Science

1. Legislation and Regulation

The Stationery Office
http://www.hmso.gov.uk/legis.htm
The Stationery Office (formerly HMSO) contains text of all UK legislation enacted by the UK Parliament as well as delegated legislation (Statutory Instruments). Has links to the equivalent sites for the devolved administrations (Scotland, Wales and Northern Ireland).

1.1 General

The Department of Health (DH)
http://www.doh.gov.uk/publications/index.htm
Key documents including the Health Act 1999, which lays out the duty of quality.

1.2 Genetics and Embryology

The Human Genetics Commission
http://www.hgc.gov.uk
Contains links to the main bodies concerned with regulation and advice on human genetics

The Human Fertilisation and Embryology Authority (HFEA)
Human Fertilisation and Embryology Act 1990
http://www.hfea.gov.uk/frame.htm
All records involving the creation, keeping or use of human embryos outside the body must be licensed by the HFEA. Includes a section on research and licence requirements.

The Polkinghorne Report
Review and Guidance on the Research Use of Foetuses and Fetal Material. CM 762, HMSO 1989. In addition, there are also Department of Health guidelines: Guidance on the supply of fetal tissue for research, diagnosis and therapy, 1995.

The UK Xenotransplantation Interim Regulatory Authority (UKXIRA)
http://www.doh.gov.uk/ukxira.htm
UKXIRA advises government on Xenotransplantation including on specific applications to proceed with such research in patients.

1.3 Medicines

Medicines Control Agency
http://www.open.gov.uk/mcahome.htm
The Medicines Act 1968.
Licensing, inspection and other activities to promote and safeguard public health through ensuing appropriate standard of safety, quality and efficacy for medicine in the UK.
Site will soon expand to give information about all aspects of the medicines regulation process in the UK

Home Office
Misuse of Drugs Act, 1971
Regulations and amendments are to be found at
http://www.homeoffice.gov.uk/ato7/drugs.htm

1.4 Medical Devices

Medical Devices Agency
http://www.medical-devices.gov.uk
Information about all aspects for ensuring that medical devices meet appropriate standards of safety, quality and performance.

1.5 Miscellaneous

The EC Novel Foods and Novel Food Ingredients Regulation (258/97) which came into force on 15 May established a mandatory pre-market approval system for novel foods or processes

1.5.1 Misconduct

The Public Interest Disclosure Act came into force in July 1999. The Act provides employees - in both the private and public sectors - with protection against victimisation should they "blow the whistle" in certain circumstances.

1.5.2 People

The Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly
Helsinki, Finland, June 1964
and amended by the:

- 29th WMA General Assembly, Tokyo, Japan, October 1975
- 35th WMA General Assembly, Venice, Italy, October 1983
- 41st WMA General Assembly, Hong Kong, September 1989
- 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

and the:

- 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

http://www.wma.net

Council for International Organisations of Medical Sciences

- International guidelines for ethical review of epidemiological studies, 1aa1
- International ethical guidelines for biomedical research involving human subjects, 1aa3

Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine; Convention on Human Rights and Biomedicine (ETS 164) at:
http://conventions.coe.int/treaty/EN/cedreprincipal.htm
The Royal College of Paediatrics and Child Health has published Guidelines for the ethical conduct of medical research involving children. Archives of Diseases in Childhood 82:177-182 (2000).

The MRC has published guidance on The Ethical Conduct of Research on the Mentally incapacitated
http://www.mrc.ac.uk/ethics_c.html

The Human Rights Act 1998
http://www.hmso.gov.uk/acts/acts1998/19980042.htm

The UN Convention on Children's Rights
http://eurochild.gla.ac.uk/Documents/UN/Rights/unconvention.htm

The text of the convention on the 'Rights of the Child'.
http://www.unicef.org/crc/
UNICEF's site on the Convention on the Rights of the Child including a number of other children's rights resources as well as the full text of the convention.

The Race Relations Act 1976 was amended by the Race Relations (Amendment) Act 2000
http://www.hmso.gov.uk/act/acts2000/20000034.htm

Explanatory guidance is provided by the Commission for Racial Equality
http://www.cre.gov.uk

Regulation of Investigatory Powers Bill
http://www.homeoffice.gov.uk/oicd/ripbill.htm
Legislation relating to interception of communications, intrusive investigative techniques and access to encrypted data

2. Other DH Requirements

2.1 Animals

2.1.1 Peer Review

The Committee on Standards in Public Life, reports are available at
http://www.public-standards.gov.uk
The first report covers appointments and openness, is relevant to the appointment of members of Non Departmental Government Bodies.

OST Guidelines on Use of Scientific Advice in Policy Making

The DTI's use of Scientific Advice in Policy Making sets out some key principles on the use and presentation of scientific advice in policy making.
http://www.dti.gov/ost/ostbusiness/policy.htm

Medical Research Council
The MRC will publish in early 2001 "Guidance on Reviewing Research proposals for its peer review community."
Key principles of peer review are set out in MRC's "Principles in the Assessment and Conduct of Medical Research and Publishing Results"
The World Association of Medical Editor's sites has references and links on Peer review in editing and publication
http://www.wame.org

Council of Europe
The UK is a signatory to the Council of Europe Convention for the Protection of Vertebrate Animals used for Experiment and Other Scientific Purposes, the aim of which is to reduce the number of experiments and animals in research
http://conventions.coe.int/treaty/EN/cadreprincipal.htm

2.1.2 Other

The Boyd Group has published guidance on ethical review of research involving animals; refinement : and genetic engineering, animal welfare and ethics
http://www.boyd.group.demon.co.uk

Good practice guidelines are published by the Laboratory Animal Science Association
http://www.lasa.globalnet.co.uk

The Fund for Replacement of Animals in Medical Research
http://frame-uk.demon.co.uk
provides information on alternatives and links to research references on alternatives.

The Universities Federation for Animal Welfare (UFAW) produces publications on animal welfare and links to other organisations http://ufaw.org.uk

The MRC Centre for Best Practice for Animals in Research has newly been established to provide guidance to researchers and others on the reduction, retirement and replacement of animals in biomedical research.

2.2 Codes of Professional Conduct

2.2.1 The General Medical Council

http://www.gmc-uk.org/standard/good/good.htm
Good Practice in Medical Research: The Role of Doctors - specific guidance on good practice in medical research due to be published in 2001

2.2.2 Research Councils

The Biotechnology and Biological Sciences Research Council, the Engineering and Physical Sciences Research Council (EPSRC), the Medical Research Council (MRC) have all produced statements on best practice, to prevent allegations of fraud or scientific misconduct.

2.2.3 Others

Organisations other than HE institutions and research centres run courses or training events for researchers, for instance, the Institute of Physics (IOP). The EPSRC also supports a number of career development schools for post-doctoral contract researchers.

Employers are responsible for ensuring health and safety. The Health and Safety Executive (HSE) produces a book on health and safety guidelines specifically for research in further and higher education.

2.2.4 Links

Biotechnology and Biological Sciences Research Council (BBSRC)
BBSRC statement on ensuring good scientific practice in research.
http://www.bbsrc.ac.uk/funding/overview/safeguard.html

Engineering and Physical Sciences Research Council (EPSRC)
EPSRC guidelines on good research practice in science and engineering
http://www.epsrc.ac.uk/Documents/Guides/Misconduct/Contents.htm

Career development schools for post-doctoral contract research
http://www.epsrc.ac.uk/Documents/Announcements/Career Development Schools NOW.htm

Health and Safety Executive (HSE)
Government agency responsible for ensuring health and safety work
http://www.hse.gov.uk/hsehome.htm

HERO
The Higher Educational and Research Opportunities site provides a valuable set of links targeted to new researchers.
http://www.hero.ac.uk/research/good_practice_for_new_researchers 230.cfm

Medical Research Council (MRC)
MRC statement on allegations of scientific misconduct
http://www.mrc.ac.uk/ethics_a.html

Good Research Practice guidelines issued in 2000
http://www.mrc.ac.uk
click on the PDF document

Institute of Physics (IOP)
Offers a range of training courses for physics researchers
http://iopevents.com/Courses

Association of Medical Research Charities
http://www.amrc.org.uk/aboutus/publicationsandarticles.html
Implementation of Peer Review (£5-00) AMRC guide to best practice of the peer review process - website address for ordering publications

British Psychological Society
http://www.bps.org.uk/index.cfm
Code of conduct

British Sociological Association's
http://www.britsoc.org.uk
Guidelines on conduct, ethical practice and related issues. Web-site under development.

The Chartered Society of Physiotherapy
http://www.csp.org.uk
Rules of Professional Conduct

The Public Health Laboratory Service
http://www.phls.co.uk
Guidance related to Scientific Misconduct and Good Scientific Practice

The Allied Health Professions
Codes of Conduct

The Market Research Society's (MRS) Code of Conduct.
http://www.marketresearch.org.uk/
Site also includes MRS's best practice guides including employee research, qualitative research, data collection, and research with children and young people.

Cabinet Office
http://www.cabinet-office.gov.uk/quango/index/nhscode.htm
Codes of conduct and accountability for NHS Boards

Home Office
http://www.homeoffice.gov.uk/animact/hcasp.htm
Code of Practice for the housing and care of animals used in scientific procedures

2.2.5 Clinical Trials

Guidance specifically relevant to clinical trials

Good Laboratory Practice

Department of Health (Good Laboratory Practice Monitoring Authority) Code of Practice.

Radioactive Substances and Neutron Irradiation
Research that requires the use of radioactive substances or in vivo neutron activation analysis in humans, needs approval from the Administration of Radioactive Substances Advisory Committee (ARSAC) at the National Radiological Protection Board, Chilton, Didcot, Oxon, OX11 0RQ.

Genetic Modification
The Genetically Modified Organisms (Contained Use) Regulations 1992 and The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996 require laboratories that intend carrying out genetic modification to register with the Health and Safety Executive. All such work is subject to risk assessment and according to the assessment some work may additionally require specific consent. Notifications are sent to the Directorate of Science and Technology, Unit E4, Magdalen House, Stanley Precinct, Bootle, L20 3QZ (Tel: 0151 951 4772). Detailed guidance notes are available from the HSE at Bootle or from HSE Health Directorate B2, Floor 7SW, Rose Court, 2 Southwark Bridge, London, SE1 9HB, (Tel: 0171 717 6348).

Dangerous Pathogens
Institutions/Departments proposing to accommodating projects involving the use of dangerous pathogens must comply with the safeguards recommended by the Advisory Committee on Dangerous Pathogens in their report Categorisation of Biological Agents According to Hazard and Categories of Containment, HMSO, 4th Edition, 1995.

Pre-clinical trials
Laboratories conducting toxicological studies on animals should be registered with the Good Laboratory Practice programme of the GLP Monitoring Authority
http://www.doh.gov.uk/busguide/goodlab/glpma7.htm

Pre-licensing or licence-extension Trials
Guidance for clinical trials prior to licensing and which are intended to lead to licensing application, or which might lead to licence extension for an existing product, are to be found in the following document, "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (commonly referred to as the ICH)". (New regulations are to be introduced in compliance with proposed European Union Directive on the conduct of clinical trials)
ICH Guidelines on Clinical Trials are at http://www.ifpma.org/ich5e.html
Developments in European Union legislation can be accessed through
http://europ.eu.int
The Directive on Good Clinical Practice in Clinical Trials is currently accessible as EU document 597PC0369.

Trials on patients should be notified to the Medicines Control Agency. Advice on the conduct of trials in accordance with 'ICH GCP' and on the preparation of investigational products in accordance with Good Manufacturing Practice may both be obtained from the MCA Inspection Division
http://www.open.gov.uk/mca/mcahome.htm

All Other Trials
The MRC/Department of Health Good Clinical Practice Guidelines can be found at:
http://www.mrc.ac.uk/Clinical trials/ctg.html

Advice aiming to improve the design and management of clinical trials is available from several sources, e.g. The Resource Centre for Randomised Trials
http://www.rcrt.ox.ac.uk

The MRC Trial Managers Network
http://www.epi.bris.ac.uk/tmn/home.htm

The British Oncology Data Managers Association (BODMA) at
http://www.bodma.com and
The Clinical Trial Managers Association (CTMA) at
http://www.ctma.org.uk

MRC advice on Developing and Evaluating RCTs for complex Interventions to Improve Health are at
http://www.mrc.ac.uk/complex_packages.html

MRC advice "The Ethical Conduct of Aids Vaccine Trials" is available from the Publications Section of MRC.

Trials under the NHS Priorities and Needs Programme
Interpretative note for trials conducted within programmes for research under the Priorities and Needs System will be made available at; http://www.doh.gov.uk search for 'Trials ' under the 'NHS Priorities & Needs Programme' see doc.' Research Governance'

2.2.6 Registration of Randomised Clinical Trials

Registration of RCIs is in the interest of funders, researchers and consumers.
The MRC requires MRC trials to be registered in the international metaRegister of RCTs, and for its trials to use a unique identifier, the International Standard RCT Number (ISRCTN). The metaRegistor contains details of some 6000 trials supported by 18 agencies. The metaRegistor and ISRCTNs can be accessed on
http://www.controlled-trials.com

In the USA,
http://clinicaltrials.gov
provides patients, families and the public with information about clinical research studies and draft FDA guidance on registering trials on "life threatening diseases" is available from http://www.fda.gov/cder/guidance/3585dft.htm

The Journal of the American Medical Association
Reporting of Trials
Trials should be reported according to principles laid out in the CONSORT statement
http://www.ama-assn.org or http://consort-statement.org/

International
In the USA, the Office for Human Research Protection is responsible for overseeing research which involves the use of human participants.
http://ohrp.osophs.dhhs.gov

2.2.7 General Practice

Royal College of General Practitioners
Good Medical Practice for General Practitioners
http://www.rcpg.org.uk
search for 'Good Medical Practice for GPs
Describes what is expected of a GP under three broad headings: Professional competence, Good relations with patients and colleagues, Professional ethical obligations. The last of these includes a paragraph on research.

2.2.8 Social Care and Science Research

Best Value
http://www.local-regions.detr.gov.uk/bestvalue/bvindex.htm
Department of the Environment, Transport and the Regions' site providing information on all policy aspects of Best Value in England as well as the Government's best value publications and research.

Economic and Social Research Council
http://www.esrc.ac.uk/resfund.htm
The ESRC's funding regulations including not only details required under ESRC funding but also useful guidance on research ethics and confidentiality.

Social Services Research Group
http://www.ssrg.demon.co.uk
The Social Services Research Group website, including Guidelines for Good Practice in Research and Collaborative Research.

2.2.9 Samples and collections

Human Tissue Act 1961
The Anatomy Act 1984 and the attendant Anatomy Regulations 1988
Legislation covering human cadavers donated to departments of anatomy in British Medical Schools for the study or teaching of, or for research into, anatomy

Nuffield Council on Bioethics
http://www.nuffield.org.uk/bioethics/index.html
Human Tissue: Ethical and Legal Issues - Report published in April 1995.
Conclusions and recommendations available on the website.

The Royal College of Pathologists
http://www.rcpath.org/news/reports.html
Guidelines for the Retention of Tissues and Organs at Post-Mortem Examination

Royal College of Physicians
Statement from the Royal College of Physicians' Committee on Ethical Issues in Medicine "Research based on archived information and samples".
Journal of the Royal College of Physicians (1999) 33:264-6

Medical Research Council
http://www.mrc.ac.uk.tissues.htm
The MRC is formulating guidance on ethical, legal and management issues concerning human tissue and biological samples for use in research.

UK National Culture Collection
http://www.uknc.co.uk/cap
The NCC offers a number of services including the supply of quality cultures, identification of cultures, safe deposit facilities and deposit of cultures It provides guidance on collection management and on the supply of cultures.

European Collection of Cell Cultures
http://www.ecacc.org
ECACC provides quality cell cultures to the academic community and industry, provides guidance on culture deposition and access.

Brain Tissue
"The MRC's Role and Guidelines for MRC-funded Brain Banks" is available from the publication section of MRC

2.2.10 Statistics

The White Paper "Building Trust in Statistics" (Stationery Office 0-10-144122-3) sets out the framework for quality assuring national statistics. National Statistics provides and draws in a range of advice on methods and quality
http://www.statistics.gov.uk
The Statistics Code of Practice sets out shared good practices and 12 key principles for providers of national statistics and is available from National Statistics.

The Royal Statistical Society has a code of professional conduct for its Fellows
http://www.rss.org.uk

A comprehensive "Ethical Guidelines for Statistical Practice" has been published by the American Statistical Association
http://www.amstat.org/profession/ethicalstatistics.html

3. Other Established Standards

3.1 Peer Review

ExPeRT
http://www.expert-caspe.demon.co.uk/
The ExPeRT project was set up to study and exchange practical experience of external peer review systems in health services within the EU and associated countries, the project is funded by the European Union, as part of the BIOMED II public health research programme.

3.2 Sources of Research Information

The Department of Health's Research Findings Register (ReFeR)
http://www.doh.gov.uk/research

Cochrane Collaboration
http://www.cochrane.org
The Cochrane Collaboration provides guidelines, manuals and software relevant to preparing and making accessible of systematic reviews of the effects of healthcare interventions.

Preparing, maintaining and promoting the accessibility of systematic reviews of the effects of health care interventions.

NHS Centre for Reviews and Dissemination
The CRD undertakes and commissions rigorous reviews of research findings on the effectiveness of healthcare relevant to the NAS, and provides guidelines for conducting and commissioning systematic reviews.
http://www.york.ac.uk/

Effective Health Care Bulletin is a bi-monthly bulletin for decision-makers which examines the effectiveness of a variety of health care interventions.
http://www.york.ac.uk/inst/crd/ehcb.htm

The National electronic Library for Health (NeLH)
http://www.nelh.nhs.uk/
The NeLH will provide easy access to knowledge and know-how, to improve health care, clinical practice and patient choice

Centre for Research Support
Turning Research into Practice (TRIP)
http://www.ceres.uwcm.ac.uk
Supports primary healthcare in Wales

COPAC: Consortium of University Research Libraries
http://copac.ac.uk/copac/
Unified access to the catalogues of some of the largest university research libraries in the UK and Ireland holding documents in many languages.

3.3 Training for Research

NHS Education Consortia
http://www.consortia.nhsweb.nhs.uk/
This site deals with the recruitment and retention of nurses, scientist and technicians and allied professions in the NHS.

Universities UK
http://www.cvcp.ac.uk/
Http://www.universitiesuk.ac.uk/links
Universities UK (formerly CVCP) provides links to its member institutions via National Information Services and Systems (NISS) and to organisations that are related to higher education sector in the UK. Also, contains reports of policy development in relation to training and learning in UK Universities.

Quality Assurance Agency for Higher Education
The QAA Code of Practice for the Assurance of Academic Quality and Standards in Higher Education provides a set comprehensive, system-wide expectations relating to the management of academic quality
http://www.hefce.ac.uk/Pubs and http://www.qaa.ac.uk

HERO (Higher Education and Research Opportunities)
http://www.hero.ac.uk
Provides links for new scientists to research funders, codes of professional ethics, research career opportunities and to the Research Careers Initiative including the Concordat on contract research staff, agreed by Research Councils, The Royal Society, The British Academy and Universities UK (formerly CVCP). It, also, has links to guidance on disclosing research findings and managing intellectual property.

Next Wave
http://nextwave-uk.sciencemag.org/
Science's Next Wave site is a weekly on-line publication devoted to scientific training and career development internationally.

MRC Research Careers
Studentships, fellowships and clinical research funding.

BBSRC Training
http://www.bbsrc.ac.uk/
and then search for 'BBSRC Training'
Key areas that BBSRC-supported Research Training

3.4 Other useful contacts

Institute for Healthcare Management
http://www.ihm.org.uk/
The largest UK professional body for managers working in healthcare and health services.

The Institute for Social Research
http://www.soc.surrey.ac.uk/
Includes consultancy services in the design and implementation of research, including evaluation

The Help for Health Trust
http://www.hfht.org/ConsumersinNHSResearch/index.htm
Consumers in NHS Research aims to ensure that consumer involvement in R & D in the NHS improves the way that research is prioritised, commissioned, undertaken and disseminated.

The Social Research Association
http://www.the-sra.org.uk/index2.htm
Includes guidelines on ethics and safety of interviewers

Qualidata : qualitative data archive resource centre
http://www.essex.ac.uk/qualidata
Includes guidelines for sharing of qualitative data

UK Data Archive
http://www.data-archive.ac.uk
Includes guidelines for preparation of data for archiving and for access to archived social sciences data.

The Association of the British Pharmaceutical Industry (ABPI)
http://www.abpi.org.uk/
Guidance for Pharmaceutical Companies doing research, developing, manufacturing and supplying medicine.

The National Centre for Clinical Audit (NCCA) now part of the National Institute for Clinical Excellence
http://www.nice.org.uk/nice-web/Article.asp?a=953
Explains what clinical research is.

King's Fund
http://www.kingsfund.org.uk/
Independent Healthcare Charity -working both nationally and internationally to carry out research and development for better health policies and services.

Information

This domain sets out standards relating to the provision of information about research being conducted in health and social care and about the findings of that research. Standards relating to the use of patient and client information are set out in the Ethics domain.

Legislation and Regulation

Freedom of Information Act
http://www.hmso.gov.uk
This Act sets out the requirements on public bodies (including Institutes of Higher Education) to provide information in response to requests from the public.

Other Department of Health Requirements

National Research Register Revised Guidelines to Data Providers on Data Submissions for 2000 Update Software Ltd
http://www.update-software.com
This sets out the current requirements on the NHS for submission of information on research funded or hosted by the NHS for inclusion on the National Research Register (NRR). The NRR is available free to the public at
http://www.doh.gov.uk/research

NHS Support for Science NHS Priorities and Needs R&D Funding Information for Health and Social Care Research
http://www.doh.gov.uk/research
These documents set out requirements on those sponsoring and hosting research in or through health and social care in relation to the collection and collation of information on R&D and the provision of this information to patients, clients, other researchers, the public and the Department of Health.

The Research Findings Register (ReFeR): Guidance for Principal Investigators
http://www.doh.gov.uk/research
This guidance sets out the requirement on Principal Investigators to submit to the register a structured summary of the findings of research funded by the Department of Health.

Other Established Standards

Research Data, Documentation and Archiving

Safeguarding Good Scientific Practice. A joint statement by the Director General of the Research Councils and the Chief Executives of the UK Research Councils, December 1998
http://www.esrc.ac.uk/Resfund/annex2.htm
This joint statement by the Director General of the Research Councils and the Chief Executives of the UK Research Councils, sets out standards for securing primary data used in research.

International Conference on Harmonisation of Technical requirements for Registration of Pharmaceuticals for Human Use (ICH) guideline, 1996
http://www.kifpma.org/ich1.htm
These guidelines set out the information that should be retained in relation to clinical trials that are likely to lead to the registration of medicinal products. The guidelines explain who should retain data and documents, and for how long.

MRC Guidelines for Good Clinical Practice in Clinical Trials, 1998
http://www.mrc.ac.uk/Clinical_trials/ctg.htm
These guidelines provide further guidance about the retention of documents for MRC trials that are not likely to lead to the registration of medicinal products.

ESRC qualitative data archive resource centre (Qualidata)
http://www.essex.ac.uk/qualidata/
These guidelines relate to the preparation of qualitative data and any associated documentation for deposit in a repository via 'Qualidata'.

Publication

Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting randomised controlled trials: the CONSORT statement. JAMA 1996; 276: 637-9.
http://www.ama-assn.org/public/journals/jama/jamahome.htm
This paper sets out guidelines for reporting randomised controlled trials.

The NHS Centre for Reviews and Dissemination. Undertaking systematic reviews of research on effectiveness. CRD Report No 4 (2nd edition) February 2001.
http://www.york.ac.uk/inst/crd
This report is the CRD's guidance for carrying out or commissioning reviews. It contains guidance about reporting systematic reviews.

The Health Technology Assessment Programme
http://www.hta.nhsweb.nhs.uk/research.htm
The NCCHTA sets out standards for the reporting and publication of research funded through the NHS HTA Programme.

Copyright issues
http://www.doh.gov.uk/nhsexec/ipr.htm
Copyright issues are dealt with by the Department of Health's Policy Framework for the Management of Intellectual Property arising from R&D, and two associated documents: The Management of Intellectual Property and Related Matters, and Handling Inventions and Other Intellectual Property.

OST guidelines on the use of scientific advice in policy making
http://www.dti.gov.uk/ost/ostbusiness/index_policy_making_old.htm
Further guidance is provided by the Office of Science and Technology. The guidelines are due to be updated this year.

Health, Safety & Employment

Legislation and Regulation

General

The Department of Trade and Industry (DTI)
http://www.dti.gov.uk/access/index.htm
DTI's guide to regulations including advice to small firms, employment rights and regulations affecting the biotechnology and chemical industry.

Specifics

Health and Safety

Health and Safety Executive Health and Safety at Work etc Act 1974
http://www.hse.gov.uk/action/index.htm
Site includes guides on law, regulations and employer's liability
http://www.hse.gov.uk/sources/index.htm
This page is currently being developed but will include details of relevant legislation.

Documents available from HMSO
http://www.hmso.gov.uk/
include: Guidelines for the Testing of Chemicals for Toxicity, HMSO (1982).
Guidelines for the Testing of Chemicals for Carcinogenicity, HMSO (1991).
Guidelines for the Testing of Chemicals for Mutagenicity, HMSO (1989).

GLP

Department of Health Good Laboratory Practice Monitoring Authority Code of Practice
http://www.doh.gov.uk/practice.htm
The application of GLP to studies allows Government regulatory authorities to use the data generated in hazard and risk assessments. The Good Laboratory Practice Regulations 1997 ("the GLP Regulations") contain all the legislative measures necessary for the implementation in the UK of the three EC Directives on GLP. This site includes links to the application of GLP regulations to computer systems and field studies.

COSHH

Control of Substances Hazardous to Health (COSHH) Regulations 1994
http://www.hse.gov.uk/pubns/chindex.htm
Chemical hazards at work including guidance on the COSSH regulations and biological monitoring.

Genetically modified organisms

Environmental Protection Act 1990 (EPA) Genetically Modified Organisms (Deliberate Release) Regulations 1992 The EC Directive on the Deliberate Release into the Environment of GMOs (90/220/EEC) Genetically Modified Organisms (Deliberate Release) Regulations 1995 DETR & HSE

The HSE has produced a booklet which provides guidance on how to comply with Contained Use Regulation for GMOs, as well as a series of detailed notes on good practice prepared with advice from the Advisory Committee on Genetic Modification (ACGM). The HSE's specialist inspectors provide advice on risk assessment and containment.

Radiation

Ionising Radiations Regulations 1999 Board Statements and supporting material from the National Radiation Protection Board.
http://www.nrpb.org.uk/Docslib.htm
A wide range of material including guidelines on exposure, radiology standards, reports on risk etc.

Other DH Requirements

Pathogens

http://www.doh.gov.uk/danpath.htm
Advice on working with dangerous pathogens, including infection hazards arising from the use of research animals

Radiation

Radioactive Substances Division, in the Department of Environment, Transport and the Regions
http://www.environment.detr.gov.uk/radioactivity/index.htm
Includes radioactive waste management policy and legislation; environmental radioactivity, including radioactive discharges, contaminated land and radon in the home and response to overseas radiological emergencies.

Training, monitoring, instrument testing and other services available from the National Radiation Protection Board
http://www.nrpb.org.uk/Services.htm

Other Established Standards

Institution of Occupational Safety and Health (IOSH)
http://www.iosh.co.uk/inform/links.html
The site for IOSH the professional body for safety and health practitioners. Has links to a large number of organisations with an interest in health and safety issues.

Social Research Association
http://www.the-sra.org.uk/safe.htm
A Code of Practice for the Safety of Social Researchers

Public Health Laboratory Services
http://www.phls.co.uk/services/safety/safety6.htm
Health and Safety Profile

Infectious micro-organisms Health Canada Material Safety Data Sheets (MSDS)
http://www.hc-sc.gc.ca/hpb/lcdc/biosafty/msds/
Data sheets for common infectious micro-organisms including details of hazards, precautions and handling information.

Finance & Intellectual Property Rights

Introduction

Spending on R&D is subject to the rules of financial governance, in the same way as any activity undertaken within the NHS. R&D do have special characteristics, but is not special in respect of financial governance. Researchers should conform to the financial regime within their own NHS Trust or that, which is to host the R&D.

Policy and Guidance adopted by the host trusts may be available on their own web site under the headings of:

- Financial Governance
- Standing Financial Instructions

However, the central guidance that underpins the financial regime adopted by the individual trusts can be found on the following web pages.

Legislation and Regulation

Her Majesty's Stationery Office
http://www.hmso.gov.uk/legislation/lexhome.htm
Contains text of all UK legislation enacted by the UK Parliament as well as delegated legislation (Statutory Instruments). Has links to the equivalent sites for the devolved administrations (Scotland, Wales and Northern Ireland).

The Department of Health (DH)
http://tap.ccta.gov.uk/doh/finman.nsf/
The Financial Governance section of the NHS Finance Manual includes an outline of the legislation enacted that supports Financial Governance in NHS organisations.

The Patent Office
http://www.patent.gov.uk
The Patents Act 1977 and the Copyright: Designs and Patents Act, 1988 is the legislative framework in the UK for intellectual property. Copies of these acts are available from the Sales Section, the Patent Office, Concept House, Cardiff Road, Newport NP10 8QQ

Other DH Requirements

Financial Management

The Department of Health (DH)
http://tap.ccta.gov.uk/doh/finman.nsf/
The NHS Finance Manual is the principal reference site for Financial Management in the NHS. It refers to roles of senior officials, accountability and Financial Governance.

http://www.hm-treasury.gov.uk/pub/html/docs/cup/guidance.html
HM Treasury Central Unit on Procurement guidelines including references to contract management, Quality Assurance, Ethics and Strategic Partnering in Government.

NHS Trusts' Financial Governance

The Department of Health (DH)
http://tap.ccta.gov.uk/doh/finman.nsf/
The NHS Trust detailed guidance section of the NHS Finance Manual outlines appropriate financial procedures that should be adopted in NHS Trusts to ensure probity is maintained.

Health Authority Financial Governance

The Department of Health (DH)
http://tap.ccta.gov.uk/doh/finman.nsf/
The Health Authority detailed guidance section of the NHS Finance Manual outlines appropriate financial procedures that should be adopted in Health Authorities to ensure probity is maintained

Primary Care Group Corporate Governance

The Department of Health (DH)
http://tap.ccta.gov.uk/doh/finman.nsf/
The Primary Care Group Corporate Governance section of the NHS Finance Manual outlines the responsibilities of PCTs with respect to Financial Governance.

http://www.doh.gov.uk/pct/index/htm
Summarises the entire Corporate Governance Framework and other guidance that applies to Primary Care Trusts with links to other key sources of information.

http://www.doh.gov.uk/pricare/pcts.htm
Contains links to key documents including DH guidance regarding Primary Care Trusts Corporate Governance Framework and Financial Framework.

Other Established Standards

Controls Assurance

The Department of Health (DH)
http://tap.ccta.gov.uk/doh/finman.nsf/
The Controls Assurance section of the NHS Finance Manual indicates the responsibilities of NHS organisations with respect to the NHS Controls Assurance Project.

http://www.doh.gov.uk/riskman.htm
This site provides support to all NHS Trusts and Health Authorities in achieving the requirements of the NHS Controls Assurance Project.

Fraud Prevention

Her Majesty's Treasury (HMT)
http://www.hm-treasury.gov.uk/fraud/index.html
H.M.Treasury advice on managing the risk of fraud

The Department of Health (DH)
Directorate of Counter Fraud Services
http://www.doh.gov.uk/dcfs/directionstrusts.htm
Guidance on countering fraud and corruption in NHS Trusts.

NHS IM & T Procurement

The Department of Health (DH)
http://www.doh.gov.uk/nhsexipu/resource/procurev/procurev.htm
Contains a review of NHS IM &T procurement and is designed to assist local health communities in IM&T procurement activities.

Economic potential of public sector research

Her Majesty's Treasury (HMT)
http://www.hm-treasury.gov.uk/docs/1999/baker.html
Investigates the commercialisation of research in the Government's public sector research establishments ("PSREs") focusing on areas of good practice, barriers to successful commercialisation, culture, management and the PSRE-sponsor body relationship.

Intellectual Property

The Department of Health (DH)
http://www.doh.gov.uk/nhsexec/ipr.htm
NHS Policy framework was published in July 1998, HSC 1998/106. Guidance was published alongside the HSC and these documents are available on the above website.

The Guidance consists of:

- 1998 The Management of Intellectual Property and Related Matters. HSC (1998/106) NHS Executive.
- 1998 Handling Inventions and other Intellectual Property. NHS Executive.

The first is an introductory handbook for R&D Managers and Advisers, the second is basic guidance for researchers.

Under the policy the following apply:

NHS Executive funding of NHS bodies: intellectual property belongs to NHS body with obligation to identify and exploit. NHS body to retain any net revenue shared with employees.

NHS Executive and DH funding of external research bodies e.g. universities: intellectual property belongs to the research body with obligation to identify and exploit, net revenue shared with NHS Executive or DH.

The established guidance takes account of the following policy drivers.

http://www.dti.gov.uk/ost/aboutost/dtiwhite/
2000 White Paper 'Excellence and Innovation - a Science and Engineering Strategy for the 21st Century'
http://www.hm-treasury.gov.uk/pdf/2000/baker270700.pdf
including Government response to the Baker Report
http://www.hm-treasury.gov.uk/docs/1999/baker.html

Other relevant policy and guidance in preparation is listed below:

- 2000 Intellectual Property in Government Research Contracts; Guidelines for Departments and Research Establishments [to be published, after consultation, alongside White Paper 2000] Statement of Partnership on Intellectual Property (in preparation)
- 2000 Guidance for NHS Bodies on Employment and Management Issues under the Intellectual Property Policy Framework (in preparation)
- 2000 Financial Framework for the Management of Intellectual Property with the NHS (in preparation)
- Common NHS/DH policy framework incorporating NHS policy and including recommendations of Baker Report to cover NHS bodies and DH sponsored Non Departmental Public Bodies (NDPBs) and Special Health Authorities (SHAs) (in preparation)
- DH funding of NDPBs and SHAs: policy to be reviewed following Baker Report.

Department of Trade and Industry (DTI)

http://www.dti.gov.uk/comp/competitive/
The 1998 White Paper 'Our Competitive Future; Building the Knowledge-Driven Economy' sets out government measures to make better use of its most valuable assets of knowledge, skills and creativity and particularly to improve performance in capturing outputs of research.

Her Majesty's Treasury (HMT)

http://www.hm-treasury.gov.uk/pub/html/docs/sgswm.html
The Treasury policy document 'Selling Government Services into Wider Markets' encourages Government departments, agencies and NDPBs (including NHS Trusts and NDPBs of DH) to make better use of their assets (including intellectual property) by engaging in commercial services based on them.

http://www.hm-treasury.gov.uk/pub/html/docs/cup/procpol.html
Procurement policy guidelines with reference to the legal framework, EC Treaty provisions and links to other sources of information.

Professional standards

The Accounting Standards Board of the Institute of Chartered Accountants in England and Wales issue accounting standards governing UK Accounting Practice and Financial Reporting which form the basis of all UK accounting practice.
http://www.icaew.co.uk or
http://www.icaewmembers.co.uk for members.

Other Standards

Biotechnology and Biological Sciences Research Council
http://www.bbsrc.ac.uk/business/ip/Welcome.html
Intellectual property management and exploitation.

A to Z of Websites

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Non www.

http://clinicaltrials.gov
http://consort-statement.org/
http://conventions.coe.int/treaty/EN/cedreprincipal.htm
http://copac.ac.uk/copac/
http://eurochild.gla.ac.uk/Documents/UN/Rights/unconvention.htm
http://europ.eu.int
http://frame-uk.demon.co.uk
http://iopevents.com/Courses
http://nextwave-uk.sciencemag.org/
http://ohrp.osophs.dhhs.gov
http://ufaw.org.uk
http://who.int/tdr/publications/publications/pdf/ethics.pdf

A

http://www.abpi.org.uk/
http://www.ama-assn.org
http://www.ama-assn.org/public/journals/jama/jamahome.htm
http://www.amrc.org.uk/aboutus/publicationsandarticles.html
http://www.amstat.org/profession/ethicalstatistics.html

B

http://www.bbsrc.ac.uk/
http://www.bbsrc.ac.uk/funding/overview/safeguard.html
http://www.bodma.com
http://www.boyd.group.demon.co.uk
http://www.bps.org.uk/index.cfm
http://www.britsoc.org.uk

C

http://www.cabinet-office.gov.uk/quango/index/nhscode.htm
http://www.ceres.uwcm.ac.uk
http://www.cochrane.org
http://www.consortia.nhsweb.nhs.uk/
http://www.controlled-trials.com
http://www.cre.gov.uk
http://www.csp.org.uk
http://www.ctma.org.uk
http://www.cvcp.ac.uk/

D

http://www.data-archive.ac.uk
http://www.doh.gov.uk
http://www.doh.gov.uk/busguide/goodlab/glpma7.htm
http://www.doh.gov.uk/danpath.htm
http://www.doh.gov.uk/genetics/acgt.htm
http://www.doh.gov.uk/genetics/gtac.htm
http://www.doh.gov.uk/nhsexec/ipr.htm
http://www.doh.gov.uk/practice.htm
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http://www.doh.gov.uk/research
http://www.doh.gov.uk/research/recs
http://www.doh.gov.uk/ukxira.htm
http://www.dti.gov.uk/access/index.htm
http://www.dti.gov.uk/ost/ostbusiness/index_policy_making_old.htm
http://www.dti.gov/ost/ostbusiness/policy.htm

E

http://www.ecacc.org
http://www.environment.detr.gov.uk/radioactivity/index.htm
http://www.epi.bris.ac.uk/tmn/home.htm
http://www.epsrc.ac.uk/Documents/Announcements/CareerDevelopment Schools NOW.htm
http://www.epsrc.ac.uk/Documents/Guides/Misconduct/Contents.htm
http://www.esrc.ac.uk/resfund.htm
http://www.esrc.ac.uk/Resfund/annex2.htm
http://www.essex.ac.uk/qualidata/
http://www.expert-caspe.demon.co.uk/

F

http://www.fda.gov/cder/guidance/3585dft.htm

G

http://www.gmc-uk.org/n_hance/good.consent.htm
http://www.gmc-uk.org/standard/good/good.htm

H

http://www.hc-sc.gc.ca/hpb/lcdc/biosafty/msds/
http://www.hefce.ac.uk/Pubs
http://www.hero.ac.uk
http://www.hero.ac.uk/research/good_practice_for_new_researchers 230.cfm
http://www.hfea.gov.uk/frame.htm
http://www.hfht.org/ConsumersinNHSResearch/index.htm
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http://www.hta.nhsweb.nhs.uk/research.htm

I

http://www.ifpma.org/ich5e.html
http://www.ihm.org.uk/
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J

K

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http://www.kingsfund.org.uk/

L

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http://www.local-regions.detr.gov.uk/bestvalue/bvindex.htm

M

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http://www.medical-devices.gov.uk
http://www.mrc.ac.uk
http://www.mrc.ac.uk.tissues.htm
http://www.mrc.ac.uk/Clinical_trials/ctg.htm
http://www.mrc.ac.uk/complex_packages.html
http://www.mrc.ac.uk/ethics_a.html
http://www.mrc.ac.uk/ethics_c.html

N

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http://www.nice.org.uk/nice-web/Article.asp?a=953
http://www.nrpb.org.uk/Docslib.htm
http://www.nrpb.org.uk/Services.htm
http://www.nuffield.org.uk/bioethics/index.html

O

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P

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http://www.phls.co.uk/services/safety/safety6.htm
http://www.public-standards.gov.uk

Q

http://www.qaa.ac.uk

R

http://www.rcn.org.uk/library/library.htm
http://www.rcpath.org/news/reports.html

http://www.rcpch.ac.uk
http://www.rcpg.org.uk
http://www.rcrt.ox.ac.uk
http://www.rss.org.uk

S

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http://www.statistics.gov.uk

T

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http://www.the-sra.org.uk/safe.htm

U

http://www.uknc.co.uk/cap
http://www.unicef.org/crc/
Http://www.universitiesuk.ac.uk/links
http://www.update-software.com

V

W

http://www.wame.org
http://www.wma.net

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Y

http://www.york.ac.uk/
http://www.york.ac.uk/inst/crd
http://www.york.ac.uk/inst/crd/ehcb.htm

Z

MRC Policy

Health Departments Research Governance Frameworks for Health & Social Care

1. The MRC has declared to the UK Health Departments that it is willing and able to accept the responsibilities of Sponsor* under the terms of the English Department of Health's **Research Governance Framework for Health and Social Care** (RGF) and the equivalent **Frameworks for Scotland and Wales**. We expect to have the same responsibilities in relation to the MRC funded research in Northern Ireland.

2. The Council expects to be the RGF Sponsor for research programmes and projects with identified clinical components for which the Council has (a) assessed the quality of research and the risks to the Council, and (b) which it has agreed to fund either in the form of a grant or fellowship awards to universities, NHS Trusts or directly as an allocation within an MRC Institute, Unit or Team. Sponsorship does not include MRC Studentships awarded in the form of a block grant.

3. RGF Sponsorship is project-specific and does not extend to new work or to the continuation of work beyond the agreed funding period without specific MRC approval. On the other hand, it does accommodate reasonable changes within the scope and duration of the approved project or required by research ethics committees.

4. Key to good governance is the allocation, acceptance and execution of responsibilities within a sound research and project management framework and consistent with standards. Systematic documentation of key decisions and approvals, particularly in relation to work with patients, their organs, tissues and data is crucial. Ensuring that management and monitoring systems are in place is the responsibility of the institution to which the grant has been awarded.

5. MRC requires Host Institutions to ensure that the research undertaken under an award by the institution itself complies with **MRC Terms and Conditions** including **MRC's ethics and best practice guidance** and the **requirements of the Employing Organisation under the RGF**.

6. In relation to the inter-institutional requirements of the RGF, MRC requires Host Institutions to ensure that the necessary agreements and systems are put in place, so as to be consistent with NHS plans for full implementation by March 2004.

7. In particular, a Host Institution must ensure that it or a partner organisation systematically documents NHS Trust, ethical and regulatory submissions, approvals and amendments. No work involving patients, their organs, tissues or data should be permitted by Host Institution or its partners without these approvals being in place.

8. When MRC offers an award, the Host Institution will be asked to sign a declaration that it accepts these responsibilities.

9. MRC's RGF policy and guidance will be reviewed in the light of the approach taken by government to implementing the EU Directive on Good Clinical Practice in Clinical Trials of Medicinal Products.

* For definitions of "Sponsor" see Appendix 1 of the **accompanying Guidance** or refer to the Health Departments' own declaration.

Medical Research Council

Guidance: Applying the Health Departments / NHS *Research Governance Frameworks* to MRC-funded Research in Universities and other non-MRC Institutions

1. This Guidance accompanies MRC's policy statement[1] in relation to MRC grant and fellowship-funded research involving NHS patients, their organs, tissues or data, and which falls within the scope of the UK Health Departments' Research Governance Frameworks.

2. You need to read this Guidance if you are

   - The Head or Senior R&D Administrators of an organisations ("Host Institutions") that has a funding agreement with the MRC, or wishes to– principally Universities but also some NHS Trusts and other organisations.
   - Principal Investigators with MRC grant and fellowship funding
   - Lead applicants preparing new proposals for assessment.

   It may also be of value to R&D policy makers and managers in other organisations with roles under the UK Health Departments' Research Governance Frameworks.

Structure of this Guidance

[1] http://www.mrc.ac.uk/index/funding/funding-clinical_research_governance/funding-mrc_policy.htm

Purpose and Scope of this Guidance

3. This Guidance aims to assist Host Institutions in implementing their responsibilities in relation to MRC awards that fall within the scope of the Health Departments' RGF requirements. It would not be appropriate for this Guidance to give Host Institutions detailed instructions or research management standards by which they should manage their business.

4. The MRC will discharge the duties described in Section 3.8 of the Department of Health's Research Governance Framework for Health & Social Care (2001) in accordance with this Guidance and the detailed provisions set out in the MRC's Terms & Conditions. The Terms & Conditions shall prevail in the event of a conflict between the RGF, Terms & Conditions and this Guidance.

RGF Model

As an RGF Sponsor, MRC is not commissioning the Council's research: it supports the research initiated, proposed and managed by the Host Institution. While "Sponsor" under the RGF is a new concept for non-commercial trials, the responsibilities it entails are not new other than ensuring clarity about the allocation of responsibilities between the research partners. Nor are the responsibilities of organisations that receive funds new. Because the EU Directive on GCP in Trials of Medicinal Products uses a definition of "sponsor more appropriate to commercial trials, the MRC will review its position on accepting sponsorship when the implications of the Directive for UK law are clearer.

5. The RGF defines the roles of Sponsor, Employing Organisation, Principal Investigator etc. (Appendix 1).

6. The MRC's principal relationship as funder and Sponsor is with the Employing Organisation: it this organisation (as the Host Institution) with which MRC has a funding agreement and which is therefore accountable to MRC for the conduct of the research (Figure 1). As Sponsor, the MRC is not specifying or initiating the Council's own Project, nor is it contracting the Host Institution to carry out research on the Council's behalf. In other words, the research is owned by the Host Institution. The MRC's relationship with the Host Institution is more hands off than that of a commercial organisation contracting a clinical research organisation or university to do the company's research[2].

7. Research starts with the Principal Investigator: he/she initiates the Project, identifies research partners and the key competencies required, and takes the lead in allocating and agreeing responsibilities between the Co-investigators and within their own research team. Co-investigators in turn define further sets of relationships and responsibilities. However, it is the Host Institution, that has employment, health and safety and other statutory responsibilities and which is in a position to develop the policies and systems to support effective research management and to enter into agreements with the other parties.

8. The duties of Sponsor are essentially the same as those the Council has exercised as a funder of research prior to the publication of the Frameworks. What is new is the requirement for greater clarity about responsibilities, particularly for managing and monitoring the research.

[2] It has been the practice for MRC to sign agreements with Commercial Organisations providing an Investigational Product to a clinical trial. However, under the RGF, it is not appropriate for MRC to take responsibility for aspects of the trial that are outside its control.

9. The EU Directive on *Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use* takes a much broader definition of "sponsor" and in the developing EC Guidance sets out duties which go significantly beyond those which MRC accepts under the RGF. The EU Directive definition of sponsor is more appropriate to commercial trials than non-commercial ones. MRC will review its position as a "sponsor" (RGF and EU Directive) once the implications of the Directive for UK law and the RGF have been clarified.

Principles

The RGF provides a valuable framework for ensuring that research in the NHS is of high quality and that risks are identified and managed effectively. In implementing the RGF, the policies and systems must be proportionate and appropriate. Responsibilities are best allocated in a way that reflects who is best placed to exercise those responsibilities.

10. In implementing the RGF Sponsorship role, the MRC is guided by the following principles

- The aim of the RGF is to ensure that research is of high quality and that risks, in particular to participants, are effectively identified and managed.
- The parties must allocate responsibilities between them in a way that reflects which person or organisation is best placed to exercise them (or is required by law or regulation to do so) than it is for the parties to stick rigidly to the allocation in RGF document. The RGF does not have the force of law.
- In setting out its policy and the requirements of Host Institutions, MRC is not seeking to delegate functions for which MRC is best placed to take responsibility. By the same token, it would be inappropriate for MRC to accept responsibility for activities that are best managed by others or that they are required by law to undertake.
- Quality and risk management systems must be appropriate and proportionate and should not divert effort disproportionately from enabling and doing the research. It is sensible to give priority to controlling those activities that have a direct effect on patient health, safety and well-being, and where "grey-areas" of responsibility are possible.
- Effective quality assurance systems promote an aware, thinking, communicating and responsive culture that values quality, respect and learning. They do not focus exclusively on misconduct and fraud.
- The organisation receiving MRC funding must work closely with the partner NHS trust's(s') R&D office(s) from the outset, before a proposal is even submitted for peer review.

11. While there are small differences in the RGF documents produced by the different UK Health Departments, the purpose and principles are identical. Arrangements that meet the requirements of one of the national Frameworks should be accepted as meeting the requirements of the others.

12. While this Guidance is specific to the RGF, the principles and many of the responsibilities are just as valid in research involving human participants not in the health and social care organisations (e.g. psychological research with volunteers).

Fulfilling MRC's Sponsorship Role

MRC fulfils its RGF responsibilities primarily through peer review of research proposals to assess quality, strategic merit and risks; developing and promoting codes of research ethics and best practice; receiving assurances from Host Institutions that they can fulfil MRC Terms and Conditions[3] and - as appropriate to the risks to be managed - monitoring through

[3] http://www.mrc.ac.uk/index/funding/funding-terms_and_conditions.htm

steering groups and reviews. None of these remove from the Host Institution and others their responsibilities to manage and monitor work on the ground.

Quality

13. As Sponsor, MRC provides quality assurance in relation to research proposals through a prior (*ex ante*) peer assessment of the importance of the research question and the likely impact of the proposed research on health and wealth; the design and methodology; deliverability; value for money; and safety and well-being of the participants (patients and human volunteers).

Strategic Merit

14. Through the mechanisms provided by the Concordat between the Health Departments and the MRC, the Council provides an assurance of the strategic relevance of MRC-sponsored research to the Health Departments and the NHS.

Standards

15. MRC also provides and promotes a set of research Ethics and Good Practice standards[4] to guide their execution. In implementing these standards, the Host Institution and Partner Organisations need to make judgements about how best to assure quality and minimise risks. Many of the principles of MRC *Good Clinical Practice in Clinical Trials* are also valid for non-trials research involving human participants.

Risks

16. MRC peer review involves a consideration of risks, in particular to the following

- ethical failure: harm to participants
- failure of feasibility and deliverability: e.g. inappropriate methodology; inadequate research capability or capacity; poor planning.
- value for money: e.g. not addressing the most important question, leading to low impact or otherwise poor value for users of research; unrealistic targets for recruitment of clinical centres and participants, leading to a likelihood of cost over-runs.
- reputational failure: potential harm to the reputation of medical research generally and of the MRC in particular; damage to strategic partnerships.

17. When they sign MRC's Terms & Conditions, Host Institutions provide an assurance to MRC that they are able to manage and monitoring the research. Many Projects require no additional external, monitoring by MRC. Where MRC identifies potential risks, it has a variety of means for monitoring and managing that risk. For instance,

- randomised clinical trials: Principal Investigators and their Host Institutions are required to establish Trial Steering Committees with independent members, which report to the Principal Investigator, the Host Institution and the MRC
- for some non-trials studies, MRC may deploy supervisory and steering committees, reviews or audit.

18. These mechanisms do not remove from the Host Institution, its Partner Organisations or the investigators their responsibilities for monitoring and managing quality and risks in the work that they undertake or supervise.

[4] http://www.mrc.ac.uk/index/publications/publications-ethics_and_best_practice.htm

The Scope of MRC Sponsorship

MRC normally accepts RGF Sponsor's responsibilities in relation to all Projects that it has assessed and where funding agreements and Terms & Conditions are in place. This generally includes clinical elements of MRC Programme grants but excludes Studentships and other "block grant" awards.

19. The Council expects to be the RGF Sponsor for any Project involving human participants, their organs, tissues or data for which MRC has

    - assessed the quality of the research proposed and the risks[5] to the Council; and
    - entered into a funding agreement with a Host Institution and is also the lead funder[6]; and
    - received the appropriate assurances from the Host Institution that it is willing and able to undertake its responsibilities under MRC Terms & Conditions.

20. The MRC is the Sponsor of Projects directly funded by the Council in its establishments (for which parallel Guidance has been developed).

21. Exceptionally, the Council may agree to act as Sponsor on behalf of another funder[7].

22. Sponsorship normally includes future clinical research outlined within larger (sometimes non-clinical) programmes such as MRC Programme Grants, the details of which can be developed only on the completion of the earlier stages of the programme. This is an area where an element of trust is appropriate. Nevertheless, investigators should make a clear case for the future clinical studies and demonstrate that they have the capability and capacity to develop the details and carry out the kind of work envisaged in the proposal for funding, so that they can be assessed. In some cases MRC may decide that the uncertainty and potential risks involved are such that detailed proposals for the clinical work need to be assessed at some specified point during the course of the programme[8].

23. MRC does not routinely accept the role of sponsor for the following:

    - Projects for which MRC is not the majority funder[9]
    - Projects that have met MRC quality standards but which the Council has been unable to fund[10]
    - Studentships or other awards made on a "block grant" basis, for which the Host Institution - and not the MRC - assesses the quality and risks of an individual Project. The assumption is that the Host Institution is best placed to act as Sponsor or to negotiate the appropriate sponsorship arrangements with a Partner Organisation – such as the relevant NHS Trust in the case of clinical fellowships and where the Trust is willing and able to accept the responsibilities of sponsorship.

5 See previous section - Risks.

6 Lead funder in terms of the direct marginal costs of the research (i.e. *excluding* NHS Support for Science, Excess Treatment Costs; the overhead paid on grants; and the buildings, services and other infrastructure)

7 An example could be a project (a) funded largely by a UK charity or foundation, or an overseas governmental funder such as the US National Institutes for Health, operating to standards at least equivalent to those of MRC, and (b) in which MRC had a significant stake.

8 Inevitably there is potentially a grey area between embedded clinical work outlined in a programme and "new" work. If in doubt, Principal Investigators and the Host Institution should seek an interpretation from their MRC Programme Manager. Assessment of the detailed work may be warranted if new and significant risks are evident and which were unforeseen in the original proposal.

9 In the exceptional cases, MRC will wish to have a specific agreement with the other funder(s).

10 Often referred to as an "alpha unfunded" proposal.

The Duration of MRC Sponsorship

MRC sponsorship is limited to the period of approved funding. MRC must approve any extension of sponsorship to cover further work involving the NHS including long term follow-up. .

24. MRC sponsorship is limited to the period of the funding agreement. It does not automatically extend to research beyond the end of the funding agreement.

25. The kind of extended work that must have an RGF Sponsor includes further contact with patients, e.g. clinical examinations; questionnaire-based follow-up; new tests on the organs, tissues; new data collection – including long term accrual and analysis of mortality or other outcomes data from the Office of National Statistics. As a rule of thumb, if the work requires ethical approval it must also have a sponsor[11]. RGF sponsorship is needed even if the intention is that the research be unfunded.

26. The Principal Investigator is responsible for obtaining either an extension of MRC sponsorship or approval from another organisation that it is willing to accept the sponsorship responsibilities for the extended research.

27. If the extended work has MRC sponsorship, it must comply with the requirements set out elsewhere in this Guidance.

28. For randomised controlled trials (RCTs), the duration of the trial is determined by the MRC on the advice of the independently chaired Trial Steering Committee, taking account of the views of the independent members, the Investigators, the views of the MRC Boards and Council, and in consultation with the Host Institution. The TSC itself is usually advised by a Data Monitoring & Ethics Committee[12].

New Work and Protocol Modifications

MRC sponsorship is specific to a Project and does not extend to new investigations. Significant modifications required by ethics or regulatory authorities must be reported to MRC.

29. MRC sponsorship is specific to a Project and does not extend to *new* studies[13] of patients, their tissues, organs or data, i.e. work outside the MRC-approved research proposal. This may pose challenges where investigators are used to initiating new work under the umbrella of existing funding. From April 2004 (revised by DH from April 2003), the work must have an RGF Sponsor if it involves Participants in the NHS. It is worth noting that new work on tissues and data "banked" outside the NHS will require not only new sponsorship and ethics committee approval but also the approval of the NHS trusts involved in the original study even if trust staff and premises are not involved in the new work: this is because the new work may still have implications for their patients.

30. Sponsorship of new work can be obtained through

    - approval of a distinct new MRC Project
    - an MRC-approved amendment to the relevant existing MRC Project[14]
    - another organisation accepting the Sponsor's responsibilities for the new work.

11 After termination of the award, sponsorship is not required for the work to publish and otherwise disseminate research findings, for quality control, or any other activities where there is no element of research on Participants, their organs, tissues or data.

12 See the MRC *Good Clinical Practice in Clinical Trials* Guidelines for details.

13 Sometimes termed "sub-studies," "bolt-on projects," "follow-on studies" or "pilot studies."

14 MRC does not supplement or extend funding except under limited circumstances specified in the Terms & Conditions.

31. After MRC has made an award, Research Ethics Committees or regulatory authorities may require modifications. The Host Institution must be assured that it or a Partner Organisation has an effective system for documenting these modifications[15]. MRC must be informed when a change is likely to impact significantly on

    - the balance of likely benefits and harm to the Participants
    - the MRC-approved objectives of the Project
    - the progress, quality of the research and its outcomes
    - the costs to MRC.

32. Oversight committees (such as Trial Steering Committees) must be kept informed of the requirements of regulatory and ethical authorities.

33. Otherwise, these kinds of amendment (Paragraphs 31 & 32) do not need to be reported to MRC Head Office.

Use of MRC's Name

34. MRC's name may be used in the form "The MRC-*sponsored* study of..." in association with an award to a university or other non-MRC institution to acknowledge RGF sponsorship as described in this Guidance. The wording "The MRC trial of..." (omitting "sponsored") may be used *only* when a trial is initiated and managed under the direction of an MRC establishment[16].

The Host Institution's Lead Role in Managing & Monitoring Projects

The Host Institution is accountable to the MRC for the management of the Project. It must take the lead in ensuring that the agreements necessary for good day-to-day management and monitoring are in place, and must have documented systems and policies in respect of its responsibilities. If a Project fails to progress, the Host Institution and MRC need to work together, and with the Investigators (and any steering committee), to develop a solution. MRC will not accept financial responsibility for delays due to staff changes or failure by the Host Institution to put in place management and monitoring arrangements.

35. The Host Institution is accountable to the MRC as Sponsor for the ongoing management the Project in accordance with MRC Terms & Conditions and consistently with the RGF. In signing proposals for funding, the Host Institution in effect declares that it is a fit organisation to manage the conduct the research. In its own directly funded establishments, MRC manages and monitors projects taking place by virtue of being the Employing Organisation.

36. At a Project-specific level, MRC requires the Host Institution to ensure that the key responsibilities of the Principal Investigator, Co-Investigators and Lead Site Investigators are documented[17]. The Project protocol approved by the Research Ethics Committee may be a suitable vehicle for this[18].

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15 In practice, this responsibility is usually accepted by a Co-ordinating Centre or lead NHS Trust.

16 "MRC Trial of..." would also be appropriate were MRC, exceptionally, to commission a trial.

17 Much of the work of a clinical Project will take place within a Care Organisation. For instance, the consenting process and physical checking of consent forms can take place only within the Care Organisation; and that it is appropriate for those responsibilities to be allocated to the Care Organisation by agreement. The same will be true for other aspects of the work.

18 The research proposal submitted to MRC may also contain the information required by the Host Institution, but the roles set out in it may need to be reviewed following the MRC decision and feedback. Ethics Committee documentation is usually more up-to-date than the research proposal itself.

37. The Host Institution must take the lead in ensuring the necessary agreements are in place with the Partner Organisations, particularly with the Care Organisations and any Commercial (or other) Organisations supplying Interventional Products, through appropriate Project-specific or generic framework agreements. MRC expects that each of the organisations involved has documented policies and systems in place to discharge its own responsibilities.

38. Work is in hand under the auspices of the Department of Health's NHS/University Partnership Group to define a generic *Model Agreement for Research*. This is likely to be a valuable source of good practice and consistent MRC's requirements of Host Institutions. A checklist for Host Institutions based on the model agreement is at Appendix 2.

39. In relation to individual projects, good practice requires that the Host Institution brings other parties - particularly the NHS Trusts[19]. - into the picture at the earliest sensible opportunity – (Figure 2).

40. The Host Institution must take care that agreements it enters into with Partner Organisations do not conflict with MRC Terms & Conditions or the RGF. Particular care needs to be taken in writing agreements with Commercial Organisations to supply interventional products to the Project: MRC's Terms & Conditions set out new MRC requirements in this area. Where other agreements do conflict, MRC may treat them as breaching MRC Terms & Conditions.

41. MRC *Good Clinical Practice in Clinical Trials* identifies the Principal Investigator as responsible for ensuring that serious adverse events are notified to the MRC and to the ethics and regulatory authorities. The Host Organisation needs to assure itself that sound research and project management systems are in place to do this[20].

42. Project do sometimes fail to progress. When this happens the Host Institution and MRC have a responsibility to alert each other and to work together, and with the Investigators (and any steering committee), to develop a solution. MRC will not accept financial responsibility for delays due to staff changes or failure by the Host Institution to put in place management and monitoring arrangements. MRC will take responsibility where the scientific assumptions tested through peer review were inaccurate or have changed.

Documenting Ethical and Regulatory Approvals

43. While MRC has a responsibility to consider whether proposed research is ethical, the detailed ethics assessment is made by the RECs. MRC holds the Host Institution responsible for ensuring that work which requires regulatory or ethical project is not undertaken without that approval. Consequently,

    - MRC no longer routinely requires copies of Ethics Committee or regulatory submissions and approvals to be sent routinely to MRC Head Office. However, documentation must be produced to MRC promptly if requested.
    - As part of MRC's Terms & Conditions, a Host Institution must systematically document submissions and approvals, or it must make the necessary arrangements with its Partner Organisation(s) to do this.
    - The Project must also have documented NHS trust approval before any work starts that involves the NHS.

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19 NHS Trusts commonly complain that they are not consulted at an early enough stage to enable efficient planning and provision of NHS support for the research.

20 UK drug trials will need to be compliant with the EU Directive on Good Clinical Practice in Trials of Medicinal Products, which will define roles and responsibilities, including for reporting serious adverse events.

- Approval is not required to be in place at the time of *submitting* a proposal to MRC or at the time MRC makes a *funding decision* but must be in place before the project commences.

MRC Policy on Warranties, Indemnities and Insurance

44. Government policy requires that MRC does not use indemnities to define boundaries between its liability and that of other public bodies, as exchanging indemnities in this way is in its view wasteful. Instead, it concentrates on ensuring roles and responsibilities for Projects are well defined.

45. The Host Institution must ensure that appropriate warranties and indemnities from Commercial and overseas Partner Organisations are in place to protect itself and the MRC from liability in relation to manufacture, formulation, packaging and supply of investigational products[21].

46. As a public sector organisation, the MRC acts as its own insurer. Host Institutions and Partner Organisations will need to determine whether they need to make provision for insurance in managing their risks.

47. The Host Institution will need to determine whether it or its Partner Organisations should make provision for claims of non-negligent harm.

48. In the event of a claim of negligence, or of non-negligent harm, the organisation receiving the claim must as a matter of good practice notify the other organisations with responsibilities for the research, including the re MRC. They must also consult each other about management of any claim.

Implementation: Putting the Research Governance Framework into Effect

Revision of MRC Terms & Conditions

49. MRC's Terms & Conditions are currently being revised to clarify responsibilities and ensure they are consistent with the RGF and this Guidance. They will be posted on the MRC Website by the end of November. We will also notify existing Host Institutions directly that they are required to familiarise themselves with the new version.

A New Award Acceptance Letter

50. For new awards, the Host Institution and the Lead Applicant / Principal Investigator will be required to sign a new Award Acceptance Letter. This will be accompanied by a Host Institution declaration to give MRC an assurance that the organisation accepts its responsibilities to manage and monitor the research, and ensure agreements are put in place with Partner Organisations (draft at Appendix 3).

Compliance with Good Practice and other Aspects of the RGF

51. **Existing Requirements** MRC requires Host Institutions and investigators to be able to demonstrate a high degree of compliance with well established good practice guidance.

52. **By March 2004** where inter-institutional RGF policies and agreements are not yet in place, MRC requires Host Institutions to develop and work to a compliance plan, with improvement priorities based on an assessment of the risks. The target dates for implementation must be consistent with the Health Departments' RGF implementation

[21] In practice, making the arrangements may best be delegated to another organisation. For instance, a lead site or Co-ordinating Centre may be better placed and may accept responsibility for arranging the indemnity for all sites.

timetable, i.e. March 2004, "unless there are well-documented reasons for a longer timetable."

53. MRC recognises that work has still to be done by government and the NHS to bring primary care trusts and social care providers into the RGF.

54. MRC is developing its approach to auditing MRC sponsored clinical research (including but not confined to clinical trials). The aim is to work with and to help all parties concerned to ensure that these studies are safe, ethical, of continued high quality and that risks are appropriately managed. These RGF/Good Practice audits are additional to the MRC's dipstick audits of financial and administrative systems (in Host Institutions).

55. If MRC identifies significant risks to MRC's ability to discharge its responsibilities, it will discuss the implications with the Host Institution and reserves the right to withdraw its Sponsorship and funding.

Status of this Guidance

56. This Guidance has been developed through discussions with the Department of Health, other funders and sponsors of research and R&D administrators. Amendments will be made in the light of feedback from the research community, consumers and other MRC partners. The policy will be reviewed (1) following further feedback on this Guidance; and (2) once the implications of UK law to put the EU Directive on Good Clinical Practice in Clinical Trials of Medicinal Products are clear.

Contacts

57. If you have comments or questions about the MRC's approach to implementing the Research Governance Framework, you are encouraged to contact one of the following:

Policy

- Peter Dukes & Rachel Williams (RGF policy lead; relations with the NHS; RGF audit; advice to MRC Institutes, Units and Teams)

Specific areas

- Jerry Folkson & Olivia Ramsbottom (Grants and Personal Awards – Terms & Conditions; Awards process)
- Joe McNamara (Clinical Trials; trials audits)
- Imogen Evans / Joan Box (other Clinical Research).