



Web Resources

This is a list of websites that provide information related to clinical trial research. There are a number of sites relating to the EU Directive but also more general resources. Websites are arranged under the following headings, those marked with a star are particularly useful:

1. EU Directive-implications & implementation.
2. Other related UK Legislation
3. General Information - Clinical Trials
4. General Information - Drug Development & European Union
5. Research Quality
6. Ethics and Informed Consent
7. US Legislation & Regulatory Bodies

[Accessed and correct to 01/06/2009]

1. EU Directive-implications & implementation

www.nres.npsa.nhs.uk ★

National Research Ethics Service (NRES). The organisation responsible for co-ordinating ethics committees in the UK. From this site you may obtain the electronic ethics committee application form and guidance on obtaining ethical approval for all NHS related research, including clinical trials subject to the EU Directive.

<http://www.ct-toolkit.ac.uk/> ★

This is an extremely useful site for guidance on the practical implementation of the EU Directive, particularly for non-commercial research. It provides access to a wide range of relevant documents including forms, guidance documents and related materials. It has been created by the **DOH/MRC joint working groups** that were set up to advise on the implementation of the clinical trials directive.

<http://www.emea.europa.eu/> ★

The European Agency for the Evaluation of Medicinal Products (EMA) – This body was established by Council Regulation EEC 2309/93 of 22 July 1993. It co-ordinates and supports the EU licensing system.

<http://eudract.emea.europa.eu/> ★

This website provides access to the **EudraCT** system where you may apply for a eudraCT number and obtain supporting documentation.

<http://eudravigilance.emea.europa.eu/highres.htm>

This also allows access to the **EudraVigilance** pages.

<http://www.mhra.gov.uk/index.htm> ★

This is the official site of the **Medicines and Health Products Regulatory Agency (MHRA)**. This is the executive agency of the Department of Health, controlling medicines, healthcare products and medical equipment. It was formed from a merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA) on 1 April 2003.

From the home page the quick links box provides access to pages related to the Clinical Trials Directive. These include:

- The text of the EU Clinical Trials Directive & Medicines for Human Use (Clinical Trials) Regulations
- Information about the CTA and Manufacturing Authorisation
- Advice on Responsibilities, Liabilities and Risk Management.
- Adverse event reporting for medicines, medical devices

<http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007544.pdf>

A useful 19-page reference entitled *A Guide to what is a medicinal product* which has been produced by the MHRA to help clarify this sometimes thorny issue.

<http://www.opsi.gov.uk/si/si2004/20041031.htm>

Medicines for Human Use (Clinical Trials) Regulations 2004. The statutory instrument which transposes the EU directive into UK law. This was laid before parliament on 1st April 04

www.opsi.gov.uk/si/si2006/uksi_20061928_en.pdf

2006 No. 1928 Amendment to **Medicines for Human Use (Clinical Trials) Regulations 2004.** The amendment to the Statutory Instrument No. 1031

www.opsi.gov.uk/si/si2006/uksi_20062984_en.pdf

2006 No. 2984 Amendment to **Medicines for Human Use (Clinical Trials) Regulations 2004.** The amendment to the Statutory Instrument No. 1031

www.opsi.gov.uk/si/si2008/pdf/uksi_20080941_en.pdf

2008 No. 941 Amendment to **Medicines for Human Use (Clinical Trials) Regulations 2004.** The amendment to the Statutory Instrument No. 1031

www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf

Text of the **EU clinical trials directive** (2001/20/EC).

europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.pdf

Text of the **EU GCP directive** (2005/28/EC) which clarifies what is required in order to conduct a clinical trial in accordance with Good Clinical Practice.

<http://www.ich.org/cache/compo/276-254-1.html>

Text of the **ICH Good Clinical Practice Guidelines** can be found using the side menus going through Guidelines / Efficacy / Good Clinical Practice

<http://pharmacos.eudra.org/F2/pharmacos/dir200120ec.htm>

EU commission site to access all the **guidance documents** for the implementation of Directive 2001/20/EC.

<http://www.pharmaschool.co.uk/>

Commercial company providing training resources relating to clinical trials. Short, free, GCP quizzes are available on-line. Good self assessment exercise.

<http://www.tmn.ac.uk/>

The UK Trial Managers' Network (UKTMN) is a forum for those running 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.wma.net/e/policy/b3.htm>

The **Declaration of Helsinki**, which was first published in 1964 and has been updated frequently since.

<http://eur-lex.europa.eu/en/index.htm>

Text of the EU clinical trials directive (2001/20/EC) and EU GCP directive (2005/28/EC) can be found in PDF format through the search pages of this site. These documents clarify what is required in order to conduct a clinical trial in accordance with Good Clinical Practice

2. Other related UK Legislation

<http://www.opsi.gov.uk/>

Office of Public Sector Information, which now includes **Her Majesty's Stationery Office (HMSO)** online. This provides access to UK legislation.

http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900023_en_1.htm

Access to Health Records Act, 1990 (c.23)

http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900018_en_1.htm

The Computer Misuse Act, 1990

<http://www.opsi.gov.uk/acts/acts1998/19980029.htm>

The Data Protection Act, 1998

<http://www.opsi.gov.uk/acts/acts1998/19980042.htm>

The Human Rights Act, 1998

<http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm>

The Adults with Incapacity (Scotland) Act 2000. Part 5 deals with medical treatment and research.

<http://www.opsi.gov.uk/acts/acts2000/20000023.htm>

Regulation of Investigatory Powers Act, 2000

<http://www.opsi.gov.uk/legislation/scotland/acts2000/20000011.htm>

Regulation of Investigatory Powers (Scotland) Act, 2000

<http://www.opsi.gov.uk/acts/acts2004/20040030.htm>

Human Tissue Act 2004

<http://www.show.scot.nhs.uk/confidentiality/publications/6074NHSCode.pdf>

NHS Code of Practice on Protecting Patient Confidentiality. Includes guidance on the requirements of the Data Protection Act, patient consent for use of their information and anonymisation.

<http://www.sehd.scot.nhs.uk/cso/>

Scottish Executive Health Department website where the publications section provides a copy of **Research Governance Framework for Health and Community Care**

3. General Information - Clinical Trials

<http://www.actmagazine.com/appliedclinicaltrials/>

Website of the *Applied Clinical Trials* journal, which provides a forum for the pharmaceutical industry and medical researchers.

<http://clinicaltrials.gov/>

Clinical Trials. Gov – A service of the US **National Institutes of Health**, developed by the National Library of Medicine. It provides a free trial registration site plus general information on the purpose of clinical trials and recruitment.

http://www.controlled-trials.com/mrct/mrct_about.asp

The *meta*Register of Controlled Trials (*mRCT*) is a major international searchable database of ongoing randomised controlled trials in all areas of healthcare, built by combining registers held by public, charitable and commercial sponsors of trials. It is a free service that allows users to search all participating registers and meets the requirements of the International Committee of Medical Journal Editors (ICMJE) for registration of clinical trials.

<http://www.icr-global.org/>

The **Institute of Clinical Research** (formerly ACRPI) has been in existence since 1978. Its aim is to provide a forum for education and sharing of best practice among clinical research professionals.

<http://www.jameslindlibrary.org>

A site managed by the Royal College of Physicians Edinburgh illustrating James Lind's contribution to the **development of controlled clinical trials**.

<http://courses.epigeum.co.uk/gcp/home>

An on-line GCP course that is available free for NHS GG&C and University of Glasgow staff.

4. General Information - Drug Development & EU

<http://emc.medicines.org.uk/>

This is the electronic Medicines Compendium which contains information about UK licensed medicines. Provides the latest new, updated and retired (removed) Summaries of Product Characteristics ([SPCs](#)) and Patient Information Leaflets ([PILs](#)) on the eMC website.

<http://eur-lex.europa.eu/en/index.htm>

Site for searching for html versions of **EU legislation**, including legislation in preparation.

www.ich.org/

International Conference on Harmonisation (ICH) – Official Web site.

<http://heads.medagencies.org/>

The **European Heads of Agencies (EEC-MRFG)** web site lists all European medicines regulatory agencies and links to their sites.

5. Research Quality

<http://www.barqa.com/>

British Association of Research Quality Assurance – assuring good scientific practice in research and development.

<http://www.diahome.org/DIAHome/>

The **Drug Information Association (DIA)** was founded in the USA in 1964 as a non-profit, scientific association of professionals employed in academia and the pharmaceutical industry. It publishes a quarterly Drug Information Journal.

<http://www.efgcp.be/>

European Forum for Good Clinical Practice (EFGCP). This is a European ‘think tank’ for considering the ethical, regulatory, and scientific framework of clinical research.

<http://www.nice.org.uk/>

NICE - The National Institute for Clinical Excellence - was set up as a Special Health Authority for England and Wales. It is part of the National Health Service (NHS), and its role is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current “best practice”.

<http://www.rdforum.nhs.uk/>

A network for those involved in planning and managing research in health and social care. Membership of the Forum is open to anyone involved in or interested in managing and planning research in the NHS or social care. Joining the Forum ensures that you receive regular email newsletters.

<http://www.show.scot.nhs.uk/cso/>

The Chief Scientist Office (CSO) is part of the Scottish Executive Health Department and promotes high quality research in Scotland.

6. Ethics and Informed Consent

www.myresearchproject.org.uk

IRAS - Integrated Research Application System. Streamline application form for submission of applications to several systems for approvals to conduct a clinical trial. This is part of the UKCRC work to streamline the approvals process.

www.nres.npsa.nhs.uk/

NRES guidance on Informed Consent and template for patient information sheet and consent forms.

<http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Consent/fs/en>

DH site providing information and guidance on obtaining consent from patients, for treatment or research.

<http://www.wma.net/e/>

The **World Medical Association** (WMA) is an international organization representing physicians. It was founded in 1947, to work for the highest possible standards of ethical behaviour and care by physicians. It has been responsible for a number of ethical guidelines including the **Declaration of Helsinki**

7. US Legislation & Regulatory Bodies

<http://www.access.gpo.gov/index.html>

US Government Printing Office Site – Searchable site listing entire Code of Federal Regulations (CFR) including title 21 (Food and Drugs).

http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr312_98.html

21 CFR 312 Investigational New Drug Regulations

<http://www.fda.gov/cder/>

Home page for the **Centre for Drug Evaluation & Research** (CDER). This is part of the FDA that deals with new drug applications.

<http://www.fda.gov/default.htm>

Home page of the **Food & Drugs Administration** (FDA), which is the US public health agency responsible for overseeing human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation.