GUIDANCE ON GOOD CLINICAL PRACTICE AND CLINICAL TRIALS IN THE NHS

1. The NHS has responsibilities for the clinical research it conducts or hosts. This guidance is concerned with management of clinical trials; further guidance on the governance of research in general will be issued at a later date.

2. Clinical trials conducted in the NHS may be sponsored by industry, the Medical Research Council (MRC), medical research charities, universities, the Department of Health (including the NHS Executive), health authorities, primary care groups, NHS trusts, general practitioners and, in due course, primary care trusts.

3. Industry ensures that trials it sponsors with a view to submissions to regulatory authorities are conducted to the International Committee on Harmonisation Good Clinical Practice (ICH GCP) Guidelines.

4. The MRC, in consultation with the Department of Health, has drawn up parallel guidelines[1] for the conduct of trials sponsored by MRC and other publicly funded bodies. The Guidelines are intended to be of relevance to any prospective study involving human participants and the administration of a treatment or type of management, including diagnosis, prevention and the provision of lifestyle advice. They have been drawn up with controlled, Phase III trials primarily in mind. Some provisions may be overly complex for small Phase I or II studies. All research studies involving patients should, nonetheless, have ethics committee approval and clear lines of accountability for ensuring that approved protocols and procedures are followed.

5. The MRC Guidelines define responsibilities for the Sponsor, Principal Investigator and Host of trials. The **Sponsor** is the organisation taking overall responsibility for the management and financing of a trial. The **Principal Investigator** is the person responsible for the conduct of the trial on a daily basis. The **Host Institution** is the organisation in receipt of funding from the Sponsor and in which the trial is based.

6. Health authorities, primary care groups, NHS trusts, general practitioners and, in due course, primary care trusts have responsibilities for clinical trials for which they are the Host or Sponsor or the organisation for which the Principal Investigator works. It is therefore good practice for them to:

   i. have systems in place to review <u>all</u> ongoing and proposed R&D studies they fund or intend to fund or which involve patients in their care, and identify those studies which fall within the scope of the MRC Guidelines;

[1] MRC Guidelines for Good Clinical Practice in Clinical Trials

and, for each study falling within the scope of the MRC Guidelines they should:

ii ensure that a Sponsor, Principal Investigator and Host have been identified;

iii. ensure that the responsibilities of Sponsor, Principal Investigator and Host and related structures have been defined in ways consistent with the Guidelines and commensurate with the possible risks to which patients might be exposed;

iv. ensure that, for work undertaken in partnership with a university or other non-NHS body, the respective responsibilities of their own and the other organisation, and of staff in each, have been clearly and appropriately defined;

v. ensure that they and their staff understand and discharge the responsibilities falling to them as Host, Principal Investigator and/or Sponsor; this is particularly important for studies which they or their staff have themselves initiated and are funding, and for which they are therefore themselves the Sponsor;

vi. ensure that any other organisation involved in the study understands, accepts and is equipped to discharge the responsibilities falling to them; this is particularly important when an external organisation is deemed to be the Sponsor; the MRC, Department of Health (including the NHS Executive) and other major funders of medical research accept and discharge the responsibilities ascribed to the Sponsor in the MRC Guidelines; but if there are doubts about an organisation's willingness or ability to undertake the duties falling to the Sponsor, the NHS organisation must either itself assume them or withhold permission for the trial to proceed.

7. In the case of multi-centre trials, a lead provider (usually the organisation where the Principal Investigator works) should take overall responsibility and establish clear lines of responsibility with collaborating centres and/or funders.

8. Well designed and conducted trials are essential for high quality patient care. Such trials cannot proceed without the co-operation of the NHS. Any NHS organisation or employee with doubts about their ability to meet standards of good practice in the management of trials should seek help from their Regional Director of Research and Development to ensure that they can continue (or begin) to support this important aspect of the work of the NHS.

9. The MRC Guidelines and this publication do not alter:

   i. responsibilities for the clinical care of patients;

   ii. arrangements for industrially sponsored trials conducted to the ICH GCP Guidelines;

   iii. arrangements for the ethical review of trials by Local or Multi-centre Research Ethics Committees and other specific groups such as the Gene Therapy Advisory Committee (GTAC);

   iv. previous guidance on R&D in the NHS.

ACTION

10. NHS trusts, general practitioners, health authorities, primary care groups and, in due course, primary care trusts, should take action to ensure that good clinical practice standards for clinical trials involving NHS patients are implemented for all relevant research they are involved in (not only that funded by the MRC).

CONTACTS

The MRC guidelines are available at its website at
http://www.mrc.ac.uk/clinical_trials/ctg.html

or via the R&D pages on the Department of Health website at
http://www.doh.gov.uk/research

or in hard copy from the R&D Director at your Regional Office.

General enquiries should be addressed to the R&D Director at your local Regional Office.

Specific enquiries as follows:

Trial methodology, management and service support issues:

Clinical Trials Adviser
Professor Richard Lilford
West Midlands Regional Office

Issues on research ethical review:

Professor Terry Stacey
South East Regional Office

Information on Clinical Trials Exemption or Doctors and Dentists Exemption (CTX and DDX certificates):

The Clinical Trials Unit
Medicines Control Agency
12th Floor
Market Towers
Nine Elms Lane
London SW8 5NQ

Device trials carried out for regulatory purposes:

European Regulatory Affairs
Medical Devices Authority
Hannibal House
Elephant and Castle
London SE1 5NQ

This guidance has been issued by:

Professor Sir John Pattison, Director of Research and Development