

From the Chief Medical Officer, Sir Liam Donaldson



**Department
of Health**

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Dear Colleague,

A recent ruling in the Appeal Court and earlier proceedings have highlighted the dangers of keeping informal medical records that are separate from the main official patient record. It is essential that if separate records are kept (which should be unusual except in research studies, see below) that this be explicitly signposted in the main record. Your clinical colleagues and records staff must be able to access all parts of the clinical record. On balance, you are advised very strongly not to keep separate records.

Maintaining Separate Clinical and Research Records

Special rules govern clinical records generated as part of trials or other clinical research studies. For trials of medicines, investigators must keep records of clinical information according to Good Clinical Practice standards. The Medicines and Healthcare products Regulatory Agency (MHRA) recommends that a trial protocol specify which clinical events are to be recorded in the clinical notes as well as on Case Report Forms. The research records enable research teams to assess which adverse events to report to the MHRA and the ethics committee and to make the safety reports required by law.

Guidance recommends that other clinical research not covered by the clinical trials regulations should also observe the internationally recognised principles of Good Clinical Practice. One of these is that all clinical trial information shall be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification. While the Care Record Service aims to drive up the quality of routine healthcare records, at present these do not meet all the requirements for research records. You should therefore use properly maintained and approved separate research records but again ensure that vital information about the patient's clinical condition, treatment and special characteristics (e.g. allergies) is replicated in the main, formal care record.

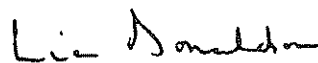
People give consent to take part in research separately from their consent to treatment. Research may reveal medical information about a research participant that is not known to the treating clinicians. It is for that person to decide whether the researchers should disclose the medical information to clinicians for incorporation in medical records. This is because researchers owe research participants a duty of confidentiality separate from the confidential relationship between patient and clinician.

Guidelines do allow sponsors and investigators to take urgent safety measures in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety. However, doctors may have a duty of confidentiality to a trial participant that could conflict with the duty to ensure that the clinical notes contain all information that might be relevant to the patient's care. This situation is most likely if the doctor is an investigator but not the treating clinician. To avoid this, I recommend that trialists consider routinely including consent to this sort of disclosure in the patient information sheet. I have indicated further guidance below.

Acting as an Expert Witness

The Crown Prosecution Service (CPS) and the Association of Chief Police Officers (ACPO) have published guidance for expert witnesses entitled *Guidance Booklet for Experts*. This sets out obligations that apply to all experts in criminal cases, which can be summarised in the key actions of **retain, record and reveal**. You should also be aware of other advice that is available on information disclosure and acting as a professional witness. Details of these and the CPS/ACPO guidance, with weblinks, can be found below.

Yours sincerely



Sir Liam Donaldson
Chief Medical Officer

Guidance on information sharing and acting as an expert witness

CPS/ACPO *Guidance Booklet for Experts* available at
http://www.cps.gov.uk/publications/docs/experts_guidance_booklet.pdf

Confidentiality: NHS Code of Practice, November 2003, sets out the policy and principles governing access to patient information, and obligations and standards governing its use. This guidance can be found at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253

GMC guidance. *Good Medical Practice* sets out the duties of doctors, including record keeping. *Acting as an expert witness* explains how the principles set out in *Good Medical Practice* apply to the work of the medical expert witness. 0-18 years: guidance for all doctors refers specifically to children's confidentiality. All these are available at: http://www.gmc-uk.org/guidance/ethical_guidance/index.asp

Research records. The MHRA's guidance can be found at:
<http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm>