

**ABPI (ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY):**

The trade association for about a hundred companies in the UK producing prescription medicines. See <http://www.abpi.org.uk>

**ACADEMY OF MEDICAL SCIENCES REPORT:** Over the past decade, the Royal Society has taken a particular interest in the science associated with transmissible spongiform encephalopathy (TSE) diseases, which all appear to involve abnormal isoforms of prion related protein. An urgent study is required into the theoretical risk of abattoir premises and equipment being contaminated with BSE, according to a this report. See [http://www.acmedsci.ac.uk/n\\_tse.htm](http://www.acmedsci.ac.uk/n_tse.htm)

**ADVERSE EVENT:** An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

**AMRC (ASSOCIATION OF MEDICAL RESEARCH CHARITIES):** The AMRC works to advance medical research in the UK. Its activities focus upon improving the effectiveness of the charitable sector in medical research. See <http://www.amrc.org.uk>

**“BEST RESEARCH FOR BEST HEALTH”:** *Best Research for Best Health* is the Government R&D Strategy which was launched in January 2006 and was developed with input and support from other government departments and by talking with and formally consulting our many and diverse stakeholders. The strategy is designed to tackle the challenges that were collectively identified and to put in place the changes that are essential to creating a health research system where the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public. Full details are available here: [http://www.dh.gov.uk/en/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentStrategy/DH\\_4127109](http://www.dh.gov.uk/en/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentStrategy/DH_4127109)

**BIGT REPORT (BIOSCIENCE INNOVATION AND GROWTH TEAM):** The task of the Bioscience Innovation and Growth Team has been to identify any barriers that could significantly hold back the growth of bioscience in the UK. Recommendations were made as to how these obstacles could be overcome and the recommendations will help influence the future shape of Government policy. See <http://www.dti.gov.uk/bio-igt/overview.html>

**BIOMEDICAL RESEARCH CENTRES:** Biomedical Research Centres will drive innovation in the prevention, diagnosis and treatment of ill-health and to translate advances in biomedical research into NHS practice. Eleven Biomedical Research Centres have been established within leading NHS and University partnerships to drive progress on innovation and translational research in biomedicine. They are in Cambridge, London, Oxford, Newcastle and Liverpool. Full details at [http://www.nihr.ac.uk/infrastructure\\_biomedical\\_research\\_centres.aspx](http://www.nihr.ac.uk/infrastructure_biomedical_research_centres.aspx)

**CALDICOTT GUARDIAN:** Caldicott Guardians are responsible for agreeing and reviewing internal protocols governing the protection and use of patient-identifiable information by the staff of their organisations.

**CANCER RESEARCH NETWORKS:** The NCRN has increased involvement and recruitment into trials through the creation of 34 regional Cancer Research Networks across England, closely aligned to cancer service networks. NCRN funding is allocated to networks to appoint research staff, such as research nurses, data managers and medical staff sessions and to access pharmacy, pathology, radiology and other areas of support, such as information systems and training, all of which are integral to high quality research. Each network is required to appoint a clinical and administrative lead (Clinical Lead for Research and Research Network Manager) with responsibility for the overall leadership and management of the local networks. For a map of the English Cancer Research Networks see <http://www.ncrn.org.uk/networks/index.asp>

**CANCER RESEARCH UK:** Cancer Research UK is the largest volunteer-funded cancer research organisation in the world. Cancer Research UK began operating in 2002 as a result of the merger between The Cancer Research Campaign and Imperial Cancer Research Fund. Cancer Research UK supports and

undertakes a comprehensive programme of research in institutes, hospitals, universities and medical schools throughout Britain and Northern Ireland. See <http://www.cancerresearchuk.org>

**CANCER SERVICE NETWORKS:** Cancer Service Networks are the organisational model for cancer services to implement the Cancer Plan with responsibility to develop an annual Strategic Service Delivery Plan, which is underpinned by workforce, education & training and facilities strategies. The objectives of the Network are to ensure that all commissioners and providers of cancer care, the voluntary sector and local authorities within the network work effectively together to deliver high quality care.

**CDISC (CLINICAL DATA INTERCHANGE STANDARDS FORUM):** CDISC is an open, multi-disciplinary, non-profit organisation committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. CDISC has developed a comprehensive glossary of terms relating to clinical trials. This is available via <http://www.cdisc.org/glossary/Glossary-October2002.pdf>

**COCHRANE REVIEWS:** Cochrane Reviews investigate the effects of interventions for prevention, treatment and rehabilitation in a healthcare setting. They are designed to facilitate the choices that doctors, patients,

policy makers, and others face in health care. Most Cochrane Reviews are based on randomised controlled trials, but other types of evidence may also be taken into account, if appropriate. The Cochrane Library can be accessed electronically: <http://www.update-software.com/publications/cochrane/>

**COMPREHENSIVE RESEARCH NETWORK (CRN):** The NIHR Comprehensive Research Network (CRN) was created as part of the government's research and development strategy, "Best Research for Best Health" to provide a world-class infrastructure for clinical trials in all areas of disease and clinical need within the NHS.

The aims of CRN are:

- To ensure that patients and healthcare professionals from all parts of the country and from all areas of healthcare can take part in and benefit from clinical research
- To improve the quality, speed and coordination of clinical research by removing the barriers to research within the NHS
- To streamline and performance manage NHS support for clinical studies to ensure that the costs of research are met in a timely and efficient manner
- To unify and streamline administrative procedures associated with regulation, governance, reporting and approvals
- To strengthen research collaboration with industry and ensure that the NHS can meet the health research needs of industry
- To further integrate health research and patient care.

In order to achieve these aims, CRN will:

- Establish and fund an excellent clinical research infrastructure to support a high quality portfolio of clinical research studies and facilitate patient participation into studies
- Provide those NHS Service Support Costs which were previously provided through other NHS R&D funding streams
- Provide and deploy resources for research management in order to ensure that the research portfolio is delivered to the highest standards of research governance.

CRN consists of a number of Comprehensive Local Research Networks (CLRNs) which will be managed locally and will support participation in the national portfolio of UKCRN studies.

**COMPREHENSIVE LOCAL RESEARCH NETWORKS (CLRNs):** 25 CLRNs have been established covering the whole of England. CLRNs are the primary vehicle for providing infrastructure to support study involvement. They will encourage participation in the range of high quality clinical studies in the UKCRN portfolio and will provide a coordinated and efficient infrastructure of research personnel and facilities to support recruitment. A map of the CLRNs is available at <http://www.ukcrn.org.uk/index/networks/comprehensive/map.html>

**CONSENT FORM:** This form must be completed for every individual who enters a clinical trial. Guidelines on the design and content of consent forms are provided on the NRES website [http://www.nres.npsa.nhs.uk/docs/guidance/Info\\_sheet\\_and\\_consent\\_form\\_guidance.pdf](http://www.nres.npsa.nhs.uk/docs/guidance/Info_sheet_and_consent_form_guidance.pdf)

**CRD (CENTRE FOR REVIEWS AND DISSEMINATION):** The CRD was established in January 1994 at the University of York to provide the NHS with information relating to the effectiveness of treatments and the delivery and organisation of health care. CRD helps to promote research based practice in the NHS by offering rigorous and systematic reviews on selected topics; a database of good quality reviews; and a dissemination and an information service. See <http://www.york.ac.uk/inst/crd/>

**CTRU (CLINICAL TRIALS RESEARCH UNIT):** The Clinical Trials Research Unit at the University of Leeds is a leader in the field of clinical trials. The Unit conducts national and international randomised clinical trials in a variety of clinical fields (cancer, women and child health, cardiovascular disease, care of the elderly, mental health) and has an associated research portfolio. CTRU is one of the NCRI Accredited Trials Units. See <http://www.ctruleeds.co.uk/>

**CTU (CLINICAL TRIALS UNIT):** CTUs undertake and manage clinical trials in a wide range of disease areas. There are currently 9 CTUs which are accredited by the NCRI. These include:

- Cancer Research UK CTU Birmingham
- MRC CTU London
- UKCCSG Leicester
- CTRU Leeds
- Cancer Research UK & UCL CTC London
- ICR-CTSU Surrey
- WCTN Wales in collaboration with MRC CTU
- CACTUS Scotland
- BRTC Bristol, with a specific remit to work with the new NCRI Clinical Studies Development Groups

**DECLARATION OF HELSINKI:** The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data. It was first adopted by the 18th WMA General Assembly in Helsinki, Finland, June 1964. It has since been amended 5 times at a succession of WMA General Assembly meetings, the latest of which the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000. Also there have been two notes of clarification provided since 2000. See <http://www.wma.net/>

**DEMENTIAS AND NEURODEGENERATIVE DISEASES RESEARCH NETWORK (DeNDroN):** The Dementias and Neurodegenerative Diseases Research Network supports research in the field of dementia and neurodegenerative, covering major diseases including Alzheimer's, motor neurone disease, Parkinson's and Huntington's disease. Seven Local Research Networks support work in this area. <http://www.dendron.org.uk>

**DEPARTMENT OF HEALTH (DH):** The aim of the Department of Health (DH) is to improve the health and wellbeing of people in England. The website contains information, publications and links to other health related information sources: <http://www.dh.gov.uk/Home/fs/en>

**DIABETES RESEARCH NETWORK (DRN):** The primary goal of the Diabetes Research Network is to achieve benefits for people with diabetes, or those at risk of developing diabetes, through excellence in clinical research. Eight Local Research Networks support work in this area. [www.ukdrn.org](http://www.ukdrn.org)

**EU DIRECTIVE FOR CLINICAL TRIALS:** The final version of this was published in the *Official Journal of the European Communities* on 1 May 2001. The UK Regulations were implemented on 1 May 2004. In the UK the requirements of this Directive are implemented with the UK Medicines for Human Use Regulations 2004. The Directive covers the conduct of all clinical trials in the EU on human subjects involving medicinal products (as defined in Article 1 of Directive 65/65/EEC). See <http://medicines.mhra.gov.uk/ourwork/licensingmeds/types/clintrialdir.htm>

**EUDRACT: (THE EUROPEAN CLINICAL TRIALS DATABASE):** EUDRACT is designed to be a register of all clinical trials in the Community, information on the content, commencement and termination of the clinical trials and on inspections. See [http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2003/april/cp-guidance-eudract\\_230403.pdf](http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2003/april/cp-guidance-eudract_230403.pdf) (Note: This database is not publicly available)

**EUDRAVIGILANCE:** EudraVigilance is the European data-processing network and database management system for the exchange, processing and evaluation of Individual Case Safety Reports (ICSRs) related to medicinal products authorised in the European Economic Area (EEA). See <http://www.eudravigilance.org/>

**EXCESS TREATMENT COSTS:** Excess Treatment Costs are the difference between the Treatment Costs, incurred as a result of a particular piece of Research and Development, and those that would have been incurred had the patients concerned been receiving the standard alternative service. By definition, Excess Treatment Costs only arise where experimental services are being provided, or where standard care is being provided in a different way or location to routine practice.

**EXPERIMENTAL MEDICINE (EM):** Experimental Medicine incorporates a variety of research activity and hence is very difficult to define in specific terms. It can be considered as early clinical agent studies in humans, especially Phase I trials, trials to validate effects of an agent on the intended target, including attempts to image the target effect, pharmacokinetics and pharmacodynamics, etc. It can also be considered to incorporate correlative research that employs specimens and clinical data, often from later or larger trials, to investigate predictive or prognostic biomarkers (genomic, proteomic, metabolomic, etc.) to develop and test hypotheses as well as to feedback to preclinical scientists who can refine the agents being developed. The UKCRC partners recognise the need to enhance the national capacity for experimental medicine by developing a national framework of clinical research facilities. The major funders are working on providing an infrastructure to create a broadly based framework to underpin experimental medicine. Part of this initiative has included an expansion of existing Wellcome Trust Clinical Research Facilities in partnership with the Health Departments and other funders. Further information at:  
<http://www.ukcrc.org/activities/infrastructureinthenhs/experimentalmedicine.aspx>

**FDA (FOOD AND DRUG ADMINISTRATION USA):** FDA is the federal agency within the USA responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA also ensures that these products are honestly, accurately and informatively represented to the public see <http://www.fda.gov/>

**GMP (GOOD MANUFACTURING PRACTICE):** GMP refers to principles and specifications for good manufacturing of medicinal products that are set by the Federal Therapeutic Goods Administration (FTGA), in accordance with international standards (known as Codes of GMP). These are the standards manufacturers must comply with to provide safe and reliable products for consumers.

**NIHR HTA (NATIONAL INSTITUTE FOR HEALTH RESEARCH HEALTH TECHNOLOGY ASSESSMENT PROGRAMME):** HTA is one of the three main national programmes funded under the National Institute for Health Research, the others being New and Emerging Applications of Technology (NEAT) and Service Delivery and Organisation (SDO). The purpose of the HTA programme is to ensure that high quality research information on the cost, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. "Health technologies" include all devices, equipment, drugs and procedures across all sectors of healthcare and is not confined to new drugs or pieces of sophisticated equipment. See <http://www.ncchta.org/>

**HUMAN TISSUE AUTHORITY (HTA):** The Human Tissue Authority has replaced the Retained Organs Commission. The Authority has oversight of the use of human tissue for a widely drafted series of purposes including anatomical examination, education and training relating to human health and research, research and transplantation. As such it will subsume HM Inspectorate of Anatomy and ULTRA. Any person carrying out any of the activities specified in the act must be licensed and there are strict guidelines and procedures governing the use of tissue to be used for donation or research purposes. For more information about the Human Tissue Act and the HTA download the relevant reports from <http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsLibrary/fs/en> or visit <http://www.hta.gov.uk>

**ICH-GOOD CLINICAL PRACTICE (GCP):** International Conference on Harmonization Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that clinical trial data are credible. See <http://www.emea.eu.int/pdfs/human/ich/013595en.pdf>

**INSTITUTE OF CLINICAL RESEARCH (ICR):** The Institute of Clinical Research (formerly ACRPI) has been in existence since 1978. The Institute encourages communication between all its members by supporting the various subcommittees and special interest groups and continues to fulfil its original goal of providing a forum for education and sharing of best practice amongst clinical research professionals. See <http://www.instituteofclinicalresearch.org/>

**INSURANCE INDEMNITY:** Indemnity provides protection against any action by an individual, a group or an organisation that believe they received bad or negligent services, and incurred a loss as a result. Most professional bodies have professional indemnity cover; in some cases it is compulsory. The limit of an indemnity policy relates to the maximum amount of money that an individual or organisation will pay out in the event of a claim being made.

**INVESTIGATIONAL MEDICINAL PRODUCT:** An Investigational Medicinal Product is an active substance or placebo being tested or used as a reference in a clinical trial. It includes licensed medicinal products that are being used either off licence, within the licence but where the study involves assessing the efficacy and/or safety of the product, or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation. See <http://medicines.mhra.gov.uk/ourwork/licensingmeds/types/clintrialdir.htm>

**INVOLVE:** (Formerly Consumers in NHS Research). Involve aims to ensure that consumer involvement in R&D in the NHS, Public Health and Social Care improves the way that research is prioritised, commissioned, undertaken and disseminated. See <http://www.invo.org.uk/>.

**mCTA (MODEL CLINICAL TRIALS AGREEMENT):** The revised model Clinical Trial Agreement (mCTA) is designed to be used without modification for industry-sponsored contract research trials in patients in NHS hospitals throughout the UK. Four versions of the mCTA have been developed to ensure compliance with the law and to reflect regional institutional arrangements across the UK. The accompanying Guidance Notes cover all four versions of the Agreement. Full details at: <http://www.ukcrc.org/activities/regulationandgovernance/modelclinicaltrialagreement.aspx>

**MEDICINE FOR CHILDREN RESEARCH NETWORK (MCRN):** The MCRN aims to facilitate the development of medicines that are both safe and effective in the treatment of children. Six Local Research Networks in England support this work. <http://www.mcrn.org.uk>

**MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004:** The UK Statutory Instrument, which implement the requirements of EU Directive 2001/20/EC for Clinical Trials. It came into force on 1 May 2004. See <http://www.hmso.gov.uk/si/si2004/20041031.htm>

**MENTAL HEALTH RESEARCH NETWORK (MHRN):** The UK MHRN is a network designed to provide a research infrastructure. The network supports vital large-scale research which will help to raise the standard of mental health and social care research throughout England. <http://www.ukmhrn.info>

**META REGISTER:** The *meta* Register of Controlled Trials is a free, searchable, international database of more than 14000 ongoing randomised controlled trials in all areas of healthcare. At present, the *mRCT* also contains some completed trials. See <http://www.controlled-trials.com/>

**MHRA (MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY):** The MHRA is the Executive Agency of the Department of Health protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely. The MHRA was formed from a merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA) on 1 April 2003. See <http://www.mhra.gov.uk/>

**MRC (MEDICAL RESEARCH COUNCIL):** The MRC is a national organisation funded by the UK Government. It promotes research into all areas of medical and related science and is independent in its choice of which research to support, though it does work in close partnership with Health Departments, other Research Councils, industry and others to identify and respond to current and future health needs. See <http://www.mrc.ac.uk/>

**MRC-CTU (MEDICAL RESEARCH COUNCIL CLINICAL TRIALS UNIT):** Formed by the amalgamation of the MRC HIV Clinical Trials Centre and MRC Cancer Trials Office it undertakes trials in a wide range of diseases. While maintaining a portfolio of high-quality research in cancer and HIV trials, it also undertakes research in areas such as rheumatoid arthritis, respiratory disorders, infectious diseases, and haematological disease. MRC CTU is one of the NCRI Accredited CTUs see <http://www.ctu.mrc.ac.uk/>

**NATIONAL INSTITUTE FOR HEALTH RESEARCH (NIHR):** The National Institute for Health Research provides a key mechanism through which the Department of Health will deliver the new R&D strategy set out in 'Best Research for Best Health'. The R&D strategy outlines the direction that NHS research will take to build a vibrant and world-class research environment in England. <http://www.nihr.ac.uk>

**NCRI (NATIONAL CANCER RESEARCH INSTITUTE):** The NCRI represents a formal partnership of the UK's main cancer research funders (Medical Research Council, Cancer Research UK, Leukaemia Research Fund, Department of Health) and offers strategic coordination and leadership for cancer research conducted in the UK. The NCRN has been working closely with the NCRI on a range of common issues that impact on the quality and development of cancer research. See <http://www.ncri.org.uk>

**NCRI CLINICAL STUDIES GROUPS:** The NCRI Clinical Studies Groups are a central component of the new framework for cancer research in the UK, providing the primary route through which new ideas for clinical trials are developed. At present 21 NCRI Clinical Studies Groups exist. 15 of the groups cover specific cancer sites, 5 are generic, a Consumer Liaison Group. The groups are funded by the major cancer charities and the MRC and are UK wide in their remit. They are charged with the development of national cancer clinical trials and the provision of tumour specific or task specific advice and work to a broad, but common, remit. For more information about each of the Clinical Studies Groups, see <http://www.ncrn.org.uk/Csg/index.htm> and select the appropriate page.

**NCRN (NATIONAL CANCER RESEARCH NETWORK):** The NCRN was established by the Department of Health in April 2001 to provide the NHS with an infrastructure to support prospective trials of cancer treatments and other well-designed studies and to integrate and support research undertaken by cancer charities. Its aim is to improve the speed, quality and integration of research, ultimately resulting in improved patient care. The NCRN will increase involvement and recruitment into trials through the creation of 34 cancer research networks across England, closely aligned to cancer service networks. See <http://www.ncrn.org.uk>

**NEAT (NEW AND EMERGING APPLICATIONS OF TECHNOLOGY):** NEAT is one of the three main national programmes funded under the National Institute for Health Research, the others being Health Technology Assessment (HTA) and Service Delivery and Organisation (SDO). NEAT supports work which applies recent advances in fundamental knowledge and technology to the development of new products and interventions for improved health and social care or for disease prevention and treatment. See <http://www.neatprogramme.org.uk/>

**NeLH (NATIONAL ELECTRONIC LIBRARY AFOR HEALTH):** This website is a digital library designed for NHS staff, patients and the public. See <http://www.nelh.nha.uk> The website has a section about how clinical trials work and what people may expect if they are asked to take part in a one. The section was developed with patients and members of the public, and is designed for the people in the UK who might be asked to take part in a clinical trial during the course of their healthcare. This section does not provide information about specific trials. See <http://www.nelh.nhs.uk/clinicaltrials/>

**NESC (NATIONAL ELECTRONIC SCIENCE CENTRE):** e-Science refers to the large scale science that will increasingly be carried out through distributed global collaborations enabled by the Internet. Typically, a feature of such collaborative scientific enterprises is that they will require access to very large data collections, very large scale computing resources and high performance visualisation back to the individual user scientists. <http://www.nesc.ac.uk/index.html>

**NHS PLAN:** Published in July 2000, this report set out the Government's plans for investment and reform across the NHS. It identified cancer services as a high priority to benefit from these improvements. The report can be located and downloaded from <http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsLibrary/fs/en>

**NHS R&D FORUM:** The NHS Research and Development Forum is an organisation for individuals and departments involved in the management and planning of R&D activities and in conducting R&D in health and social care. The purpose of the Forum is to improve the environment for research within organisations delivering health and social care by encouraging high standards and providing support and communication networks. The Forum is an inclusive organisation open to all involved in R&D, including directors, managers, administrators, consumers and researchers themselves. The activities of the Forum encompass research across the full range of health and social care including community and primary care, secondary and tertiary care, public health and social services. See <http://www.rdforum.nhs.uk/>

**NHS RESEARCH GOVERNANCE FRAMEWORK:** The NHS Research Governance Framework (RGF) defines the broad principles of good research governance and is key to ensuring that health and social care research is conducted to high scientific and ethical standards. The publication of the research governance framework is the first stage in a continuing process for promoting improvements in health and social care research across the board. It will help to enhance the contribution of research to the partnership between services and science. It sets standards, details the responsibilities of the key people involved in research,

outlines the delivery systems and describes local and national monitoring systems. The RGF “came into force” on 1 April 2004 but is not actually legislation. See

<http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en>

**NHSC (NATIONAL HORIZON SCANNING CENTRE):** The National Horizon Scanning Centre (NHSC) aims to provide advance notice to the Department of Health in England and Wales of selected key new and emerging health technologies (including changing applications and uses of existing technologies) that might require urgent evaluation, consideration of clinical and cost impact or modification of clinical guidance. See <http://www.publichealth.bham.ac.uk/horizon/>

**NICE (NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE):** NICE was set up as a Special Health Authority for England and Wales on 1 April 1999. It is part of the NHS, and its role is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current “best practice”. The guidance will cover both individual health technologies (including medicines, medical devices, diagnostic techniques, and procedures) and the clinical management of specific conditions. See <http://www.nice.org.uk>

**NIHR SCHOOL FOR PRIMARY CARE RESEARCH:** The School comprises the leading academic centres for primary care research in England and their focus is on research to improve everyday practice in primary care. There is a total fund of £3 million per year available to support clinical trials and other well-designed studies in primary care and at the interface with secondary care. The following five universities are the founding members of the School: Birmingham, Bristol, Cambridge, Manchester and Oxford. Full details at [http://www.nihr.ac.uk/infrastructure\\_primary\\_care\\_research.aspx](http://www.nihr.ac.uk/infrastructure_primary_care_research.aspx)

**NRES (NATIONAL RESEARCH ETHICS SERVICE):** The National Research Ethics Service (NRES) is a directorate within the National Patient Safety Agency and provides help and leadership for Research Ethics Committees by co-ordinating the development of operational and infrastructure arrangements in support of their work. Further details at: <http://www.nres.npsa.nhs.uk/recs/index.htm>

**NUREMBERG CODE:** The Nuremberg Code arose as part of the trial of the United States v. Karl Brandt. Karl Brandt and others were tried at Nuremberg for crimes against humanity committed in their roles as the Nazi high command. The code states that “The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity”. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182.* Washington, D.C.: U.S. Government Printing Office, 1949. There are 10 requirements to the code: see <http://www.med.nus.edu.sg/phar/sgcpp/nuremberg.htm>

**ONCORE UK (NATIONAL CANCER TISSUE RESOURCE):** NTRAC led work on behalf of the NCRI to develop proposals for a National Cancer Tissue Resource (NCTR). The NCTR will facilitate research that advances cancer therapeutics and diagnostics from the laboratory to the clinic and will ultimately provide benefit for UK citizens. This initiative is an important development for cancer research and depends upon the willingness of surgical patients to engage with researchers to combat cancer by donating surplus surgical samples to the national resource. See <http://www.ntrac.org.uk/Initiatives/NCTR/NCTR.aspx>

**OREC MANAGERS (MANAGERS FOR THE OFFICES OF RESEARCH ETHICS COMMITTEES):** OREC Managers have been appointed in eleven English regions. Working with REC Leads in Strategic Health Authorities, they are responsible for leading the organisational development process in their area to ensure that the revised structure and arrangements for Research Ethics Committees are fit for purpose. See <http://www.nres.npsa.nhs.uk/recs/contacts/contacts.htm#orecs>

**ORPHAN DRUGS/STUDIES:** An orphan drug is any drug developed under the 1983 U.S. Orphan Drug Act, which concerns drugs for rare diseases such as those affecting less than 200,000 people in the US. This has been adopted as a subclause of the FDA. Developing a drug for these small groups would be financially

unsound. Therefore, development of drugs for such diseases is rewarded by tax reductions and a monopoly for that drug for a limited time (7 years). See <http://www.fda.gov/orphan/index.htm>

**PCTs (PRIMARY CARE TRUSTS):** PCTs are free-standing, legally-established, statutory NHS bodies that are accountable to their Health Authority. PCTs have responsibility for securing the provision of the fuller range of services for the local populations. They have responsibility for all family health services practitioners allowing a coherent view of the development of all NHS services in the area. PCTs have responsibility for the management, development and integration of all primary care services including medical dental, pharmaceutical and optical. A list of PCTs is available at <http://www.nhs.uk/England/AuthoritiesTrusts/Pct/list.aspx>

**PHARMACOVIGILANCE:** Pharmacovigilance is defined as watchfulness in guarding against danger from drugs or providing for safety of drugs. It can also be a dedicated department whose role is to monitor toxicity and safety of drugs both in the developmental phase and post marketing. A joint MRC/DoH workstream on pharmacovigilance aims to develop workable operating procedures for the publicly funded research community for reporting, monitoring and managing adverse reactions and events that will satisfy the requirements of the Medicines for Human Use (Clinical Trials) Regulations. It is also envisaged that the group will review and make a statement of good practice of use of existing pharmacovigilance systems including Data Monitoring Committees, Drug Information Services and ADR Monitoring Centres. The group will also produce a draft capacity building plan to achieve the requirement for the operating procedures. See <http://www.ncchta.org/eudirective/pharmaco.asp>

**PICTF (PHARMACEUTICAL INDUSTRY COMPETITIVE TASK FORCE):** PICTF brings together the expertise and experience of the industry leaders in the UK with Government policy makers to identify how the competitiveness of the UK business environment for the pharmaceutical industry can be retained and strengthened. The Task Force meets regularly in order to commission specific work from such joint industry-Government working groups that it has established. Representatives of these working groups (senior officials and industry representatives) attend the Task Force meetings, as appropriate, to report on activity and progress. See <http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsLibrary/fs/en>

**PRIMARY CARE RESEARCH NETWORK (PCRN):** The PCRN works closely with the UKCRN topic-specific Clinical Research Networks to support research in primary care. It has as a central objective, the development of the evidence base to inform the prevention, diagnosis, treatment and management of illness and disease in primary care. <http://www.ukcrn.org.uk/index/networks/primarycare.html>

**RESEARCH AND DEVELOPMENT COSTS:** R&D Costs are one of three categories into which the costs of externally funded non-commercial R&D can be divided (the other two are Service Support Costs and Treatment Costs). R&D costs are the costs of the R&D itself and are met by the research funder. They include the costs of data collection and analysis and other activities needed to answer the question being addressed. They can include pay and indirect costs of staff employed to carry out the R&D. For more information see <http://www.dh.gov.uk/Home/fs/en>

**RESEARCH CENTRES FOR PATIENT SAFETY AND SERVICE QUALITY:** Two Research Centres for Patient Safety and Service Quality have been established to drive improvements in the safety, quality and effectiveness of the services the NHS provides to its patients and the public. The Centres will bring together NHS professionals with academic experts from a wide range of backgrounds, including management and the social sciences, to focus on investigating ways to improve the care of patients. Full details at [http://www.nihr.ac.uk/infrastructure\\_research\\_centres\\_for\\_nhs\\_patient\\_safety\\_and\\_service\\_quality.aspx](http://www.nihr.ac.uk/infrastructure_research_centres_for_nhs_patient_safety_and_service_quality.aspx)

**RESEARCH FOR PATIENT BENEFIT WORKING PARTY REPORT:** The Research for Patient Benefit Working Party was set up following the reports of the Biosciences Innovation and Growth Team (BIGT) and the Academy of Medical Sciences (AIMS). Its remit was to bring forward to ministers practical proposals for implementing the recommendations in the two reports. The final report from the working party is available via [http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/PrioritiesForResearch/fs/en?CONTENT\\_ID=4082668&chk=xUzx/B](http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/PrioritiesForResearch/fs/en?CONTENT_ID=4082668&chk=xUzx/B)

**SDO (SERVICE DELIVERY AND ORGANISATION):** SDO is one of the three main national programmes funded as part of the National Institute for Health Research, the others being Health Technology Assessment (HTA) and New and Emerging Applications of Technology (NEAT). The SDO programme has been established to produce and promote the use of research evidence about how organisation and delivery of services can be improved to increase the quality of patient care, ensure better strategic outcomes and contribute to improved health. For more information see <http://www.sdo.lshtm.ac.uk/>

**SERVICE SUPPORT COSTS:** Service Support Costs are one of three categories into which the costs of externally funded non-commercial R&D can be divided (the other two are R&D Costs and Treatment Costs). These costs are the *additional* patient care costs associated with the research, which would end once the R&D activity in question had stopped, even if the same patient care service continued to be provided. For more information see <http://www.dh.gov.uk/Home/fs/en>

**SPONSOR:** The concept of a “Sponsor” for a clinical trial was introduced by the EU Clinical Trials Directive (2001/20/EC) and was adopted into the Department of Health’s Research Governance Framework for Health and Social Care for all clinical research. The definition of Sponsor for trials of investigational medicinal products (IMPs) is the individual, organisation or group of organisations/individuals that take responsibility for the initiation, management and financing (or arranging financing) for the study. Sponsors of trials involving IMPs have specific legal responsibilities as specified in the EU Clinical Trials Directive and the UK’s Medicines for Human Use (Clinical Trials) Regulations 2004. For all other studies, (i.e. research that falls within the scope of the Research Governance Framework but that is not a trial of an IMP), the definition of sponsor is the individual, organisation or group of organisations/individuals that takes the lead in confirming that there are proper arrangements in place for the initiation, management, monitoring and financing of a study. There is more information about the responsibilities of Sponsor on the Department of Health website: <http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en>

**STRATEGIC HEALTH AUTHORITIES (SHAs):** From July 2006 there are 10 SHAs across England. Strategic Health Authorities manage the NHS locally and are a key link between the Department of Health and the NHS. They hold all local NHS organisations (apart from NHS Foundation Trusts) to account for performance. Details at <http://www.nhs.uk/England/AuthoritiesTrusts/Sha/list.aspx>

**STROKE RESEARCH NETWORK (SRN):** The aim of the SRN is to facilitate stroke research by bringing about focused, effective investment to enhance NHS research infrastructure for stroke. Eight Local Research Networks in England support this work. <http://www.uksrn.ac.uk>

**SUSAR (SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION):** All adverse events that are suspected to be related to an investigational medicinal product and that are both unexpected and serious are considered to be SUSARs. For more information see <http://eudract.emea.eu.int/docs/Detailed%20guidance%20SUSAR.pdf>

**TREATMENT COSTS:** Treatment Costs are one of three categories into which the costs of externally funded non-commercial R&D can be divided (the other two are Service Support Costs and R&D Costs). Treatment costs are the patient care costs which would continue to be incurred if the patient care service in question continued to be provided after the R&D activity had stopped. Where patient care is being provided which differs from the normal, standard, treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given) the difference between the total Treatment Costs and the costs of the “standard alternative” (if any) can be termed the *Excess Element of Treatment Costs* (or just “*Excess Treatment Costs*”), but is nonetheless part of the Treatment Cost, not a Service Support or R&D Cost. For more information see <http://www.dh.gov.uk/Home/fs/en>

**UKCRC (UNITED KINGDOM CLINICAL RESEARCH COLLABORATION):** The UK Clinical Research Collaboration (UKCRC) is a partnership of organisations working to establish the UK as a world leader in clinical research, by harnessing the power of the NHS. Its aim is to re-engineer the environment in which clinical research is conducted in the UK, to benefit the public and patients by improving national health and increasing national wealth. UKCRN forms part of the UK Clinical Research Collaboration See <http://www.ukcrc.org>

**UKCRN (UNITED KINGDOM CLINICAL RESEARCH NETWORK):** The UKCRN aims to improve the speed, quality and integration of research with the ultimate aim of improving patient care. The network will initially cover the existing NHS networks in cancer and mental health and new ones in the priority areas of medicines for children. <http://www.ukcrn.org.uk>

**UKTMN (UK TRIAL MANAGERS NETWORK):** The UK Trial Managers’ Network (UKTMN) is a forum for the people who run UK publicly-funded trials. Its primary functions are to link trial managers together to ensure the sharing and dissemination of expertise and experience and to provide training tools developed by the members of the network to new trial managers. <http://www.tmn.ac.uk/>

**WTCRF (WELLCOME TRUST CLINICAL RESEARCH FACILITIES):** Wellcome Trust Clinical Research Facilities are staffed, equipped and run specifically to promote high quality, GCP compliant, studies and

Version 3 – April 2007

novel research activities within an optimal NHS/academic environment. The facilities are located in Manchester, Edinburgh, North West Wessex, Birmingham and Southampton and have been funded by the Wellcome Trust. Additional funding was announced in July 2006 to develop and strengthen clinical research facilities around the UK in Belfast, Birmingham, Cambridge, Edinburgh, the Institute of Cancer Research, Imperial College London, King's College London, Manchester, Newcastle, Oxford and University College London. Further information at <http://www.wellcome.ac.uk/doc%5Fwtd003508.html> and <http://www.ukcrc.org/publications/news/£84millionboostforexperime.aspx>