

GMC – Consent to Research Consultation August 2008

Faculty of Pharmaceutical Medicine Response

Responses to Questions

1. Given that guidance on ethical issues in research is issued by a number of different bodies (e.g. the departments of health, the Medical Research Council, the National Patient Safety Agency) is it useful for the GMC to provide guidance to doctors on their obligations when undertaking research?

The existing documents on consent and research are good and useful. GMC guidance often carries a different weight with doctors and the public and this would have a valuable role and complement the GMC's sister document 'Consent: patients and doctors making decisions together'.

2a. Do you agree that the principles set out in 'Consent: patients and doctors making decisions together' are also applicable to research?

Yes and as expressed in the Faculty's response to the previous consultation on 'Consent: patients and doctors making decisions together'.

2b. What, if any, additional principles do you think might apply?

There are probably no additional principles - research differs from routine clinical practice by having the infrastructure of Ethics Committees etc but these are practical considerations (fully enshrined in all existing advice/codes/declarations) rather than matters of principle.

3a. What have been the major organisational and other changes relevant to consent to research since 2002?

There have been no major organisational or other relevant changes relevant to consent to *per se*.

3b. Have these changes affected the way that research, including clinical trials, is conducted?

There have been a number of changes which have influenced the actual conduct of research (for example the Clinical Trials Directive) but these changes are not around the area of consent.

4. What do you see as the most important research issues relevant to doctors?

Some of these currently are in the area of consent to research on 'vulnerable groups' such as ITU patients, acutely ill patients and in pregnant women and young babies. The requirement to undertake treatment which maximises future options may limit the ability to undertake research into potentially very useful interventions which might reduce future options - if there is real equipoise about the benefits of treatments (and more especially if there is a clear suggestion that a treatment which limits options is significantly more beneficial) this places researchers and clinicians in a difficult position.

5. How might we make our guidance on consent to research useful to doctors?

The existing format is satisfactory but worked examples particularly in challenging areas would be useful.

6. How might we make our guidance on consent to research accessible to patients and the public?

This could be achieved through researchers, availability in waiting rooms etc. Some worked examples would be essential to show patients what the principles and guidance actually mean. The idea that, by definition, the outcome of research is not known before the project is undertaken is one which patients often struggle with ('they wouldn't ask me to take this new drug unless they knew it was better' is a common misconception).

Perhaps consideration could be given to the Faculty of Pharmaceutical Medicine's guidelines being included in the 'reading list' These are available via this link <http://www.fpm.org.uk/committees/ethics>