Response to GMC consultation on *Good practice in research* and *Consent to research*

Questions relating to *Good practice in research*

Principles of good research practice (paragraphs 1-27)

1. Do you think this section covers the most important principles that doctors must consider when they are involved in research?

~~Yes~~ **No** ~~Not sure~~

If not, please say why not.

UKRIO recognises that strong principles are essential to define the responsibilities and values in the conduct of research and welcomes the inclusion of this section. The content is excellent but we feel it could benefit from a few additional points.

Additional paragraph – the principle of Excellence: we would welcome the addition of a requirement to strive for excellence when conducting research and to aim to produce and disseminate work of the highest quality and ethical standards. This could be inserted at the beginning of the section on Good Research Design and Practice.

Paragraph two, Law and Governance (page 3): a reference to the legal and ethical requirements of research involving collaboration with research in other countries would be helpful.

For example, UKRIO's *Code of Practice for Research: promoting good practice and preventing misconduct* states:

> "When conducting, or collaborating in, research in other countries, organisations and researchers based in the UK should comply with the legal and ethical requirements existing in the UK and in the countries where the research is conducted. Similarly, organisations and researchers based abroad who participate in UK-hosted research projects should comply with the legal and ethical requirements existing in the UK as well as those of their own country." (para. 3.1.2, page 9).

Paragraph eight (page 4) states that leaders of research teams must ensure "that all members of the team have the necessary skills, experience, training and support to carry out their research responsibilities as effectively as possible."

It would be useful to add a sentence to the effect that members of a research team have a duty to identify needs for training when they arise and report them to their manager or other appropriate person as identified by their organisation.

The draft guidance aims to make clear that doctors must ensure that the safety, dignity and well-being of participants take precedence over the development of treatments and the furthering of knowledge. The guidance makes reference (in footnote 4 of paragraph 4) to the advice in the Declaration of Helsinki that placebo should only be used where there is no existing proven therapy.

2. Do you think that a reference to the advice in the Declaration of Helsinki on

using placebo-controlled trials is sufficient?

Yes ~~No~~ ~~Not sure~~

If not, please say why not.

Questions relating to *Consent to research*

Responsibility for seeking consent (paragraph 7)

The draft guidance aims to make clear that consent to participate in research can be sought by any member of a research team, as long as they meet the requirements set out in paragraph 7.

3. Do you think that this is a reasonable approach?

Yes ~~No~~ ~~Not sure~~

If not, please say why not.

We think that this is a reasonable approach but suggest that if the person(s) seeking consent is (are) not the Investigator, they must be designated this responsibility by the Investigator, and this should be recorded in the project documentation.

Sharing information with others involved in care (paragraph 9)

The draft guidance aims to make clear that where participants give consent doctors should share information with others involved in the care of participants, even when the research involves people who are not patients.

4. Do you think that this is a reasonable approach?

Yes ~~No~~ ~~Not sure~~

If not, please say why not.

Research involving children and young people (paragraphs 10-12)

The principles in *Consent to research* apply to research involving children and young people but there are particular sensitivities and legal and other requirements when making decisions about involving children or young people in research. To avoid duplication, *Consent to research* signposts to the advice in *0-18 years: guidance for all doctors (2007)* and more detailed guidance published by other organisations. Specific advice on some of the legal requirements for involving children and young people under 16 in clinical trials is set out in the legal annex.

5. Do you think that this is a reasonable approach to take?

Yes ~~No~~ ~~Not sure~~

If not, please say why not.

Research involving neonates (paragraphs 13-14)

The draft guidance sets out advice on seeking consent to involve neonates in research, including during an emergency. It acknowledges that it is often an emotional and difficult time for parents when treatment is available only as part of research and a decision is required quickly.

6. Do you agree with the guidance about seeking consent to involve neonates in research?

Yes ~~No~~ ~~Not sure~~

If not, please say why not.

Research involving adults without capacity (paragraphs 17-25)

Paragraphs 18 and 19 of the draft guidance set out the circumstances when people who lack capacity might be involved in research. It aims to take account of the complex legal framework that governs the involvement of people (over 16) who lack capacity in research.

7. Do you think that the guidance set out in paragraphs 18 and 19 about when people who lack capacity might be involved in research is clear?

Very clear ~~Clear~~ ~~Neutral~~ ~~Unclear~~ ~~Very unclear~~

If you can, please tell us which parts are unclear and make suggestions about how it could be made clearer.

General questions about the guidance

The following 9 questions relate to both pieces of draft supplementary guidance, *Good practice in research* and *Consent to research*.

8. Do you think the draft guidance contains the right level of detail?

Please give your answer for *Good practice in research*

~~Too detailed~~ **About right** ~~Not detailed enough~~

Please give your answer for *Consent to research*

~~Too~~ ~~detailed~~ **About right** ~~Not~~ ~~detailed~~ ~~enough~~

If you can, please indicate the issues on which you think there is too much or too little detail.

9. Do you think the guidance is clear?

Please give your answer for *Good practice in research*

Very clear ~~Clear~~ ~~Neutral~~ ~~Unclear~~ ~~Very~~ ~~unclear~~

Please give your answer for *Consent to research*

Very clear ~~Clear~~ ~~Neutral~~ ~~Unclear~~ ~~Very~~ ~~unclear~~

If you can, please tell us which parts are unclear and make suggestions about how it could be made clearer.

10. Do you think the guidance accurately reflects the law that applies to research in the UK where you live or work?

Please give your answer for *Good practice in research*

Yes ~~No~~ ~~Not~~ ~~sure~~

Please give your answer for *Consent to research*

Yes ~~No~~ ~~Not~~ ~~sure~~

If not, please say why not.

11. Can you point to any other guidance documents, information or resources that would be useful to refer to in the guidance? These may include other guidance about, for example:

a) appropriate record retention periods in research;

b) involving children and young people in research; or

c) conducting clinical trials.

Yes ~~No~~ ~~Not~~ ~~sure~~

Please identify any other documents, information or resources as specifically as you can.

Good Practice in Research requires researchers to take action when they suspect fraud or misconduct in research (para. 11, page 5 and para. 15, page 6). It might be helpful to mention that the UK Research Integrity Office (UKRIO) provides independent, confidential and expert advice to anyone with concerns about the conduct of research.

Set up as the UK Panel for Research Integrity in Health and Biomedical Sciences, we have particular expertise n the fields of health and biomedicine and often provide independent support to doctors and NHS organisations, as referred to in the *Research Governance Framework* (para. 5.10, page 48). Further information can be found on our website, www.ukrio.org .

We have also published two guidance documents that might be useful additions to the section "Other Sources of Information and Guidance".

The first is our *Code of Practice for Research: promoting good practice and preventing misconduct*. This provides principles and standards for the conduct of research, applicable to all subject areas, and offers more detailed guidance on some issues than the GMC's draft *Good Practice in Research*. UKRIO's Code is not mandatory but reflects best practice in the conduct of research and addressing misconduct. Particular attention has been paid to areas where UKRIO has most often been approached for guidance, in the hope of passing on lessons learned to the research community.

We have also produced a model *Procedure for the Investigation of Misconduct in Research*, which has been adopted by higher education institutions and NHS Trusts.

References:

UK Research Integrity Office, 2009. *Code of Practice for Research: promoting good practice and preventing misconduct* [online]. Available from: http://www.ukrio.org/resources/UKRIO%20Code%20of%20Practice%20for%20Research.pdf [Accessed 8th August 2009]

UK Research Integrity Office, 2008. *Procedure for the Investigation of Misconduct in Research* [online]. Available from: http://www.ukrio.org/resources/UKRIO%20Procedure%20for%20the%20Investigation%20of%20Misconduct%20in%20Research.pdf [Accessed 8th June 2009]

12. Can you point to any important inconsistencies between the draft guidance and the guidance published by other relevant organisations? Other organisations may include, for example, the National Research Ethics Service, Medical Research Council, or the Royal College of Physicians.

Please give your answer for *Good practice in research*

~~Yes~~ **No** ~~Not sure~~

Please give your answer for *Consent to research*

~~Yes~~ **No** ~~Not sure~~

Please indicate inconsistencies as specifically as you can.

13. Can you identify any changes that would be needed in order to meet the standards set out in the guidance? (For example, in the recruitment of participants or any reporting or other system in place to protect research participants from harm).

Please give your answer for *Good practice in research*

~~Yes~~ **No** ~~Not sure~~

Please give your answer for *Consent to research*

~~Yes~~ **No** ~~Not sure~~

Please identify any changes as specifically as you can.

14. Do you think that applying the standards in this guidance will have an adverse impact on particular groups of people that might be involved in research? (For example, people living in care homes or other institutions or people with learning disabilities or mental illness).

Please give your answer for *Good practice in research*

~~Yes~~ **No** ~~Not sure~~

Please give your answer for *Consent to research*

~~Yes~~ **No** ~~Not sure~~

If you can, please describe any adverse impact that you can identify.

15. We would welcome any additional comments you may have on the draft guidance *Good practice in research* or *Consent to research*. These may include, for example:

a) How clearly *Good practice in research* and *Consent to research* link together.

b) Whether you think we have achieved the right balance between setting out the key principles that apply to research and referring to more detailed guidance elsewhere.

The two documents link together well and there is a good balance between key principles that apply to research (though please see our response to question one) and other sources of guidance (though please see our response to question eleven).

We would like to make three additional comments on *Good Practice in Research*.

1. In the section on Principles of Good Research Practice, paragraph one (page three) states that:

> "This guidance sets out principles of good research practice, which you must work within if you are involved in research with patients as well as healthy volunteers who are not patients."

As most of the principles listed in paragraphs. 2 – 27 are fundamental to good practice in all types of research, whether involving research participants or not, we feel that this sentence should be amended as follows (changes in bold):

> "This guidance sets out principles of good research practice, which you must work within if you are involved in **any** research, **in particular research** with patients as well as healthy volunteers who are not patients."

Existing GMC guidance for doctors involved in research states that doctors should "act with honesty and integrity, and follow the appropriate national research governance guidelines" whether the research involves participants or not (*Good Medical Practice* (2006), paragraph 71). As the purpose of *Good Practice in Research* is to provide more detailed advice about how to comply with this principle, among others, we feel it would be appropriate for the publication to state that its principles apply to all types of research that doctors are involved in. The current wording suggests that it applies only to research involving human participants.

2. In the section on Avoiding Conflicts of Interest, paragraph 22 (page seven) states that:

> "You must make sure that your judgement about a research project is not, or is not seen to be, influenced by financial, personal, political or other external interests at any stage. You should always declare any conflicts that may arise to the research ethics committee, as well as to the participants.

Conflict of interest, like bias, operates unconsciously and it may be insufficient to state that doctors should avoid being influenced, what is important is that potential or actual conflicts of interest are identified and addressed appropriately.

We suggest that paragraph 22 be amended as follows (changes in bold):

> "You must make sure that your judgement about a research project is not, or is not seen to be, influenced by financial, personal, political or other external interests at any stage. **Conflicts of interest must be identified, declared and addressed in order to avoid poor practice in research or potential misconduct.** You should always declare any conflicts that may arise to the research ethics committee, as well as to the participants, **as soon as you become aware of them**.

3. The second paragraph on page two states:

> "This guidance does not apply to clinical audit as it involves no experimental study."

It can often be difficult to draw a line between research and clinical audit. We suggest that the sentence be amended to the effect that if doctors have any doubt whether their work should be treated as research or as clinical audit, they should err on the side of caution and treat it as research and therefore within the remit of this and guidance for research.

We would like to make three additional comments on *Consent to research*.

1. There should be arrangements to ensure that participants receive any information that becomes available during the course of the research relevant to their continued participation.
2. Any translations provided in any participant information are must be appropriate and independent.
3. We feel that it is best practice to inform the participants in research of the results before the world is told. This is normal practice in occupational health research but not always with clinical trials. Participants should not discover the results and implications of research they have been involved in through the media.

16. Do you have any comments on the consultation documents and/or process?

~~Yes~~ **No**