

17 July 2007

General Medical Council Consultation on guidance for doctors – Consent: Patients and doctors making decisions together

Thank you for providing an opportunity for the Faculty to comment on this important document. The guidance issued in this draft appears sound, sensible and very helpful to doctors being written in clear, concise terms.

However, one aspect of consent which is missing from this document relates to that of (informed) consent for participation in clinical trials. The same precepts apply to consent whether for clinical trials or in routine care and I would have liked to have seen a reference to the fact that the same tenets and principles apply in this situation even if no further guidance on informed consent within the clinical trial setting is given in this particular document.

I do believe it is crucially important that doctors appreciate that the same standards must apply in both circumstances and that they cannot abrogate this responsibility to the clinical trial sponsor. They must remain responsible on an individual patient basis for ensuring that their clinical trial patient is fully informed and can give consent to treatment in exactly the same way as when the patient is not in a trial. The fact that medication may be blinded, that the doctor is probably being reimbursed for his/her involvement in the trial does not in any way lessen the doctors responsibility to ensure consent is given fully in accordance with the principles enshrined in this document and probably makes adherence to them even more imperative.

I would ask therefore that some reference is made to the clinical trial situation so that doctors are under no illusion that in the GMC view there are not two standards.

If the GMC consider that, in the light of the above, more than just a reinforcement of this fact is required, for example, information on trial blinding, guide lines for informed consent trials, then this Faculty would be very happy to prepare a couple of appropriate paragraphs. Equally, I would be very happy to meet with you to discuss this further if you consider this would be useful. I would be very disappointed to miss the opportunity to reinforce via the GMC the fact that in clinical trials doctors carry the same responsibilities as outwith the trial situation and cannot automatically 'delegate' these responsibilities to the trial sponsor and ethics committee. It must remain the responsibility of each doctor participating in a trial to ensure that for each patient he enters, he has ensured consent in accordance with the proposed GMC guidelines.

Faculty of Pharmaceutical Medicine