

CONDUCTING CLINICAL TRIALS

The GDC expects all registrants to follow the guidance set out in 'Standards for dental professionals' whatever area of the profession you work in. This includes all registrants associated with, undertaking or involved in clinical trials and research.

Particular relevant standards include:

- putting the patients' interests first;
- finding out about laws and regulations which may affect your work;
- finding out about current best practice;
- acting honestly and fairly; and
- making sure patients are able to claim compensation.

You must accept and fully understand your responsibility both to patients participating in clinical trials or research and to professional colleagues whose own clinical decisions will ultimately be shaped by the actions and integrity of those involved in the research itself.

You must ensure that you are aware of the legislation relating to clinical trials. The current legislation in the UK is the Medicines for Human Use (Clinical Trials) Regulations 2004 (amended 2006). These regulations include a requirement to follow the conditions and principles of the EU Directive on Good Clinical Practice.

You should make sure that you have the approval of the local ethics committee where required and that you comply with any directions given by them. Always check with your defence organisation before undertaking this kind of work.

Further advice and legislation can also be found via the following documents or at the MHRA website: www.mhra.gov.uk

- EU Clinical Trial Directive 2001/20/EC
- EU Directive on Good Clinical Practice 2005/28/EC
- Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) (as amended)
- Practice Guidance on Pharmacy Services for Clinical Trials, RPSGB and Institute of Clinical Research, June 2005
- Research Governance in Health and Social Care (Department of Health), NHS permission for R&D involving NHS patients, February 2004
- Guidance on Good Clinical Practice and Clinical Trials in the NHS, December 1999
- Good Research Practice, Medical Research Council, September 2005
- Description of the Medicines for Human Use (Clinical Trials) Regulations 2004, Medicines and Healthcare products Regulatory Agency.