
UK Research Integrity Office

Response by the Wellcome Trust

June 2009

Introduction

1. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending over £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. The Trust welcomes the opportunity to respond to UK Research Integrity Office (UKRIO) consultation on its Code of Practice for Research: Promoting good practice and preventing misconduct ('the Code').
3. We support the promulgation of good practice in research and, therefore, the general aims of this Code, namely to:
 - a. Encourage good conduct in research and help prevent misconduct;
 - b. Provide a single point of reference for researchers and research organisations on key principles and areas of regulation which must be considered when undertaking research;
 - c. Provide a benchmark for organisations developing their own codes of conduct; and
 - d. Apply the principles of good practice in research across all disciplines and not restrict them to the biomedical sciences, although this goes beyond the remit of UKRIO.
4. However, we are concerned about a number of issues with the Code, namely:
 - a. The Code needs to be clear as to where it fits in the overall framework on good research practice and good research conduct: currently there is little value added to the current framework by the Code and it may create confusion from yet another document circulating in this 'space';
 - b. The scope of the Code and the level of detail. The Code needs to be clear as to whether it is intended as an initial overview for researchers, and if so where they should go next, or a single point of reference which includes all the necessary details and referencing to undertake research. If the later, then additional annexes providing links to specific requirements for different disciplines should be included.
 - c. Further detail and an accompanying strategy are required to establish how the Code would be rolled out, and the principles implemented in practice. Codes, in and of themselves, do not change behaviour. Implementation and follow-up will be key to improved practice in this area.
5. Overall the Code is quite thorough, in that it recounts in some detail the main general principles of good practice in research. However there is a plethora of documents produced by various bodies which cover the same or similar material and hence the need for organisations to work together in standardising guidelines in this area. We have reviewed the Code in the context of other codes of practice and guidelines already in existence governing good research conduct in the UK. In our response to the Research Councils UK (RCUK) consultation on its Code of

Conduct and Policy on the Governance of Good Research Conduct¹ we encouraged RCUK, UKRIO, funders and Research Organisations (RO's) to work together to develop one set of standards that applies across the UK, in public and private research organisation. RCUK have recently released their revised code. We encourage UKRIO to work with RCUK and relevant stakeholders to ensure that work in this field is not duplicative and does not create additional and unnecessary reference points for researchers.

6. We note that encouraging good conduct requires activities such as training, awareness raising and evaluation of policy implementation. This requires organisations such as UKRIO, RCUK and ROs to work together to develop programmes in these areas and will not be achieved by the Code alone.

7. **Specific Questions from the consultation- Does the Code have potential to help:**

a. **Organisations and researchers to better understand the principles and standards of good research in practice?**

The draft Code does encapsulate the principles and responsibilities of researchers and organisations and aims to enable both to readily access the key principles of good research conduct. We are concerned however that it does not give any evidence or case examples that demonstrate: the serious impact of research misconduct; what could constitute research misconduct or why it is so important that good research practices are followed. Such examples could cover issues such as maintaining public confidence in stem cell research and the knock-on effects of data falsification. It could also include technical examples of good research conduct, e.g. interpretation of imaging, ability to reproduce data etc.

In addressing the two audiences-researchers and organisations- both jointly and separately, the Code is often repetitive. UKRIO might give consideration to separating the principles into two standalone documents: one for institutions and one for researchers, since the messages might be conveyed more effectively if they are targeted to their specific audiences and accompanied by relevant examples, as suggested above.

b. **Organisations to understand better their responsibilities in promoting and supporting a culture of good practice in research.**

The Code could be useful as a benchmark document if regularly kept up to date. However, for the reasons outlined in paragraph 4, it is not clear that the Code itself necessarily adds significant value to what already exists within ROs and the existing policy framework.

c. **Researchers to consider the wider consequences of their work and to engage critically with good practice in research, rather than treating codes of practice such as this as another procedure to be followed?**

As mentioned in (a) above, the Code does not provide any examples of good practice or case studies illustrating the impact of misconduct. As most RO's have Good Research Conduct guidelines which must be considered by researchers, the point at which they should consider the information provided in this Code is not clear. More focus should be placed on ensuring that researchers actively engage with existing good practice procedures, and that institutions keep these relevant, informed and up to date.

8. **Do you consider that there are any omissions from the Code?**

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http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTX051651.pdf

Further consideration is needed as to whether the Code and additional resources are directed to encouraging good research practice, or whether it should focus more specifically on being a high level first port of call for researchers and institutions wishing to conduct research. In its current form it is not clear what gap in information or guidance regarding best practice is filled by the Code. The Code would benefit from providing a list of references to other relevant documents, such as those published by the Office of Research Integrity in the USA² and more detailed references to regulatory frameworks for specific research such as research using human participants etc.

More specifically, the Code does not cover the following:

- i. Peer Review for funding and ethical review committees, which covers a substantial amount of peer reviewers work, is absent from the peer review section;
- ii. Clear notes in specific sections that funding bodies may require additional conditions to be met, especially in areas such as intellectual property and open access; and
- iii. A section on 'Risks of Research Misuse'.

9. Would your organisation consider using the Code when drafting or revision your own Code of Practice?

The Code summarises and pulls together the key principles from a range of good practice guidelines. If, through a collaborative process, the Code was implemented to streamline good practice guidelines across a number of funders and research organisations, the Trust would refer to the Code when revising its own Code of Practice and would encourage ROs to do likewise. For new institutions which have not already developed a code of conduct, then a 'gold standard' code which has the acceptance of a range of research funding bodies would provide a useful framework.

10. How does the Code compare to existing frameworks in your organisation for good research conduct? Are any of the elements better or worse?

The Trust already has a policy of Good Research Conduct, and additional provisions in its grant conditions regarding research conduct- the provisions and principles of which are broadly compatible with the Code. Therefore the Code does not appear to add value to the Trust's existing framework for good research conduct. As noted previously more focus is needed in actively engaging researchers with existing guidelines.

11. Would you want other organisations to use the Code?

If research organisations do not have their own Code of Conduct in place then we would support the availability of a 'gold standard' to assist them to develop their own Codes of Conduct. As has already been noted, a code of conduct alone is not sufficient in promoting and implementing a culture of good research conduct. We would therefore like to see a consistent framework for the promotion, implementation, training in and monitoring of good research conduct within each of the organisations that we fund.

12. Should the checklist require verification and signing off? Should this be a checklist for staff involved in governance of a project or for organisational systems and policies.

We are concerned that the checklist will be too prescriptive to cover a broad section of research and is likely to be rejected by the research community. Moreover, requiring the checklist be verified or signed off runs the risk of moving the responsibility for maintaining good

² <http://ori.dhhs.gov/>

research conduct from the researcher to the person verifying the checklist, be they a research supervisor or institutional representative.

The principles contained in the Code are useful for encouraging a culture of behaviour. Checklists however are in danger of making principles conditions to fulfil as opposed to encouraging a way of behaviour and therefore do not necessarily promote a culture of good research conduct. More detailed checklists for specific areas of research, for example research using human tissue are more appropriate for sign off.

13. **Other views?** As noted previously we are concerned as to how this piece of work sits within a national research governance framework. Such a framework should not only include high level principles, but also a means of implementing, enforcing and policing good research conduct. We would encourage UKRIO to work more closely with Research Councils UK, UUK and other RO's and funders if they are to take this piece of work forward so that it does usefully contribute to the UK framework for promoting good research conduct. Only then is it likely to gain the widespread acceptance that it needs to be a successful addition to the existing range of standards.