory powers<sup>70</sup> which discusses these issues further. In summary, we remain opposed to new or expanded statutory regulation for the reasons set out, except, consistent with current practice, in those areas where it is determined there are sensitive ethical issues or safety/ national security considerations.
- 43** **Why UKRIO does not seek regulatory powers for itself:** as noted earlier (paragraph 24), UKRIO has no formal legal powers. Our advice and standards are not mandatory but draw upon existing good practice and our own unique and considerable experiences in promoting good research practice and addressing misconduct<sup>71</sup>. 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.
- 44** We feel that our model of support - an independent advisory body offering confidential and expert support – is particularly important given the Government’s aims to help the sector to save money and further improve its international reputation. Our focus on appropriate and proportionate support, rather than burdensome and bureaucratic, is also in accordance with the Government’s emphasis on relying on professional responsibility and reducing unnecessary bureaucracy.
- 45** UKRIO’s does not seek to trespass on the remits of existing regulatory bodies but instead works with them as appropriate. In many ways, UKRIO was set up to fill in the gaps between the various jurisdictions, where no overall regulation applies, and to direct researchers, organisations and the public to the regulators where their jurisdiction does apply.
- 46** 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 have been endorsed by funding bodies and learned societies, and are used by many leading research organisations including over 50 universities.
- 47** The 2016 progress report on *The Concordat* recognised the ‘excellent support and leadership’ from UKRIO, a view echoed by 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.’

- 48 Whilst one might expect the research community to be hesitant about sharing problems with a non-regulatory body, our experience has shown there is no such reluctance. Employers are more than willing to adopt and use our published guidance, despite its use being strictly voluntary.
- 49 Consequently, UKRIO does not seek regulatory powers, as this would conflict with our vision and values and the way in which we have successfully provided support to the research community and the public. However, we have worked with existing regulators and, if a statutory regime of regulation was ultimately regarded as desirable, we would be very keen to work with the new regulator.
- 50 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

- 51 For further information or to discuss any of the points raised in this submission, please contact UKRIO on +44 (0)20 3828 1325 or via email [info@ukrio.org](mailto:info@ukrio.org).

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<sup>1</sup> [www.ukrio.org](http://www.ukrio.org)

<sup>2</sup> <http://ukrio.org/our-subscribers/>

<sup>3</sup> <http://ukrio.org/publications/>

<sup>4</sup> <http://ukrio.org/our-subscribers/subscribing-to-ukrio/examples-of-services-for-ukrio-subscribers/>

<sup>5</sup> <http://ukrio.org/our-work/education-and-training/>

<sup>6</sup> <http://ukrio.org/get-advice-from-ukrio/>

<sup>7</sup> Nature, 2012. 'Must Try Harder.' *Nature* doi:10.1038/483509a [online]. Available from: <http://www.nature.com/nature/journal/v483/n7391/full/483509a.html>

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