



UKRIO response to the Medical Research Council's consultation on *Good Research Practice: Principles and guidelines*

February 2012

1. Introduction

- 1.1 The UK Research Integrity Office (UKRIO) welcomes this opportunity to contribute to the consultation by the Medical Research Council (MRC) on a draft revision of its principles and guidelines on good research practice. We fully support attempts to review and improve existing guidance on research integrity, to enhance the quality and ethical standards of research and reduce burdens on researchers.
- 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. It also draws upon a number of organisations which made anonymous comments to UKRIO concerning the draft guidance.
- 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 at james.parry@ukrio.org.

2. General comments on *Good Research Practice: Principles and guidelines*

- 2.1 We feel that the document sets out, in a clear fashion, well-founded principles and standards for good practice in health and biomedical research. The content is of a high standard but we feel it could benefit from a few additional points which we describe in this submission. In addition, we feel that there are a few areas where the principles and/or standards could benefit from greater clarity.
- 2.2 Since the publication of the MRC's original *Good Research Practice*, Research Councils UK (RCUK) has issued guidance on good research practice, including how to respond to allegations of misconduct: *Integrity, Clarity and Good Management* (2009). This guidance is binding on all those in receipt of RCUK funds, including those of the MRC. It would be very helpful for researchers and organisations if it was more explicit where the requirements of *Good Research Practice: Principles and guidance* match with the existing requirements of *Integrity, Clarity and Good Management*. Similarly, *Good Research Practice: Principles and guidance* could also show where its requirements are additional to, and/or more rigorous than, those previously required by RCUK.

- 2.3 Several organisations remarked to UKRIO that the consultation period was relatively short. They felt that more time to consider the document and submit a more informed response would have been helpful.
- 2.4 Some organisations noted that smaller research institutions might find it challenging to meet the requirements of the guidance, particularly those that conducted MRC-funded research on an infrequent basis and/or were still developing their research portfolios. The MRC might consider making additional advice and support available to such institutions to ensure that they can meet and sustain the requirements of good research practice.
- 2.5 The titles of two UKRIO publications which are quoted in the 'Related Links' text boxes are listed incorrectly throughout the document, for example, in the text boxes on pages four and eight. The correct titles are:
- 'Code of practice for research: Promoting good practice and preventing misconduct'; and
 - 'Recommended Checklist for Researchers'.

3. Comments on specific sections

- 3.1 **Introduction:** in paragraph one, page four we suggest that 'recognise' be replaced with 'complement' throughout, so that the paragraph reads
- 'The principles and guidelines outlined in this document are intended to **complement** not replace statutory or regulatory requirements and codes of conduct and ethical standards relating to specific professions, research areas or research environments and settings. They also complement local organisational policies and procedures and relevant MRC policies and position statements, including those within the MRC's ethics series (5). (emphasis added)
- 3.2 **Principles:** Under '*Research excellence and integrity*', we feel it would be helpful to revise two sentences as follows:
- 'The MRC expects all of those it supports to act with care and skill at all times in the planning, conduct, management **and dissemination** of research in order to deliver high-quality science.'
 - '...The MRC is dedicated to excellence **and high ethical standards** in the **design**, conduct, publication, communication, exploitation **and storage/ archiving** of **publicly-** funded research.'
[emphasis added]
- 3.3 This would emphasise that the principles and standards apply to the entire lifespan of a research project, from the conception of a research proposal to when research data and conclusions are archived.
- 3.4 Similarly, we feel that mention of 'high ethical standards' in this section would be helpful, as they are a vital and inherent requirement for excellence and integrity in research. We recognise that the following section, '*Respect, ethics and professional standards*', addresses this topic but feel it should also be referenced here.
- 3.5 '*Supporting training and skills*' (page 5) discusses the need for senior research staff to provide appropriate direction and suitable training, resources and career development to the researchers which they manage. UKRIO strongly supports these measures. We note, however, that research organisations, as employers, also have responsibilities in this area and that strategic decisions about

training and development are made at higher levels than those of research managers and supervisors. We feel that this should be recognised in the Principles, as well as in section L of the guidelines and standards:

- a. **'Research organisations, managers and research leaders are expected...'** (emphasis added); and
- b. **'Research organisations, supervisors and research team leader should recognise...'** (emphasis added).

- 3.6 We suggest that the final sentence be revised to include '...and receive appropriate training and development throughout their careers', to recognise that researchers must keep their skills up-to-date and be made aware of changes to requirements in research practice. In addition, we feel it would be sensible to recognise the training needs of staff who are more advanced in their careers, as they have the same need to keep skills and knowledge current: 'They should also provide career development and educational opportunities for researchers who are more established in their careers.'
- 3.7 We note that the MRC states that it supports the *Concordat to Support the Career Development of Researchers* in section L of the guidelines and standards and feel this should be mentioned in the Principles also.
- 3.8 Guidelines and standards – A. Planning and conducting MRC-funded research:** one of the key lessons learned by UKRIO from its extensive experiences is that early anticipation of potential issues can prevent or at least mitigate against problems later in the lifetime of a research project. We strongly suggest that researchers be encouraged to consider in advance what challenges they might face in meeting the requirements of *Good Research Practice: Principles and guidance* and how they might resolve these. The following might be added at the end of paragraph A.1:
- a. 'They should consider how they will adhere to the principles and standards of *Good Research Practice: Principles and guidance* during the course of their research at an early stage of the design of the project and try to anticipate any issues or challenges that might arise.'
- 3.9 **Paragraph A.4** describes the importance of oversight of the scientific and ethical conduct of a research study, particularly when they involve 'patients, volunteers or confidential or identifiable data and in other complex, collaborative programmes.' We feel it would be sensible to also mention children, other vulnerable participants or patients, human tissue or material and animal research subjects.
- 3.10 **Guidelines and standards – B: Data management, retention and preservation:** we feel that there can be a lack of awareness amongst researchers about the need to ensure personal data security and to consider encryption and secure storage of personal data. Similarly, issues and problems can arise concerning data sharing and protection in collaborative working outside the standards imposed by European data protection. These issues could be given greater emphasis in the guidance.
- 3.11 **Paragraph B.9** describes the ownership and custodianship of research data. Echoing our comments in 3.8, above, we would urge the MRC to encourage organisations and researchers to consider such issues at an early stage of the design of a project. UKRIO has often seen problems arise towards or at the end of a research project which could have been avoided, or at least reduced, by earlier consideration.

- 3.12 **The text box on retaining data** might stress that data should be kept in a form that would enable retrieval by a third party, subject to limitations imposed by legislation, ethical and other relevant requirements, and general principles of confidentiality.
- 3.13 **Guidelines and standards – C. Collaborative working:** UKRIO agrees that research collaborations, though an essential part of conducting high-quality and innovative research, can sometimes raise significant risks and challenges for research governance and integrity. We welcome the inclusion of guidance on collaborative working in *Good Research Practice: Principles and guidance*.
- 3.14 **Paragraph C.1:** 'This is especially important where the work involves researchers from different disciplines and/or organisations'. We suggest that '...and/or countries' be added to the end of this sentence. We recognise that 'different... organisations' would generally be read as including organisations from different countries but feel that this should be given more emphasis.
- 3.15 **Paragraph C.2:** in the final bullet point, 'Arrangements for handling allegations of research misconduct', we feel it would be in accordance with best practice to add "..., including a statement on where researchers, participants and patients should report any concerns about the conduct of the research' at the end of the current text.
- 3.16 In our experience, researchers in collaborative projects can often be unsure about where they can get help if they are concerned about research practice or wish to raise concerns about possible misconduct. This can lead to research organisations and funders being unaware of questionable practices or misconduct and potentially serious issues remaining unchecked.
- 3.17 **Paragraph C.2:** it would be sensible to add 'responsibilities relating to research ethics and human/animal subject protection' and 'training' to the bulleted list.
- 3.18 **Guidelines and standards – G. Reporting and disseminating research:** in paragraph G2, we feel it would be sensible to suggest that the authorship agreements described should be drawn up at an early stage of the project, ideally before work has commenced. It would also be helpful to add 'recognising that, subject to legal and ethical requirements, roles and contributions may change during the time span of the research.'
- 3.19 **Paragraph G.3:** 'The MRC endorses the ICMJE guidelines on authorship and contributorship; the practice of 'honorary' authorship' 'or guest authorship' is not acceptable.' We feel it would be sensible to mention that denial of authorship when a person fulfils the relevant criteria is also unacceptable: 'Similarly, no person who fulfils the criteria for authorship should be excluded from the submitted work.'
- 3.20 **Paragraph G.6:** we suggest this paragraph be revised as follows:
- a. The outcomes of MRC-funded research should normally be published as a coherent entity rather **than** as part of a series, unless there is a legitimate need to demonstrate first discovery by publishing preliminary data. Quality is paramount and the proliferation of multi-author papers to increase **the** quantity of **publications** should be discouraged. Duplicate or redundant submission **or publication** is not acceptable as it may distort the evidence base upon which meta-analyses rely.' (emphasis added)
- 3.21 **Guidelines and standards – I. Integrity in peer review: paragraph I.3** states: 'While participating in peer review researchers are obliged to report appropriately, in confidence, any concerns they may

have relating to plagiarism, fabrication, falsification, omission, or the ethical design or conduct of a study.'

- 3.22 Is '...or conduct of a study' intended to refer to solely ethical issues/ breaches that arise during the conduct of a study or any concerns about research practice/ possible misconduct that arise during the conduct of a study? We feel that the present wording stands could be read as referring solely to ethical issues and should be revised if this is not the intent.
- 3.23 If the current wording does apply only to ethical issues, then we suggest '...or any other concerns about questionable practices or research misconduct' or similar be added to the end of the sentence.
- 3.24 **Guidelines and standards – K. Allegations of research misconduct:** We suggest that a paragraph be added emphasising that all those involved in MRC-funded research should report any concerns about the conduct of research to the appropriate organisation as soon as possible.
- 3.25 UKRIO has published a Procedure for the Investigation of Misconduct in Research and its use is recommended in RCUK's *Integrity, Clarity and Good Management*. The MRC may wish to include a reference to the UKRIO Procedure in the 'Related Links' section for this part of the document:
- a. UK Research Integrity Office, Procedure for the Investigation of Misconduct in Research (2008): <http://www.ukrio.org/what-we-do/procedure-for-the-investigation-of-misconduct-in-research/>
- 3.26 **Paragraph K.1:** We note that the definition given is less detailed than that in RCUK's *Integrity, Clarity and Good Management*, which we understand applies to all RCUK-funded research from October 2009, including research funded by the MRC. We appreciate that including the full definition would lengthen the current draft but strongly suggest this is done as certain terms, 'misrepresentation' and 'breach of duty of care', are not sufficiently well-defined in the current wording.
- 3.27 In particular, given the need to protect research participants and patients, we urge that 'breach of duty of care' be defined in more detail, drawing upon the definition given in *Integrity, Clarity and Good Management*.
- 3.28 In addition, we note that there are different definitions of research misconduct in the two documents referred to in this section, the RCUK *policy and code of conduct on the governance of good research conduct, Integrity, Clarity and Good Management* (2009) and the MRC *Procedure for investigating allegations of misconduct in research* (2009). In UKRIO's experience differing definitions can easily confuse researchers as to what is acceptable practice and what is unacceptable. In addition, when allegations are investigated, differing definitions can sometimes cause the conclusions of investigations to be dismissed on procedural grounds.
- 3.29 The MRC should consider whether it might align its own definition of research misconduct more closely with that given in RCUK's *Integrity, Clarity and Good Management*. We note that this definition is designed to cover all disciplines of research funded by RCUK and in our view contains nothing that would be inappropriate for research in the life sciences. The MRC could consider whether it wished to give additional examples of unacceptable conduct that related solely to health and biomedical research in addition to the unacceptable behaviours described in the RCUK guidance.
- 3.30 **Paragraph K.1:** we note that 'the MRC requires organisations receiving MRC funding to have processes for reporting and investigating allegations which must be swift, conclusive, and constructive.' We feel that 'swift, conclusive, and constructive', though helpful, emphasises the speed

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of an investigation above other factors and this could cause problems such as important issues being missed, involved parties feeling that they have not been treated fairly and procedural challenges against the conclusion of an investigation. The current wording also makes no mention of confidentiality to provide appropriate protection to involved parties.

- 3.31 Wording such as 'processes for reporting and investigating allegations which must be thorough, fair and timely, and with appropriate confidentiality' may be more helpful.
- 3.32 **Paragraph K.3:** it would be helpful to add something along the lines of 'The MRC expects research organisations to make appropriate reports to relevant bodies such as research funders, regulatory professional organisations, academic journals and other involved institutions at the conclusion of an investigation of research misconduct.'
- 3.33 **New and emerging areas:** we feel that the inclusion of this section is most sensible and strongly endorse the approach described.
- 3.34 **Further advice and resources:** UKRIO recognises that neither the MRC nor RCUK currently fund UKRIO, nor do they formally endorse its activities. However, our advice and guidance services remain available to all those involved in MRC- and RCUK-funded research and our work supports the work of research funders by promoting and improving research integrity in the organisations in receipt of their funds. Accordingly we would be happy for UKRIO to be listed as a source of advice on good research practice and addressing research misconduct in this section and feel this would greatly benefit the research and the researchers which the MRC supports.
- 3.35 **Acknowledgements and history:** we are grateful for the acknowledgement of the work of UKRIO and are glad that our *Code of practice for research: Promoting good practice and preventing misconduct* was helpful in the development of the new MRC guidance.

4. About the UK Research Integrity Office

- 4.1 The UK Research Integrity Office (UKRIO) is an independent, not-for-profit body which provides expert advice and guidance about the conduct of academic, scientific and medical research, whether promoting good practice or addressing misconduct. We cover all subjects and help all involved in research, from research organisations, including universities and the NHS, to individual researchers and members of the public. In both 2010 and 2011 we helped with more than one case a week and use of our services continues to grow each year. Our publications have been used or adopted by many organisations, including over 50 universities, and endorsed by professional organisations and funding bodies such as Research Councils UK.
- 4.2 For further information contact the UK Research Integrity Office, Sussex Innovation Centre, Science Park Square, Falmer BN1 9SB. Tel: +44 (0) 1273 234 697, email: info@ukrio.org , web: www.ukrio.org .