

**Development of
*Good practice in research and
Consent to research***

April 2010

www.gmc-uk.org/guidance/research_guidance

Introduction

1. This document outlines the development of two pieces of supplementary guidance on research; *Good practice in research* and *Consent to research*. These pieces of guidance update our existing advice to the profession *Research: the role and responsibility of doctors* (2002).

The role of the General Medical Council (GMC)

2. The GMC is the regulatory body for the medical profession in the United Kingdom. Our purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. More information about the GMC's role is available on our [website](#).¹

Setting standards

3. The GMC is responsible for advising the profession on medical ethics (under the *Medical Act 1983*). Until the beginning of 2009 the Standards and Ethics Committee was responsible for developing this advice. Following implementation of changes to the Council's constitution and working methods, the Committee has now been replaced by the Standards and Ethics Reference Group.

4. The GMC's core ethical guidance, [Good Medical Practice \(2006\)](#)² describes what is expected of all doctors registered with the GMC. The guidance consists of high level principles which apply to all doctors on the register, regardless of specialty, grade or whether they work in the private or public sector. It is therefore necessarily broad, but is supported by a range of supplementary guidance that provide more detailed advice on how to comply with the principles set out in *Good Medical Practice* (2006).

5. All our ethical guidance is accessible via the [Guidance on good practice](#)³ pages on the GMC website.

Background to the review

6. In April 2008 the Standards and Ethics Committee agreed proposals to develop two pieces of supplementary guidance about research to explain how the principles in our guidance *Good Medical Practice* (2006) and [Consent: patients and doctors making decisions together \(2008\)](#) apply to research. Revising the guidance ensures that GMC advice to doctors on research is up to date, fit for purpose and accurately reflects the law across the UK.

Changes in the law

7. Since the guidance was last reviewed in 2002 there have been significant changes in the law about involving people in research, and the removal, storage and use of human tissue for purposes of research.

8. Clinical trials of investigational medicinal products are now governed by the *Medicines for Human Use (Clinical Trials) Regulations 2004* which apply in all four

UK countries. Other than clinical trials of investigational medicinal products, research involving people over 16 who lack capacity is governed in England and Wales by the *Mental Capacity Act 2005* and in Scotland by the *Adults with Incapacity (Scotland) Act 2000*. In Northern Ireland, there is currently no relevant primary legislation setting out the circumstances in which research (except for clinical trials of investigational medicinal products) involving adults who lack capacity may be undertaken.

9. Research involving human organs, tissue or cells in England, Wales and Northern Ireland is now governed by the *Human Tissue Act 2004* and in Scotland by the *Human Tissue (Scotland) Act 2006*.

Other GMC guidance

10. There have been significant developments in the scope and format of GMC guidance since the guidance was last reviewed. The principles underpinning several topics in the existing research guidance are now dealt with in the 2006 edition of *Good Medical Practice (2006)* – keeping up to date, teaching and supervision, and probity. Our guidance [0-18 years: guidance for all doctors \(2007\)](#) covers research involving children or young people.

11. We have published guidance on *Consent: patients and doctors making decisions together (2008)*, which sets out the broad principles of good decision making that apply across a range of situations, including decisions on taking part in research. Our recently revised guidance [Confidentiality \(2009\)](#) contains advice on research and other secondary uses of data.

Initial consultation

12. At the end of June 2008, we launched an initial consultation to seek views on the scope and content of the new *Consent to research* guidance because this part of the guidance was likely to generate the most interest and debate. The consultation was sent to over 100 key interest groups and individuals with an interest in research issues and publicised through the GMC's website. We received over 50 responses.

13. The majority of respondents agreed it was helpful for the GMC to publish guidance on the principles of consent in research provided that it was consistent with guidance produced by other organisations. Respondents considered that the regulatory role of the GMC placed it in a unique position to give guidance to all doctors involved in research, regardless of their area of research or where in the UK they work.

14. When asked how the GMC might make the guidance useful for doctors, the overall preference was for a short, clear guidance statement which addressed some of the issues or difficulties specific to research that are not addressed in our core guidance on consent and to signpost to other, more detailed, guidance elsewhere. Most of the issues and concerns of the research community related to the complex legal and governance framework in which research is conducted in the UK and the interaction between the law, particularly on research involving children or young people and adults who lack capacity.

Formal consultation

15. On 23 June 2009 the Standard and Ethics Reference Group agreed to issue for formal consultation the draft pieces of guidance that had been developed by members of the Standards and Ethics Team. These were developed following the analysis of responses to the initial consultation. A formal written consultation was launched on 13 July 2009 via the GMC's online, public consultation site. This comprised a written questionnaire with 16 questions (the consultation questions are set out in annex A). The consultation ran for 12 weeks, ending on 25 September 2009.

16. We consulted on the draft guidance *Making and using visual and audio recordings of patients* at the same time as the draft pieces of research guidance given the likely interest from the research community on making and using visual and audio recordings for research purposes.

17. To raise awareness of the consultation, we wrote to over 1000 organisations and individuals to invite them to take part in the consultation. We also used our contacts to distribute A4 posters and A5 flyers at conferences, roadshows, student pre-registration events, and to medical school secretaries to be placed on general notice boards.

18. The consultation was advertised on the GMC website and articles were included in the May/June and July/August 2009 editions of GMCtoday to promote the consultation. Trade press coverage included an article in the Royal College of Surgeons October newsletter, Medical News Today and the Holyrood Magazine Medical Research (Scotland). The Kensington and Chelsea LINKs September E-bulletin also contained an advertisement.

19. A promotional email was cascaded through the UK Clinical Research Networks to target clinical trial leads and individual researchers. Written briefings were posted to parliamentarians informing them of the consultation.

Results of the formal consultation

Responses to the consultation

20. We received 85 responses to the consultation. 75% of the responses were received from organisations and 25% from individuals. We received one late response and their comments were taken into account in the analysis reports.

21. Respondents were asked to categorise themselves according to fixed categories or select 'other' and provide a description themselves. Below is a summary of the number of respondents and their categories.

Respondent categories	Number of respondents
Individuals	
Doctor	10
Medical educator (teaching, delivering or administration)	2
Medical student	-
Member of the public	3
Other healthcare professional	5
Other	1
Individual total	21
Organisations	
Body representing doctors	19
Body representing patients or public	8
Government department	4
Independent healthcare provider	-
Medical school (undergraduate)	4
Postgraduate medical institution	2
NHS/HSC organisation	12
Regulatory body	3
Other	12
Organisation total	64
Total	85

22. We received responses from groups representing patients and the public and key organisations in the research community, including groups within the UK Clinical Research Network, National Research Ethics Service, UK Research Integrity Office, Royal College of Physicians, Medical Research Council and the Wellcome Trust.

Analysis of questions

23. The aim of the questionnaire was to determine whether respondents agreed or disagreed with the main principles established in the draft pieces of guidance. Analysis reports were generated for each section of guidance, regardless of whether the section had a corresponding consultation question.

24. The responses were analysed by members of the Standards and Ethics Team and the analysis reports were considered by the Standard and Ethics Reference Group on 18 November 2009. The draft pieces of guidance were revised following

the Standard and Ethics Reference Group's consideration of a number of recommendations for changes to the drafts. Many of these changes add further detail or new advice in different areas covered by the guidance rather than making substantive changes to the principles of the guidance.

25. Below is a summary of the analysis of consultation question responses and some of the major revisions to the pieces of guidance in response to the analysis.

Questions relating to *Good practice in research*

26. 73% of respondents to question 1 agreed that the principles of good research practice set out in the guidance covered the most important principles that doctors must consider when they are involved in research. 20% disagreed and 7% were not sure. Respondents raised a number of specific comments about the individual principles, with many wishing to see more emphasis on a range of issues, such as publication ethics. Several respondents requested further clarification on the scope of the guidance. Some respondents raised issues outside of the remit of the GMC, such as the responsibilities of organisations and management (as different from individual doctors' responsibilities) and advice on how research pools or populations should be selected. In response to this feedback, the revised guidance sign posts to other guidance on publication and authorship and includes an additional section on the scope of the guidance, which makes clear that the guidance covers research with people, as well as research involving human tissue and records-based research that does not involve people directly.

27. 55% of respondents to question 2 agreed that it was sufficient for the guidance to refer to the advice in the Declaration of Helsinki on using placebo-controlled trials, with a large proportion (32%) disagreeing with this approach. 15% were not sure. Respondents presented a good case for expanding the footnote to cover all the situations outlined in the Declaration where the use of placebo is considered permissible.

28. The revised guidance also clarifies a number of points in the guidance in response to other comments made in question 2 about the clarity and detail of this section. This includes information about the role of research ethics committees and explains the distinction between discrimination and eligibility criteria for studies. The revised guidance also encourages the use of public and patient involvement groups at all stages of a research project.

Questions relating to *Consent to research*

29. A majority of respondents (73%) agreed with the approach that consent to participate in research can be sought by any member of a research team, as long as they meet the requirements in the guidance relating to having sufficient knowledge of the research etc (question 3). Of the 11% that disagreed and 16% that were not sure, some raised concerns about the lack of emphasis on the role of the lead clinician in seeking consent where research involved therapeutic benefit, and the non-clinical skills needed for seeking consent, such as communication skills and the ability to assess capacity. Others commented on the need for further advice on delegation and clear lines of accountability. The revised guidance now gives direct

advice to doctors on their responsibilities when they a) are responsible for seeking consent for research and b) have delegated the task of seeking consent to another member of the research team. It makes clear that when a doctor delegates the responsibility to seek consent to another person; they must make sure that this person has the appropriate skills and competence to seek consent.

30. 75% of respondents to question 4 agreed that, with the participant's consent, doctors should share information with others involved in the participant's care, even when the research involves people who are not patients. 13% disagreed and 12% were not sure. Some felt that this approach was too broad; noting that the decision to share information would depend on the nature of the research, while others felt it was unacceptable for a doctor not to be informed. The revised guidance states that doctors should usually inform GPs and other clinicians about a participant's involvement in research to acknowledge that it is good practice to share this information but that it may not always be necessary, for example, if a person is only required to complete a simple questionnaire. It makes clear that doctors should follow this advice regardless of whether the participant is a patient or a healthy volunteer and also includes guidance on what steps to take if a participant refuses to consent to information being shared in this way.

31. 83% of respondents to question 5 considered it was reasonable for the guidance to signpost to the advice in [0-18 years: guidance for all doctors \(2007\)](#) and more detailed advice published by other organisations on involving children or young people in research rather than duplicating it in *Consent to research*. 8% disagreed and 9% were not sure. The revised guidance has broadened the advice to cover particular considerations in relation to seeking and acting on consent for children or young people to participate in research that are not covered in [0-18 years: guidance for all doctors \(2007\)](#). This includes new advice on reaching a consensus with parents about a child or young person's involvement in research, getting consent from a parent who is under 16 years of age, and the circumstances in which a child may be entered into emergency research.

32. 66% of respondents to question 6 agreed with the advice about seeking consent to involve neonates (or very young children) in research with 12% disagreeing and a large proportion that were not sure (22%). Several respondents felt that this section should be expanded to cover children as it was considered that the principles apply equally to this group. As a consequence, the advice on neonates has been absorbed into the revised section on research involving children or young people.

33. 47% of respondents to question 7 considered paragraphs 18 and 19 (which summarise the law on when adults without capacity might be involved in research) were clear and 24% thought they were very clear. 14% answered neutral and 15% considered these paragraphs were unclear. No respondents answered very unclear. A number of respondents raised more general concerns about the application of the law in this area of research and provided a number of drafting suggestions to improve clarity and accuracy of the guidance. The revised guidance includes additional advice on the steps to take when seeking to involve a person in research who may lose capacity during the course of the project. In addition, it makes clear that a person's capacity to make a particular decision must be assessed at the time it

needs to be made and it signposts to the more detailed advice in the [Consent: patients and doctors making decisions together \(2008\)](#) guidance on maximising a person's ability to make decisions, and on assessing capacity.

34. In response to question 10, 72% of respondents considered that both pieces of guidance accurately reflected the law. 10% disagreed and 18% were not sure, with some respondents recommending additional references to relevant legislation. The revised guidance refers to the recent *Human Fertilisation and Embryology Act 1990* (as amended) and the proposal to develop a legislative framework for new mental capacity and mental health legislation in Northern Ireland. It also notes that research must be approved or licensed by any relevant regulators.

General questions on the detail, consistency and clarity of both pieces of guidance

35. Over 80% of respondents felt that the guidance contained the right level of detail (question 8). Several respondents thought the documents achieved the right balance between setting out the key principles and sign posting the reader to other more detailed guidance.

36. Overall nearly 90% of respondents felt that the draft guidance was clear or very clear (question 9). There were no comments that raised any serious concerns with the clarity of the guidance overall. Many people who felt the guidance was not clear (or neutral) raised issues about specific paragraphs of the draft they felt could be made clearer. Several people commented on the use of 'must' and 'should' in the guidance, which we have reviewed for consistency and appropriateness.

37. Very few respondents pointed out what they saw as inconsistencies between the draft guidance and guidance published by other organisations (question 12). Some specific comments either corrected or suggested we expand upon references to other guidance, for example in relation to how long research record should be kept.

38. A small number of respondents answering these general questions commented on the structure of the documents and recommended that the GMC should include more detailed advice about confidentiality issues and use of patient records for research. The GMC's guidance [Confidentiality \(2009\)](#) provides new advice on research and other secondary uses of personal data. Both the online and pdf version of the guidance documents provide clear links to this advice.

Approving the guidance for publication

39. The revised drafts of *Good practice in research* and *Consent to research* were presented to the Standard and Ethics Reference Group for approval in February 2010. Council agreed to the publication of the guidance on 31 March 2010.

40. The draft pieces of guidance were plain English checked and reviewed by Counsel in England (and Wales), Scotland, and Northern Ireland to ensure that it was consistent with the legal framework relevant to research in each of the four UK countries.

Launching the guidance

41. *Good practice in research* and *Consent to research* was launched on 12 April 2010 and is available on the GMC website. The launch will be publicised through an article in the May/June 2010 edition of *GMCtoday*.

Next steps

42. We are currently developing plans for promoting *Good practice in research* and *Consent to research*.

We would like to take this opportunity to thank all those who contributed to the review and took the time to send us their comments during the consultation process.

For more information on the review or to read the new guidance visit www.gmc-uk.org or contact the Standards and Ethics Team on 020 7189 5404 or standards@gmc-uk.org

¹ www.gmc-uk.org

² http://www.gmc-uk.org/guidance/good_medical_practice/index.asp

³ <http://www.gmc-uk.org/guidance/index.asp>

Annex A: Consultation questions

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.

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.

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.

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.

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

Yes No