

*Research Governance  
Framework  
for  
Health and Social Care*

Second edition, 2005 - Annex

# Annex

<b>A. ETHICS AND PATIENT INFORMATION</b> .....	<b>3</b>
A1 Legislation & Regulation .....	3
A1.1 General .....	3
A2 Patient Information .....	4
A3 Use of Human Organs and Tissues .....	7
A4 Animals .....	8
A5 Research Ethics and Research Ethics Committees .....	9
A6 Consent .....	12
A7 Genetics .....	13
A8 Other Established Standards .....	14
<b>B. SCIENCE</b> .....	<b>16</b>
B1 Legislation and Regulation .....	16
B1.1 General .....	16
B1.2 Genetics and Embryology .....	16
B1.3 Medicines .....	17
B1.4 Medical Devices .....	17
B1.5 Miscellaneous .....	18
B1.5.1 Misconduct .....	18
B1.5.2 People .....	18
B2 Other DH Requirements .....	21
B2.1 Animals .....	21
B2.1.1 Peer Review .....	22
B2.1.2 Other .....	23
B2.2 Codes of Professional Conduct .....	24
B2.2.1 The General Medical Council .....	24
B2.2.2 Research Councils .....	24
B2.2.3 Others .....	24
B2.2.4 Links .....	25
B2.3 Clinical Trials .....	27
B2.3.1 Registration of Trials .....	28
B2.4 General Practice .....	29
B2.5 Social Care and Science Research .....	29
B2.6 Samples and collections .....	31
B2.7 Statistics .....	32
B3 Other Established Standards .....	32
B3.1 Sources of Research Information .....	32
B3.2 Training for Research .....	34
B3.3 Other useful contacts .....	34
<b>C. INFORMATION</b> .....	<b>35</b>
C1 Legislation and Regulation .....	35
C2 Other Department of Health Requirements .....	35
C3 Other Established Standards .....	36
C3.1 Research Data, Documentation and Archiving .....	36
C3.2 Publication .....	36

<b>D. HEALTH, SAFETY &amp; EMPLOYMENT .....</b>	<b>38</b>
D1 Legislation and Regulation .....	38
D1.1 General.....	38
D1.2 Specifics .....	39
D1.2.1 Health and Safety .....	39
D1.2.2 Good Laboratory Practice .....	40
D1.2.3 COSHH .....	41
D1.2.4 Genetically modified organisms.....	42
D1.2.5 Radiation.....	42
D2 Other DH Requirements .....	43
D2.1 Pathogens .....	43
D2.2 Radiation .....	43
D3 Other Established Standards .....	43
<b>E. FINANCE &amp; INTELLECTUAL PROPERTY RIGHTS .....</b>	<b>45</b>
E1 Legislation and Regulation.....	45
E2 Other DH Requirements .....	45
E2.1 Financial Management .....	45
E2.2 NHS Trusts' Financial Governance.....	45
E2.3 Primary Care Trust Corporate Governance .....	45
E3 Other Established Standards .....	47
E3.1 Controls Assurance .....	47
E3.2 Fraud Prevention .....	47
E3.3 NHS IM & T Procurement .....	47
E3.4 Economic Potential of Public Sector Research.....	47
E3.5 Intellectual Property .....	47
E3.6 Department for Business Enterprise and Regulatory Reform.....	49
E3.7 Her Majesty's Treasury (HMT) .....	49
E3.8 Professional Standards.....	49
E3.9 Other Standards .....	49

# A. ETHICS AND PATIENT INFORMATION

## A1 Legislation & Regulation

### A1.1 General

1. Ethics Research Information Catalogue (ERIC). Available: <http://www.eric-on-line.co.uk> [Accessed 18 August 2008]. 2002.  
Reference Type: Electronic Citation  
Abstract: ERIC is a collection of material relevant to the ethical review of medical research, catalogued according to keywords. It is hoped that it will inform and provide consistency in ethical review. The database contains references to:
  - European Union and International directives (eg ICH-GCP)
  - National Legislation
  - Links to governmental bodies, research organisations and "august bodies"
  - Work from research and ethics bodies
  - Articles of relevance
  - Experience of researchers and ethicists in the field
  - Current public opinion
2. Human Rights Act 1998. Available: [http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980042\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_1) [Accessed 18 August 2008]. 1998. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: The scope of the Act covers the articles included in the European Convention: The right to life; Freedom from torture or inhuman or degrading treatment; Freedom from slavery; Liberty of person; Right to a fair trial; Prohibition against retrospective offences; Right to respect for private and family life; Freedom of thought, conscience and religion; Freedom of expression; Freedom of assembly and association; Right to marry and found a family; These rights to be enjoyed without discrimination on any ground; Derogation in time of war or public emergency.
3. Health and Social Care Act 2008. Available: [http://www.opsi.gov.uk/acts/acts2008/ukpga\\_20080014\\_en\\_1](http://www.opsi.gov.uk/acts/acts2008/ukpga_20080014_en_1) [Accessed 18 August 2008]. 1998. Office of Public Sector Information.  
Reference Type: Electronic Citation
4. Research Governance. Available: <http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/index.htm> [Accessed 18 August 2008]. 2005. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Material Regarding the Proper Conduct of Research.
5. National Institute for Health Research. Governance, Advice and Ethics Systems. Available: [http://www.nihr.ac.uk/systems\\_governance\\_advice\\_and\\_ethics\\_systems.aspx](http://www.nihr.ac.uk/systems_governance_advice_and_ethics_systems.aspx) [Accessed 21 August 2008]. 2008. National Institute for Health Research.  
Reference Type: Electronic Citation
6. UKCRC Regulatory and Governance Advice Service. Available: <http://www.ukcrc-rgadvice.org/> [Accessed 29 August 2008]. 2008. UK Clinical Research Collaboration (UKCRC)  
Reference Type: Electronic Citation

## A2 Patient Information

1. Health and Social Care Act 2008. Available:  
[http://www.opsi.gov.uk/acts/acts2008/ukpga\\_20080014\\_en\\_1](http://www.opsi.gov.uk/acts/acts2008/ukpga_20080014_en_1) [Accessed 18 August 2008]. 1998. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. The Health Service (Control of Patient Information) Regulations 2002. Available:  
<http://www.opsi.gov.uk/si/si2002/20021438.htm> [Accessed 18 August 2008]. 2002. Office of Public Sector Information.  
Reference Type: Electronic Citation
3. The Data Protection Act 1998. Available:  
[http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980029\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_1) [Accessed 18 August 2008]. 1998. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: Provides protection for personal data. This includes information which by itself or in conjunction with other easily obtainable information, can identify a specific person.
4. The Data Protection (Processing of Sensitive Personal Data) Order 2000. Available:  
<http://www.opsi.gov.uk/si/si2000/20000417.htm> [Accessed 18 August 2008]. 2000. Office of Public Sector Information.  
Reference Type: Electronic Citation
5. Access to Health Records Act 1990 (c. 23). Available:  
[http://www.opsi.gov.uk/acts/acts1990/Ukpga\\_19900023\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900023_en_1.htm) [Accessed 18 August 2008]. 1990. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: This Act is still relevant where the access request is to the medical record of a deceased patient
6. Regulation of Investigatory Powers Act 2000. Available:  
[http://www.opsi.gov.uk/acts/acts2000/ukpga\\_20000023\\_en\\_1](http://www.opsi.gov.uk/acts/acts2000/ukpga_20000023_en_1) [Accessed 18 August 2008]. 2000. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: Legislation relating to interception of communications, intrusive investigative techniques and access to encrypted data
7. Crime and Disorder Act 1998. Available:  
[http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980037\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980037_en_1) [Accessed 18 August 2008]. 1998. Office of Public Sector Information.  
Reference Type: Electronic Citation
8. The Human Fertilisation and Embryology (Disclosure of Information) Act 1992. Available:  
[http://www.hms0.gov.uk/acts/acts1992/Ukpga\\_19920054\\_en\\_1.htm](http://www.hms0.gov.uk/acts/acts1992/Ukpga_19920054_en_1.htm) [Accessed 18 August 2008]. 1992. The Stationery Office.  
Reference Type: Electronic Citation  
Abstract: Limits the circumstances in which licensed centres may disclose information
9. The Abortion Regulations 1991. 1991. Department of Health. Available:  
[http://www.opsi.gov.uk/si/si1991/Uksi\\_19910499\\_en\\_1.htm](http://www.opsi.gov.uk/si/si1991/Uksi_19910499_en_1.htm). [Accessed 22 September 2008].  
Reference Type: Electronic Citation  
Abstract: Impose both specific obligations and formal restrictions on disclosure of information. .
10. Personal Information in Medical Research. Available:  
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002452>

[Accessed 18 August 2008]. 2003. Medical Research Council.  
Reference Type: Electronic Citation  
Abstract: This guide, together with other MRC ethics guides, is available on this website

11. The NHS (Venereal Diseases) Regulations 1974. 1974. Department of Health.  
Reference Type: Not on the Web.  
Abstract: Impose both specific obligations and formal restrictions on disclosure of information.
12. Patient Confidentiality and Caldicott Guardians. Available:  
[http://www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Patientconfidentialityandcaldicottguardians/DH\\_4084181](http://www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Patientconfidentialityandcaldicottguardians/DH_4084181) [Accessed 18 August 2008]. 2007. Department of Health.  
Reference Type: Electronic Citation
13. Information Policy. Confidentiality: NHS Code of Practice. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4069253](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253) [Accessed 18 August 2008]. 2003. Department of Health.  
Reference Type: Electronic Citation  
Abstract: This document is a guide to required practice for those who work within or under contract to NHS organisations concerning confidentiality and patients' consent to the use of their health records.
14. Records management: NHS code of practice Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4131747](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131747) [Accessed 18 August 2008]. 2006. Department of Health.  
Reference Type: Electronic Citation
15. Singleton, P., Hunnabell, J., and Mason, R. Gaining Patient Consent to Disclosure. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4131402](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131402) [Accessed 18 August 2008]. 2001. Department of Health.  
Reference Type: Electronic Citation  
Abstract: A consultancy project for the NHS Executive
16. The NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH\\_4083027](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4083027) [Accessed 18 August 2008]. 2000. Department of Health  
Reference Type: Electronic Citation  
Abstract: Impose both specific obligations and formal restrictions on disclosure of information
17. Data Protection Act 1998 Guidance to Social Services. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH\\_4010391](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4010391) [Accessed 18 August 2008]. 2000. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Guidance from the DH Social Care Group.
18. The Caldicott Committee : Report on the review of patient-identifiable information – December 1997 . Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4068403](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4068403) [Accessed 18 August 2008]. 1997. NHS Executive.  
Reference Type: Electronic Citation  
Abstract: This Review was commissioned by the Chief Medical Officer of England owing to increasing concern about the ways in which patient information is used in the NHS in England and Wales and the need to ensure that confidentiality is not undermined.

19. Office of the Information Commissioner. Available: <http://www.ico.gov.uk/> [Accessed 18 August 2008]. 2008. Information Commissioner.  
Reference Type: Electronic Citation  
Abstract: The site of the Information Commissioner containing compliance and legal guidance for the Data Protection Act 1998 and the some information on the Freedom of Information Act.
20. Information Commissioner (May 2002) Use and disclosure of health data  
Available:  
[http://www.ico.gov.uk/upload/documents/library/data\\_protection/practical\\_application/health\\_data\\_-\\_use\\_and\\_disclosure001.pdf](http://www.ico.gov.uk/upload/documents/library/data_protection/practical_application/health_data_-_use_and_disclosure001.pdf) [Accessed 18 August 2008]. 2002. Information Commissioner.  
Reference Type: Electronic Citation  
Abstract: The Information Commissioner has produced a definitive statement on the interpretation of the Data Protection Act for pathologists.
21. Data Protection Audit Manual. Available:  
[http://www.ico.gov.uk/upload/documents/library/data\\_protection/detailed\\_specialist\\_guides/data\\_protection\\_complete\\_audit\\_guide.pdf](http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_specialist_guides/data_protection_complete_audit_guide.pdf) [Accessed 18 August 2008]. 2001.  
Information Commissioner.  
Reference Type: Electronic Citation  
Abstract: Guidance from the Information Commissioner on undertaking an audit to determine whether activities involving the processing of personal data are carried out in accordance with an organisation's data protection policies and procedures, and the requirements of the Data Protection Act 1998.
22. Notification Handbook: A complete guide to notification. Available:  
[http://www.ico.gov.uk/upload/documents/library/data\\_protection/detailed\\_specialist\\_guides/notification\\_handbook\\_final.pdf](http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_specialist_guides/notification_handbook_final.pdf) [Accessed 18 August 2008]. 2001.  
Information Commissioner.  
Reference Type: Electronic Citation  
Abstract: Guidance from the Information Commissioner on the statutory requirement of notification under the Data Protection Act 1998.
23. Information Governance. Available:  
<http://www.connectingforhealth.nhs.uk/systemsandservices/infogov> [Accessed 18 August 2008]. 2008. NHS Connecting for Health.  
Reference Type: Electronic Citation  
Abstract: Information Governance guidance including Information Governance Toolkit and Caldicott Guardian information can be found here.
24. Security of NHS patient data shared for research purposes. Available:  
<http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/whatsnew> [Accessed 26 August 2008]. 2008. Department of Health.  
Reference Type: Electronic Citation
25. Department of Constitutional Affairs. Available: <http://www.dca.gov.uk/> [Accessed 18 August 2008]. 2008. Department of Constitutional Affairs.  
Reference Type: Electronic Citation  
Abstract: Freedom of Information and Data Protection site with links to OIC, fact sheets and guidance.
26. NRES leaflet: Explaining Research  
Available: <http://www.nres.npsa.nhs.uk/rec-community/guidance> [Accessed 28 August 2008]. 2008. National Research Ethics Service (NRES).  
Reference Type: Electronic Citation
27. The Journal of Information, Law and Technology: Data Protection. Available:  
<http://www2.warwick.ac.uk/fac/soc/law/elj/jilt> [Accessed 18 August 2008]. 2007. The University of Warwick.  
Reference Type: Electronic Citation

Abstract: Contains articles and commentaries on the law surrounding data protection.

28. The Law of Confidentiality. Available: <http://www.kaltons.co.uk/confidentiality.htm> [Accessed 18 August 2008]. 2002. Kaltons.  
Reference Type: Electronic Citation  
Abstract: The common law duty of confidence.
29. Swarb Law Notes. Available: <http://www.swarb.co.uk> [Accessed 18 August 2008]. 2002. Swarb.co.uk/Wrigley Claydon Solicitors.  
Reference Type: Electronic Citation  
Abstract: Site maintained by Swarb.co.uk in conjunction with Wrigley Claydon solicitors. Clicking on "data protection" brings up a list of resources including cases, fact sheets, FAQ's, and links.

### **A3 Use of Human Organs and Tissues**

1. Human Tissue Act 2004  
[http://www.opsi.gov.uk/acts/acts2004/ukpga\\_20040030\\_en\\_1](http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1)  
[Accessed 18 August 2008]. 2004. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. Available:  
<http://www.opsi.gov.uk/si/si2006/20061260.htm>  
[Accessed 18 August 2008]. 2006. Office of Public Sector Information.  
Reference Type: Electronic Citation
3. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. Available: <http://www.opsi.gov.uk/SI/si2006/20061659.htm>  
[Accessed 18 August 2008]. 2006. Office of Public Sector Information.  
Reference Type: Electronic Citation
4. Human Tissue (Scotland) Act 2006. Available:  
[http://www.opsi.gov.uk/legislation/scotland/acts2006/asp\\_20060004\\_en\\_1](http://www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_1) [Accessed 18 August 2008]. 2006. Office of Public Sector Information.  
Reference Type: Electronic Citation
5. The Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006. Available:  
<http://www.opsi.gov.uk/legislation/scotland/ssi2006/20060310.htm> [Accessed 18 August 2008]. 2006. Office of Public Sector Information.  
Reference Type: Electronic Citation
6. Code of Practice – Post mortem examination. Available:  
[http://www.hta.gov.uk/db/documents/2006-07-04\\_Approved\\_by\\_Parliament\\_-\\_Code\\_of\\_Practice\\_3\\_-\\_Post\\_Mortem.pdf](http://www.hta.gov.uk/db/documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_3_-_Post_Mortem.pdf) [Accessed 18 August 2008]. 2006. Human Tissue Authority.
7. Code of Practice – The removal, storage and disposal of human organs and tissue. Available:  
[http://www.hta.gov.uk/db/documents/2006-07-04\\_Approved\\_by\\_Parliament\\_-\\_Code\\_of\\_Practice\\_5\\_-\\_Removal.pdf](http://www.hta.gov.uk/db/documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_5_-_Removal.pdf) [Accessed 18 August 2008]. 2006. Human Tissue Authority.  
Reference Type: Electronic Citation
8. Human tissue and biological samples for use in research - Operational and ethical guidelines. Available:



- <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420> [Accessed 18 August 2008]. 2001. The Medical Research Council.  
Reference Type: Electronic Citation  
Abstract: This document includes an annex of the amendment to the Human Tissue and Biological Samples for Use in Research - Operational and Ethical guidelines of 2004
9. Journal of the Royal College of Physicians. Available:  
[http://www.rcplondon.ac.uk/pubs/journal/journ\\_archive\\_33\\_subj.htm](http://www.rcplondon.ac.uk/pubs/journal/journ_archive_33_subj.htm) [Accessed 18 August 2008] 33, 364-266. 1999. Royal College of Physicians.  
Reference Type: Electronic Citation  
Abstract: Statement from the Royal College of Physicians' Committee on Ethical Issues in Medicine "Research based on archived information and samples".
10. Nuffield Council on Bioethics. Available:  
<http://www.nuffieldbioethics.org> [Accessed 18 August 2008].  
1995. Nuffield Council on Bioethics.  
Reference Type: Electronic Citation  
Abstract: Human Tissue: Ethical and Legal Issues - Report published in April 1995. Conclusions and recommendations available on the website.
11. UK National Culture Collection. Available:  
<http://www.ukncc.co.uk/html/Information/Index.htm> [Accessed 18 August 2008]. 2002. UK National Culture Collection.  
Reference Type: Electronic Citation  
Abstract: The National Culture Collections offer a number of services including the supply of cultures, identification of cultures, safe deposit facilities and deposit of cultures for patent purposes under the 'Budapest Treaty'. Collections also carry out industrially orientated research.
12. European Collection of Cell Cultures. Available:  
<http://www.hpacultures.org.uk/collections/ecacc.jsp> [Accessed 22 September 2008].  
2002. European Collection of Cell Cultures.  
Reference Type: Electronic Citation  
Abstract: ECACC provides quality cell cultures to the academic community and industry, provides guidance on culture deposition and access.

## **A4 Animals**

1. The Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 1998 [SI 1998 No. 1974]. Available: <http://www.opsi.gov.uk/si/si1998/19981974.htm> [Accessed 18 August 2008]. 1998. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. The Animals (Scientific Procedures) Act 1986. Available:  
<http://scienceandresearch.homeoffice.gov.uk/animal-research/legislation/> [Accessed 18 August 2008]. 2002. The Home Office Crown Copyright.  
Reference Type: Electronic Citation  
Abstract: Guidance on the operation of the Act including links to electronic forms and guidance notes. This page provides links to reference material relevant to the use of animals in scientific procedures, including the Animals (Scientific Procedures) Act 1986, Home Office guidance on the operation of the 1986 Act and codes of practice for the care and housing of laboratory animals.
3. Home Office. Animals in scientific procedures. Available:  
<http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/> [Accessed 18 August 2008]. 2008. The Home Office Crown Copyright.  
Reference Type: Electronic Citation

Abstract: This page provides links to reference material relevant to the use of animals in scientific procedures.

4. Responsibility in the use of animals in bioscience research: Expectations of the major research council and charitable funding bodies. Available: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC001897> [Accessed 18 August 2008]. 2008. Medical Research Council.  
Reference Type: Electronic Citation

## A5 Research Ethics and Research Ethics Committees

1. Governance Arrangements for NHS Research Ethics Committees (GAfREC) (Previously HSG(91)5 Local Research Ethics Committees). Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4005727](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727) [Accessed 18 August 2008]. 2001. Department of Health.  
Reference Type: Electronic Citation  
Notes: HSG(91)5 Local Research Ethics Committees (also known as "the Red Book").
2. The Declaration of Helsinki (as revised). Available: <http://www.wma.net/e/policy/b3.htm> [Accessed 29 August 2008]. 2001. The World Medical Association.  
Reference Type: Electronic Citation  
Abstract: After three years of consultation and deliberation, the 52nd WMA General Assembly unanimously approved a revised Declaration of Helsinki. This is only the fifth time that this policy has been amended since its first adoption in 1964. Notes of clarification were added in 2002 and 2004.
3. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice ('ICH GCP') 1996. Available: <http://www.ich.org/LOB/media/MEDIA482.pdf> [Accessed 26 August 2008]. 1996. International Conference on Harmonisation (ICH)  
Reference Type: Electronic Citation
4. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Available: <http://conventions.coe.int/treaty/en/treaties/html/164.htm> [Accessed 19 August 2008]. 1997. Council of Europe.  
Reference Type: Electronic Citation
5. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Available: [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm) [Accessed 19 August 2008]. 2002. Council for International Organizations of Medical Sciences.  
Reference Type: Electronic Citation
6. Operational Guidelines for Ethics Committees that Review Biomedical Research. Available: <http://www.who.int/tdr/publications/publications/pdf/ethics.pdf> [Accessed 18 August 2008]. 2000. World Health Organisation.  
Reference Type: Electronic Citation
7. Guidance on Good Clinical Practice and Clinical Trials in the NHS. Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4082934](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4082934) [Accessed 18 August 2008]. 2006. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Guidance is concerned with management of clinical trials.
8. Good Clinical Practice Directive 2005/28/EC. Available: [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l\\_091/l\\_09120050409en00130019.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.pdf) [Accessed 05 September 2008]. 2005. European Union.

Reference Type: Electronic Citation

9. Training for Research Ethics Committee Members. Available:  
<http://www.nres.npsa.nhs.uk/training-events/> [Accessed 3 October 2008]. 2008. National Research Ethics Service (NRES)  
Reference Type: Electronic Citation
10. Guidance for NHS Research Ethics Committees.  
Available <http://www.nres.npsa.nhs.uk/rec-community/guidance/#recs> [Accessed 18 August 2008]. 2008. National Research Ethics Service (NRES)  
Reference Type: Electronic Citation
11. NRES guidance on research involving adults unable to consent for themselves (incorporating guidance on the Mental Capacity Act 2005). Available:  
<http://www.nres.npsa.nhs.uk/rec-community/guidance/#consent>  
[Accessed 26 August 2008]. 2007.NRES.  
Reference Type: Electronic Citation
12. Ionising Radiation NRES guidance on approval of research involving ionising radiation Dec 2006 Available: <http://www.nres.npsa.nhs.uk/rec-community/guidance/#ionisingrad>  
[Accessed 29 August 2008]. 2006.NRES.  
Reference Type: Electronic Citation
13. Approval of medical devices research 2008. Available:  
<http://www.nres.npsa.nhs.uk/rec-community/guidance/#medicaldevices>  
[Accessed 26 August 2008]. 2008.NRES.  
Reference Type: Electronic Citation
14. Guidelines on the practice of ethics committees in medical research involving human subjects. Available: <http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=232> [Accessed 18 August 2008]. 2007. Royal College of Physicians.  
Reference Type: Electronic Citation
15. HSE Research Ethics Committee. Available:  
<http://www.hse.gov.uk/research/ethics/index.htm> [Accessed 18 August 2008]. 2002.  
Health & Safety Executive.  
Reference Type: Electronic Citation  
Abstract: This site gives details of the HSE Research Ethics Committee and provides information and links relevant to issues presented to the Committee.
16. The Role of a Research Ethics Committee. Available:  
<http://www.nres.npsa.nhs.uk/aboutus/purpose-of-recs/> [Accessed 18 August 2008]. 2008.  
National Research Ethics Service (NRES).  
Reference Type: Electronic Citation
17. Training for Research Ethics Committee Members. Available:  
<http://www.nres.npsa.nhs.uk/training-events/> [Accessed 28 August 2008]. 2008. National Research Ethics Service (NRES)  
Reference Type: Electronic Citation
18. NRES Guidelines to help researchers and RECs to decide what is appropriate/inappropriate for submission to RECs. Available:  
<http://www.nres.npsa.nhs.uk/rec-community/guidance/#researchoraudit>  
[Accessed 26 August 2008]. 2006.NRES.  
Reference Type: Electronic Citation
19. When to Apply For Ethical Review. Available:  
<http://www.nres.npsa.nhs.uk/applicants/apply/applying-for-ethical-review>  
[Accessed 18 August 2008]. 2007. National Research Ethics Service (NRES).  
Reference Type: Electronic Citation

20. Integrated Research Application System (IRAS). Available: <https://www.myresearchproject.org.uk/> [Accessed 18 August 2008]. 2008. Integrated Research Application System (IRAS).  
Reference Type: Electronic Citation  
Abstract: IRAS is a single system for applying for the permissions and approvals for health and social care/ community care research in the UK. Project information is spread across the system to prevent duplication.
21. Standard Operating Procedures. Available: <http://www.nres.npsa.nhs.uk/news-and-publications/publications/standard-operating-procedures/> [Accessed 1 September 2008]. 2008. National Research Ethics Service (NRES).  
Reference Type: Electronic Citation
22. Research Governance. Available: <http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/index.htm> [Accessed 18 August 2008]. 2005. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Material Regarding the Proper Conduct of Research.
23. Research: The Role and Responsibilities of Doctors. Available: <http://www.gmc-uk.org/guidance/current/library/research.asp> [Accessed 18 August 2008]. 2002. General Medical Council.  
Reference Type: Electronic Citation  
Abstract: The General Medical Council guidance is addressed to all doctors, but it is also likely to be of interest to anybody with an involvement in medical research, both practitioners and participants. It responds to concerns raised by the profession, patients and the public about misconduct in medical research. It is believed that the standards and principles laid down in this guidance will also be valuable to students at the start of their medical career.
24. Making and Using Visual and Audio Recordings of Patients. Available: [http://www.gmc-uk.org/guidance/current/library/making\\_audiovisual.asp](http://www.gmc-uk.org/guidance/current/library/making_audiovisual.asp) [Accessed 18 August 2008]. 2002. General Medical Council.  
Reference Type: Electronic Citation  
Abstract: The General Medical Council (GMC) has issued guidance covering all types of audio and visual recordings of patients, carried out for any purpose, including research.
25. Economic & Social Research Council. Research Ethics Framework. Available: <http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/opportunities/research%5Fethics%5Fframework/> [Accessed 18 August 2008]. 2005. Economic & Social Research Council.  
Reference Type: Electronic Citation
26. MRC Ethics and Research Governance. Available: <http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm> [Accessed 18 August 2008]. 2002. Medical Research Council.  
Series of guidance to help MRC scientists to implement good practice and meet legal and ethical requirements.
27. The Ethical Advisory Committee. Archives of Diseases in Childhood. *Royal College of Paediatrics and Child Health* 2000;**82**:177-82.  
Abstract: Guidelines for the Ethical Conduct of Medical Research involving Children
28. SSRG's Research Governance Framework Resource Pack. Available: <http://www.ssrq.org.uk/governance/files/rqf.pdf> [Accessed 29 August 2008]. 2005. Social Service Research Group.  
Reference Type: Electronic Citation

29. The BMA's handbook of ethics and law (including 2007 updates). Available: <http://www.bma.org.uk/ap.nsf/Content/MET2004?OpenDocument&Highlight=2,research,ethics> [Accessed 18 August 2008]. 2007. British Medical Association.  
Reference Type: Electronic Citation
30. The ethics of research related to healthcare in developing countries. Available: [http://www.nuffieldbioethics.org/go/ourwork/developingcountries/publication\\_309.html](http://www.nuffieldbioethics.org/go/ourwork/developingcountries/publication_309.html) [Accessed 18 August 2008]. 2002. Nuffield Council on Bioethics.  
Reference Type: Electronic Citation  
Abstract: New report published by the Nuffield Council on Bioethics. Medical research in developing countries that is funded by organisations in wealthy countries can raise difficult ethical issues. The Nuffield Council on Bioethics established a Working Party to examine these issues in 2000, and has now published its Report on the topic. The Report highlights the importance of such research and offers recommendations to help researchers design and conduct studies which meet high ethical standards. Specific recommendations in the Report focus on three main areas:  
1) Consent to participate in research  
2) Standards of care  
3) What happens when research is over  
The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper  
[http://www.nuffieldbioethics.org/go/ourwork/developingcountries/publication\\_169.html](http://www.nuffieldbioethics.org/go/ourwork/developingcountries/publication_169.html) [Accessed 27 August 2008]. 2005. Nuffield Council on Bioethics.  
Reference Type: Electronic Citation
31. Research Ethics Committees contacts. Available: <http://www.nres.npsa.nhs.uk/contacts/find-your-local-rec/> [Accessed 18 August 2008]. 2007. National Research Ethics Service (NRES).  
Reference Type: Electronic Citation  
Abstract: Addresses for NHS RECS throughout the UK.
32. The Manual for Research Ethics Committees. Available: Further details are available from King's College, London on +44 (0)20 7848 2357 . 2002. King's College, London.  
Reference Type: Electronic Citation
33. Gene Therapy Advisory Committee (GTAC). Available: <http://www.advisorybodies.doh.gov.uk/genetics/gtac/index.htm> [Accessed 18 August 2008]. 2002. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Gene Therapy Advisory Committee Information on the committee, guidance on making proposals to conduct gene therapy in human subjects and on writing patient information sheets for such studies is available at the website listed here.
34. Xenotransplantation Guidance  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_063075](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063075) [Accessed 18 August 2008]. 2006. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Clinical procedures involving xenotransplantation. Information on the committee and making proposals for trials in this field. Other sources of expertise and advice available.
35. Research Governance: Social Care Information Page. Available: [http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH\\_4002132](http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH_4002132) [Accessed 05 September 2008]. 2008. Department of Health.  
Reference Type: Electronic Citation

## A6 Consent

1. Good Practice in Consent: Achieving the NHS Plan commitment to patient-centred consent practice. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecircul ars/DH\\_4003736](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecircul ars/DH_4003736) [Accessed 18 August 2008]. 2001. Department of Health.  
 Reference Type: Electronic Citation  
 Abstract: The NHS Plan identified the need for changes in the way in which patients are asked to give their consent to treatment, care or research, in order to ensure that the process becomes properly focused on the rights of individual patients and their relatives. The Department of Health's Reference guide to consent for examination or treatment, which summarises the current law on consent to treatment, was published in March 2001. The Department has now published a circular focusing on the action necessary to ensure that the principles set out in the Reference guide are reflected in day-to-day NHS practice by:  
 -announcing the publication of the Good practice in consent implementation guide: consent to examination or treatment, containing new model consent forms and a new model consent policy;  
 -setting out the timescales for the implementation of this documentation; and  
 -clarifying what flexibility in design and use is acceptable.  
 Notes: Health Service Circular HSC 2001/023
2. Information Policy. Confidentiality: NHS Code of Practice. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4069253](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253) [Accessed 18 August 2008]. 2003. Department of Health.  
 Reference Type: Electronic Citation  
 Abstract: This document is a guide to required practice for those who work within or under contract to NHS organisations concerning confidentiality and patients' consent to the use of their health records.
3. Reference Guide to consent for Examination or Treatment. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4006757](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006757) [Accessed 18 August 2008]. 2001. Department of Health.  
 Reference Type: Electronic Citation
4. Good practice in consent implementation guide: consent to examination or treatment. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4005762](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005762) [Accessed 18 August 2008]. 2002. Department of Health.  
 Reference Type: Electronic Citation
5. NRES guidance on information sheets and consent forms. Available:  
<http://www.nres.npsa.nhs.uk/rec-community/guidance/#InformedConsent> [Accessed 02 September 2008]. 2008. National Research Ethics Service.  
 Reference Type: Electronic Citation
6. Research involving use of human tissues or records and research presenting no material ethical issues. Chapter 7 in Guidelines on the Practice of Ethics committees in Medical Research involving Human Subjects (4<sup>th</sup> edition). Available:  
<http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=232> [Accessed 18 August 2008]. 2007.  
 Reference Type: Electronic Citation
7. Code of Practice (7<sup>th</sup> Edition). Available:  
<http://www.hfea.gov.uk/en/1365.html> [Accessed 18 August 2008]. 2004. The Human Fertilisation and Embryology Authority.  
 Reference Type: Electronic Citation

## **A7 Genetics**

1. Human Genetics Commission (HGC). Available:



- <http://www.hgc.gov.uk> [Accessed 18 August 2008]. 2005.  
Reference Type: Electronic Citation  
Abstract: UK Government's advisory body on new developments in human genetics.
2. Human Genetics Commission Regulatory and Advisory Framework. Available: [http://www.hgc.gov.uk/Client/Content\\_wide.asp?ContentId=53](http://www.hgc.gov.uk/Client/Content_wide.asp?ContentId=53) [Accessed 18 August 2008]. 2000. Human Genetics Commission.  
Reference Type: Electronic Citation  
Abstract: This page provides brief descriptions of the main bodies in the UK regulatory and advisory framework for human genetics, including links to current developments in their work where this is relevant to HGC.
  3. Guidance on Making Proposals to Conduct Gene Therapy Research on Human Subjects. Available: <http://www.advisorybodies.doh.gov.uk/genetics/gtac/applicform.htm> [Accessed 18 August 2008]. 2007. Department of Health.  
Reference Type: Electronic Citation
  4. Genetics and human behaviour. Available: [http://www.nuffieldbioethics.org/go/ourwork/behaviouralgenetics/publication\\_311.html](http://www.nuffieldbioethics.org/go/ourwork/behaviouralgenetics/publication_311.html) [Accessed 18 August 2008]. 2006. Nuffield Council on Bioethics.  
Reference Type: Electronic Citation  
Abstract: Researchers in the field of behavioural genetics are attempting to locate specific genes, or groups of genes, associated with behavioural traits and to understand the complex relationship between genes and the environment. This Report considers the ethical, legal and social issues that are raised by research into behavioural genetics. It focuses on human behaviour within the normal range of variation, looking at traits such as intelligence, antisocial behaviour, personality and sexual orientation. After discussing the historical and scientific background to this research, the Report considers its implications and possible applications. It considers the issues raised by changing or selecting behavioural traits on the basis of genetic information and examines the possible uses of such information in the criminal justice system, and in the contexts of education, employment and insurance.

## **A8 Other Established Standards**

1. Commercial Sponsorship - Ethical Standards for the NHS. Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4005135](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005135) [Accessed 18 August 2008]. 2000. Department of Health.  
Reference Type: Electronic Citation
2. Health Protection Agency. Standards Unit. Available: <http://www.hpa-standardmethods.org.uk/> [Accessed 21 August 2008]. 2008. Health Protection Agency.  
Reference Type: Electronic Citation  
Abstract: The Standards Unit develops National Standard Methods (including SOPs, Algorithms and Guidance Notes) for clinical and public health microbiology
3. Guidelines on the practice of ethics committees in medical research involving human subjects. Available: <http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=232> [Accessed 18 August 2008]. 2007. Royal College of Physicians.  
Reference Type: Electronic Citation
4. HSE Research Ethics Committee. Available: <http://www.hse.gov.uk/research/ethics/index.htm> [Accessed 18 August 2008]. 2002. Health & Safety Executive.  
Reference Type: Electronic Citation

Abstract: This site gives details of the HSE Research Ethics Committee and provides information and links relevant to issues presented to the Committee.



## B. SCIENCE

### B1 Legislation and Regulation

1. Office of Public Sector Information. Available: <http://www.opsi.gov.uk/> [Accessed 19 August 2008]. 2002. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: 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).
2. UKCRC Regulatory and Governance Advice Service. Available: <http://www.ukcrc-rgadvice.org/> [Accessed 29 August 2008]. 2008. UK Clinical Research Collaboration (UKCRC)  
Reference Type: Electronic Citation

#### B1.1 General

1. Department of Health. Available: <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/index.htm> [Accessed 19 August 2008]. 2008. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Current and past DH publications, including statistical reports, surveys, press releases, circulars and legislation, are available in electronic format from this section.

#### B1.2 Genetics and Embryology

1. Human Fertilisation and Embryology Act 1990 (c. 37) . Available: [http://www.opsi.gov.uk/acts/acts1990/Ukpga\\_19900037\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm) [Accessed 19 August 2008]. 1990. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: 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.
2. Human Fertilisation and Embryology (Research Purposes) Regulations 2001. Available: <http://www.opsi.gov.uk/si/si2001/20010188.htm> [Accessed 19 August 2008]. 2001. Office of Public Sector Information.  
Reference Type: Electronic Citation
3. Xenotransplantation Guidance. Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_063075](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063075) [Accessed 19 August 2008]. 2006. Department of Health.  
Reference Type: Electronic Citation  
Abstract: This guidance explains the DH policy position on xenotransplantation, describes approval processes and points to appropriate sources of expertise and advice.
4. The Human Fertilisation and Embryology Authority (HFEA). Available: <http://www.hfea.gov.uk/> [Accessed 19 August 2008]. 2008. The Human Fertilisation and Embryology Authority (HFEA).  
Reference Type: Electronic Citation
5. Human Fertilisation and Embryology Authority. Licensed Embryo Research Centre - Application for Renewal of Research Licence. Available: [http://www.hfea.gov.uk/docs/2005\\_Research\\_Application\\_Renewal\\_final\\_2\\_.pdf](http://www.hfea.gov.uk/docs/2005_Research_Application_Renewal_final_2_.pdf) [Accessed 19 August 2008]. 2005. Human Fertilisation and Embryology Authority.  
Reference Type: Electronic Citation

6. Human Fertilisation and Embryology Authority. Licensed Embryo Research Centre - Progress Report. Available: [http://www.hfea.gov.uk/docs/2005\\_Research\\_Progress\\_Report\\_2\\_.pdf](http://www.hfea.gov.uk/docs/2005_Research_Progress_Report_2_.pdf) [Accessed 19 August 2008]. 2005. Human Fertilisation and Embryology Authority. Reference Type: Electronic Citation
7. Human Fertilisation and Embryology Authority. Licensed Embryo Research Centre - Initial Application for a Research Licence. Available: [http://www.hfea.gov.uk/docs/Initial\\_Research\\_Application\\_Form.pdf](http://www.hfea.gov.uk/docs/Initial_Research_Application_Form.pdf) [Accessed 19 August 2008]. 2005. Human Fertilisation and Embryology Authority. Reference Type: Electronic Citation
8. The Human Genetics Commission. Available: <http://www.hgc.gov.uk> [Accessed 19 August 2008]. 2002. The Human Genetics Commission. Reference Type: Electronic Citation  
Abstract: Contains links to the main bodies concerned with regulation and advice on human genetics

### **B1.3 Medicines**

1. European Union Pharmaceutical Legislation. Volume 10. Available: [http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10\\_en.htm](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm) [Accessed 17 August 2008]. 2008. European Union. Reference Type: Electronic Citation  
Abstract: Volume 10 of the publications "The rules governing medicinal products in the European Union" contains guidance documents applying to clinical trials.
2. Medicines and Healthcare products Regulatory Agency. Available: <http://www.mhra.gov.uk/> [Accessed 19 August 2008]. 2008. Medicines and Healthcare products Regulatory Agency  
Reference Type: Electronic Citation
3. Misuse of Drugs Act, 1971. Available: <http://www.ukcia.org/pollaw/lawlibrary/misuseofdrugsact1971.php> [Accessed 19 August 2008]. 2002. HM Stationery Office. Reference Type: Electronic Citation.

### **B1.4 Medical Devices**

1. Medicines and Healthcare products Regulatory Agency. How We Regulate Devices. Available: <http://www.mhra.gov.uk/Howweregulate/Devices/index.htm> [Accessed 27 August 2008]. 2007. Reference Type: Electronic Citation  
Abstract: Information about all aspects for ensuring that medical devices, including in vitro diagnostic products, meet appropriate standards of safety, quality and performance. Links can be found for all relevant directives, regulations and guidance.
2. Medicines and Healthcare products Regulatory Agency. Clinical Trials for Medical Devices. Available: <http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm> [Accessed 27 August 2008]. 2008. Reference Type: Electronic Citation  
Abstract: The guidance available covers the regulatory aspects for any person wishing to carry out clinical trials of medical devices in the UK. It sets out the requirements of the EC Medical Devices Directives, the information required by the Agency and the format in which it should be supplied.

3. British Standards Institute. BS EN ISO 14155-1:2003 and BS EN ISO 14155-2:2003 Clinical Investigation of Medical Devices for Human Subjects. Available: <http://www.bsi-global.com/en/Standards-and-Publications/> [Accessed 04 September 2008]. 2003.  
Reference Type: Published Standards.  
Abstract: These two standards specify requirements for the conduct of a clinical investigation, the preparation of a Clinical Investigation Plan, the organization, conduct, monitoring, data collection and documentation.

### **B1.5 Miscellaneous**

1. Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Available: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997R0258:EN:HTML> [Accessed 19 August 2008]. 1997. European Union.  
Reference Type: Electronic Citation  
Abstract: 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.
2. Food Standards Agency. Available: <http://www.foodstandards.gov.uk/> [Accessed 19 August 2008]. 2008. Food Standards Agency.  
Reference Type: Electronic Citation  
Abstract: The Food Standards Agency is an independent food safety watchdog set up by an Act of Parliament in 2000 to protect the public's health and consumer interests in relation to food.

#### **B1.5.1 Misconduct**

1. Public Interest Disclosure Act 1998 . Available: [http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980023\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980023_en_1) [Accessed 19 August 2008]. 1998. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: 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. Notes of clarification were added in 2002 and 2004.
2. Procedure for the Investigation of Misconduct in Research. Available: [http://www.ukrio.org/sites/ukrio2/the\\_programme\\_of\\_work/procedure.cfm](http://www.ukrio.org/sites/ukrio2/the_programme_of_work/procedure.cfm) [Accessed 04 September 2008]. 2008. UK Research Integrity Office.  
Reference Type: Electronic Citation

#### **B1.5.2 People**

1. Convention on the Rights of the Child. Available: <http://www.unicef.org/crc/> [Accessed 19 August 2008]. 2002. UNICEF.  
Reference Type: Electronic Citation  
Abstract: 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.
2. United Nations Convention on the Rights of the Child. Available: <http://www2.ohchr.org/english/law/crc.htm> [Accessed 19 August 2008]. 2002. Office of the United Nations High Commissioner for Human Rights.

Reference Type: Electronic Citation

3. The Royal College of Paediatrics and Child Health. Guidelines for the ethical conduct of medical research involving children. *Archives of Diseases in Childhood* 2000;177-82.
4. MRC Ethics Guide: Medical research involving children. Available: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430> [Accessed 19 August 2008]. 2007. Medical Research Council.  
Reference Type: Electronic Citation  
Abstract: This document was revised in 2007.
5. Human Rights Act 1998. Available: [http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980042\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_1) [Accessed 19 August 2008]. 1998. Office of Public Sector Information.  
Reference Type: Electronic Citation
6. Race Relations Act 1976 (Revised). Available: [http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1976/cukpga\\_19760074\\_en\\_1](http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1976/cukpga_19760074_en_1) [Accessed 19 August 2008]. 2006. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: The Race Relations Act 1976 was amended by the Race Relations (Amendment) Act 2000
7. Employment Act 2002. Available: [http://www.opsi.gov.uk/acts/acts2002/ukpga\\_20020022\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts2002/ukpga_20020022_en_1.htm) [Accessed 05 September 2008]. 2002. Office of Public Sector Information.
8. Disability Discrimination Act 2005. Available: [http://www.opsi.gov.uk/acts/acts2005/ukpga\\_20050013\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts2005/ukpga_20050013_en_1.htm) [Accessed 05 September 2008]. 2005. Office of Public Sector Information.  
Reference Type: Electronic Citation
9. Equality and Human Rights Commission. Available: <http://www.equalityhumanrights.com/> [Accessed 19 August 2008]. 2008. Equality and Human Rights Commission.  
Reference Type: Electronic Citation  
Abstract: Explanatory guidance
10. Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine. Available: <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=8&DF=7/24/2008&CL=ENG> [Accessed 19 August 2008]. 2002. Council of Europe  
Reference Type: Electronic Citation
11. Ethical Principles for Medical Research Involving Human Subjects. Available: <http://www.wma.net/e/policy/pdf/17c.pdf> [Accessed 19 August 2008]. 2002. World Medical Association Declaration of Helsinki.  
Reference Type: Electronic Citation
12. Ethics and Research on Human Subjects: International Guidelines. Bankowski, Z. Available: [http://www.cioms.ch/frame\\_publications.htm](http://www.cioms.ch/frame_publications.htm) [Accessed 19 August 2008]. 1991. Council for International Organisations of Medical Sciences.  
Reference Type: Electronic Citation  
Notes: 1991. ISBN 92 9036 048 8. Sw.fr. 6.
13. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Bankowski, Z. and B. Available: [http://www.cioms.ch/frame\\_publications.htm](http://www.cioms.ch/frame_publications.htm) [Accessed 19 August 2008]. 1993. Council for International Organisations of Medical Sciences .  
Reference Type: Electronic Citation

Notes: 1993. ISBN 92 9036 056 9. Sw.fr. 10.

14. The official Declaration of Helsinki (as revised). Available:  
<http://www.wma.net/e/policy/b3.htm> [Accessed 19 August 2008]. 2001. The World Medical Association.  
Reference Type: Electronic Citation  
Abstract: After three years of consultation and deliberation, the 52nd WMA General Assembly unanimously approved a revised Declaration of Helsinki. This is only the fifth time that this policy has been amended since its first adoption in 1964. Notes of clarification were added in 2002 and 2004.
15. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Available:  
[http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm) [Accessed 19 August 2008]. 2002. Council for International Organizations of Medical Sciences.  
Reference Type: Electronic Citation
16. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Available: <http://conventions.coe.int/treaty/en/treaties/html/164.htm> [Accessed 19 August 2008]. 1997. Council of Europe.  
Reference Type: Electronic Citation
17. The Mental Capacity Act and research. Available:  
[http://www.dh.gov.uk/en/SocialCare/Deliveringadultsocialcare/MentalCapacity/MentalCapacityAct2005/DH\\_078789](http://www.dh.gov.uk/en/SocialCare/Deliveringadultsocialcare/MentalCapacity/MentalCapacityAct2005/DH_078789) [Accessed 19 August 2008]. 2007. Department of Health.  
Reference Type: Electronic Citation
18. The Mental Capacity Act 2005 Code of Practice. Available:  
<http://www.dca.gov.uk/menincap/legis.htm#codeofpractice> [Accessed 19 August 2008]. 2005. Office of Public Sector Information.  
Reference Type: Electronic Citation
19. Adults with Incapacity (Scotland) Act 2000. Available:  
[http://www.opsi.gov.uk/legislation/scotland/acts2000/asp\\_20000004\\_en\\_1](http://www.opsi.gov.uk/legislation/scotland/acts2000/asp_20000004_en_1) [Accessed 19 August 2008]. 2000. Office of Public Sector Information.  
Reference Type: Electronic Citation
  - 19.1 Scottish Statutory Instrument 2007 No. 22 The Adults with Incapacity (Ethics Committee) (Scotland) Amendment Regulations 2007. Available:  
[http://www.opsi.gov.uk/legislation/scotland/ssi2007/ssi\\_20070022\\_en\\_1](http://www.opsi.gov.uk/legislation/scotland/ssi2007/ssi_20070022_en_1) [Accessed 19 August 2008]. 2007. Office of Public Sector Information.  
Reference Type: Electronic Citation
  - 19.2 Scottish Statutory Instrument 2002 No. 190 The Adults with Incapacity (Ethics Committee) (Scotland) Amendment Regulations 2002. Available:  
<http://www.opsi.gov.uk/legislation/scotland/ssi2002/20020190.htm> [Accessed 19 August 2008]. 2002. Office of Public Sector Information.  
Reference Type: Electronic Citation
20. Mental Capacity Act 2005. Available:  
[http://www.opsi.gov.uk/acts/acts2005/ukpga\\_20050009\\_en\\_1](http://www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1) [Accessed 19 August 2008]. 2005. Office of Public Sector Information.  
Reference Type: Electronic Citation
  - 20.1 Statutory Instrument 2006 No. 2810 The Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006. Available:  
<http://www.opsi.gov.uk/si/si2006/20062810.htm> [Accessed 19 August 2008]. 2007. Office of Public Sector Information.  
Reference Type: Electronic Citation

- 20.2 Statutory Instrument 2007 No. 833 (W.71) The Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007. Available: [http://www.opsi.gov.uk/legislation/wales/wsi2007/wsi\\_20070833\\_en\\_1](http://www.opsi.gov.uk/legislation/wales/wsi2007/wsi_20070833_en_1) [Accessed 19 August 2008]. 2007. Office of Public Sector Information. Reference Type: Electronic Citation
- 20.3 Statutory Instrument 2006 No. 2883 The Mental Capacity Act 2005 (Independent Mental Capacity Advocates) (Expansion of Role) Regulations 2006. Available: <http://www.opsi.gov.uk/si/si2006/20062883.htm> [Accessed 19 August 2008]. 2006. Office of Public Sector Information. Reference Type: Electronic Citation
- 20.4 Statutory Instrument 2006 No. 1832 The Mental Capacity Act 2005 (Independent Mental Capacity Advocates) (General) Regulations 2006. Available: <http://www.opsi.gov.uk/si/si2006/20061832.htm> [Accessed 19 August 2008]. 2006. Office of Public Sector Information. Reference Type: Electronic Citation
- 20.5 Statutory Instrument 2007 No. 853 (W.77) The Mental Capacity Act 2005 (Independent Mental Capacity Advocates) (Wales) Regulations 2007. Available: [http://www.opsi.gov.uk/legislation/wales/wsi2007/wsi\\_20070852\\_en\\_1](http://www.opsi.gov.uk/legislation/wales/wsi2007/wsi_20070852_en_1) [Accessed 19 August 2008]. 2007. Office of Public Sector Information. Reference Type: Electronic Citation
- 20.6 Statutory Instrument 2007 No. 679 (W.77) The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007. Available: [http://www.opsi.gov.uk/si/si2007/uksi\\_20070679\\_en\\_1](http://www.opsi.gov.uk/si/si2007/uksi_20070679_en_1) [Accessed 19 August 2008]. 2007. Office of Public Sector Information. Reference Type: Electronic Citation
- 20.7 Statutory Instrument 2007 No. 837 (W.72) The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007. Available: [http://www.opsi.gov.uk/legislation/wales/wsi2007/wsi\\_20070837\\_en\\_1](http://www.opsi.gov.uk/legislation/wales/wsi2007/wsi_20070837_en_1) [Accessed 19 August 2008]. 2007. Office of Public Sector Information. Reference Type: Electronic Citation
- 21 MRC Ethics Guide: Medical research involving adults who cannot consent. Available: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002409> [Accessed 19 August 2008]. 2007. Medical Research Council. Reference Type: Electronic Citation

## **B2 Other DH Requirements**

### **B2.1 Animals**

1. The Animal Procedures Committee. Available: <http://www.apc.gov.uk/index.htm> [Accessed 19 August 2008]. 2002. Reference Type: Electronic Citation  
 Abstract: The Animal Procedures Committee (APC) is an advisory, Non-Departmental Public Body established and appointed under the terms of sections 19 and 20 of the Animals (Scientific Procedures) Act 1986. Their role is to advise the Home Secretary on matters concerned with the Act and his functions under it, relating to any experimental or other scientific procedures applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm; and also, to examine other related subjects we consider worthy of further study.  
 Membership of the Committee reflects a wide range of views on animal use, from those who use animals in scientific experiments to those who oppose such use. All members of the committee do, however, share a common concern for the welfare of the animals bred



for or used in scientific procedures, and in considering any matter, will have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

### **B2.1.1 Peer Review**

1. NHS Support for Science – Peer review of data and information systems. Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4010658](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4010658) [Accessed 19 August 2008]. 2002. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Information for NHS organisations invited for review:  
The aim of the peer review of data and information systems is to share good practice and to promote continuous improvement in the quality of information held for research management and funding. It will also provide reassurance that funding is based on robust information.  
The funding system for NHS Support for Science relies on information required for good research governance. The peer review process will give particular attention to information weaknesses that undermine research governance.  
The initial peer review process for 2002 will focus on enabling the NHS and the Department of Health (DH) to gain a better understanding of how the NHS Support for Science data collection exercise in October 2001 was completed. This will help to improve the accuracy, validity, consistency and completeness of future data submitted to inform NHS Support for Science allocations and to identify information, support and systems development needs to underpin this. The initial process is intended to be mostly qualitative. It will encourage constructive comments from the reviewed organisations as much as exploring the processes and systems followed. The initial process for 2002 was the result of collaborative work between the NHS R&D Forum and the Department of Health. This joint approach will continue both in the production of the outputs from the 2002 process and in the development of a longer-term peer review process for NHS Support for Science for future years.
2. European Convention for the Protection of Vertebrate Animals Use for Experimental and Other Scientific Purposes (1986). Available: [http://eelink.net/~asilwildlife/eu\\_ani\\_vert.html](http://eelink.net/~asilwildlife/eu_ani_vert.html) [Accessed 19 August 2008]. 1986. Council of Europe.  
Reference Type: Electronic Citation  
Abstract: 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.
3. Committee on Standards in Public Life. Available: <http://www.public-standards.gov.uk> [Accessed 19 August 2008]. 2002. Committee on Standards in Public Life (the Wicks Committee).  
Reference Type: Electronic Citation  
Abstract: The first report covers appointments and openness, is relevant to the appointment of members of Non Departmental Government Bodies.
4. The World Association of Medical Editors (WAME). Available: <http://www.wame.org/> [Accessed 19 August 2008]. 2002. The World Association of Medical Editors (WAME).  
Reference Type: Electronic Citation  
Abstract: Site has references and links on Peer review in editing and publication
5. Government Office for Science. Available: <http://www.dius.gov.uk/policy/science.html> [Accessed 19 August 2008]. 2000. The Department for Innovation, Universities and Skills (DIUS)  
Reference Type: Electronic Citation  
Abstract: The Government Office for Science, headed by the Government Chief Scientific Adviser (GCSA) is located within DIUS.
6. Council for Science and Technology. Available: <http://www.cst.gov.uk/> [Accessed 19 August 2008]. 2002. Council for Science and Technology.

Reference Type: Electronic Citation

Abstract: The Council for Science and Technology (CST) is the UK government's top-level independent advisory body on science and technology policy issues.

7. MRC Reviewers Handbook

Available: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003184>

[Accessed 19 August 2008]. 2007. Medical Research Council.

Reference Type: Electronic Citation

8. Medical Research Council. Principles in the Assessment and Conduct of Medical Research and Publishing Results. *Medical Research Council* 2002.

Abstract: Key principles of peer review

Notes: Not on the Web, print only

### B2.1.2 Other

1. Fund for the Replacement of Animals in Medical Experiments. Available:

<http://www.frame.org.uk/> [Accessed 19 August 2008]. 2002. Fund for the Replacement of Animals in Medical Experiments.

Reference Type: Electronic Citation

Abstract: Provides information on alternatives and links to research references on alternatives.

2. MRC Policy and Guidance: Use of Animals in Medical Research. Available:

<http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/UseofAnimalsinMedicalResearch/index.htm> [Accessed 19 August 2008]. 2002. Medical Research Council (MRC)

Reference Type: Electronic Citation

3. The Boyd Group. Available: <http://www.boyd-group.demon.co.uk/> [Accessed 19 August 2008]. 2002. The Boyd Group.

Reference Type: Electronic Citation

Abstract: The Boyd Group has published guidance on ethical review of research involving animals; refinement, genetic engineering, animal welfare and ethics, and the use of nonhuman primates in research and testing

4. The Laboratory Animal Science Association . Available: <http://www.lasa.co.uk/> [Accessed 19 August 2008]. 2002. The Laboratory Animal Science Association .

Reference Type: Electronic Citation

Abstract: Good practice guidelines published.

5. The Universities Federation for Animal Welfare (UFAW) . Available:

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

[Accessed 19 August 2008]. 2002. The Universities Federation for Animal Welfare (UFAW).

Reference Type: Electronic Citation

Abstract: Produces publications on animal welfare and links to other organisations.



## B2.2 Codes of Professional Conduct

### B2.2.1 The General Medical Council

1. Guidance on good practice. Available: [http://www.gmc-uk.org/guidance/good\\_medical\\_practice/index.asp](http://www.gmc-uk.org/guidance/good_medical_practice/index.asp) [Accessed 19 August 2008]. 2006. The General Medical Council.  
Reference Type: Electronic Citation  
Abstract: Specific guidance on good practice in medical research.

### B2.2.2 Research Councils

1. Biotechnology and Biological Sciences Research Council. Available: <http://www.bbsrc.ac.uk/> [Accessed 19 August 2008]. 2002. The Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation  
Abstract: BBSRC has produced statements on best practice, to prevent allegations of fraud or scientific misconduct.
2. Engineering and Physical Sciences Research Council (EPSRC). Available: <http://www.epsrc.ac.uk/> [Accessed 19 August 2008]. 2002. Engineering and Physical Sciences Research Council (EPSRC).  
Reference Type: Electronic Citation  
Abstract: EPSRC has produced statements on best practice, to prevent allegations of fraud or scientific misconduct.
3. Medical Research Council. Available: <http://www.mrc.ac.uk/> [Accessed 19 August 2008]. 2002. Medical Research Council.  
Reference Type: Electronic Citation  
Abstract: MRC has produced statements on best practice, to prevent allegations of fraud or scientific misconduct.

### B2.2.3 Others

1. The Health and Safety Executive (HSE). Available: <http://www.hse.gov.uk/> [Accessed 19 August 2008]. 2002. The Health and Safety Executive (HSE).  
Reference Type: Electronic Citation  
Abstract: 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. UK Research Integrity Office (UK RIO). Available: [http://www.hero.ac.uk/uk/research/good\\_practice\\_for\\_new\\_researchers/uk\\_research\\_integrity\\_office\\_ukrio\\_cfm](http://www.hero.ac.uk/uk/research/good_practice_for_new_researchers/uk_research_integrity_office_ukrio_cfm) [Accessed 27 August 2008]. 2006 Higher Education Research Opportunities (HERO)  
Reference Type: Electronic Citation  
UK RIO covers misconduct in medical research and biomedical sciences and also working to develop a code of practice for staff working in the NHS, universities and the health industry.
3. The Engineering and Physical Sciences Research Council (EPSRC). Available: <http://www.epsrc.ac.uk/> [Accessed 19 August 2008]. 2002. The Engineering and Physical Sciences Research Council (EPSRC).  
Reference Type: Electronic Citation  
Abstract: The EPSRC also supports a number of career development schools for postdoctoral contract researchers.

4. Institute of Physics (IOP). Available: <http://www.iop.org/> [Accessed 19 August 2008]. 2002. Institute of Physics (IOP).  
Reference Type: Electronic Citation  
Abstract: The IOP runs courses or training events for researchers.
5. Association of the British Pharmaceutical Industry (ABPI) Publications. Available: <http://www.abpi.org.uk/category.asp?Category=4> [Accessed 27 August 2008]. 2007. ABPI.  
Reference type: Electronic Citation  
Abstract: Various guidelines related to standards in clinical research

#### **B2.2.4 Links**

1. Code of Conduct and Code of Accountability for NHS Boards (2<sup>nd</sup> Revised Edition). Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4116281](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4116281) [Accessed 19 August 2008]. 2004. Department of Health.  
Reference Type: Electronic Citation
2. Department for Environmental Food and Rural Affairs (DEFRA). Available: <http://www.defra.gov.uk/animalh/welfare/default.htm> [Accessed 19 August 2008]. 2008. DEFRA.  
Reference Type: Electronic Citation  
Abstract: Code of Practice for the housing and care of animals used in scientific procedures.
3. Good Clinical Practice (GCP). Available: <http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/index.htm> [Accessed 19 August 2008]. 2008. Medicines and Healthcare products Regulatory Agency  
Reference Type: Electronic Citation
4. Good Manufacturing Practice. Available: <http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodManufacturingandDistributionPractice/index.htm> [Accessed 19 August 2008]. 2008. Medicines and Healthcare products Regulatory Agency  
Reference Type: Electronic Citation  
Abstract: 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
5. Good research practice, ethics and integrity. Available: [http://www.hero.ac.uk/uk/research/good\\_practice\\_for\\_new\\_researchers/overview.cfm](http://www.hero.ac.uk/uk/research/good_practice_for_new_researchers/overview.cfm) [Accessed 19 August 2008]. 2002. Higher Education & Research Opportunities (HERO).  
Reference Type: Electronic Citation  
Abstract: The Higher Educational and Research Opportunities site provides a valuable set of links targeted to new researchers.
6. Medical Research Council. Available: <http://www.mrc.ac.uk/> [Accessed 19 August 2008]. 2008. Medical Research Council.  
Reference Type: Electronic Citation  
Abstract: Advice aiming to improve the design and management of clinical trials is available from several sources, e.g. Medical Research Council
7. Good Research Practice (2000). Available: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002415>. [Accessed 19 August 2008]. 2000. Medical Research Council (MRC).  
Reference Type: Electronic Citation

8. UK Trial Managers Network. Available: <http://www.tmn.ac.uk/> [Accessed 19 August 2008]. 2008. UK Trial Managers Network.  
Reference Type: Electronic Citation  
Abstract: Advice aiming to improve the design and management of clinical trials is available from several sources, e.g. UK Trial Managers Network
  
9. Rules of Professional Conduct (2nd Edition). Available: [http://www.csp.org.uk/director/libraryandpublications/publications.cfm?item\\_id=74C87598F86517AD88719CD50B3A718A](http://www.csp.org.uk/director/libraryandpublications/publications.cfm?item_id=74C87598F86517AD88719CD50B3A718A) [Accessed 19 August 2008]. 2002. The Chartered Society of Physiotherapy.  
Reference Type: Electronic Citation  
Abstract: CSP rules of professional conduct (2<sup>nd</sup> Edition) – (Priced £5)
  
10. Safeguarding Good Scientific Practice. Available: [http://www.bbsrc.ac.uk/publications/policy/good\\_scientific\\_practice.html](http://www.bbsrc.ac.uk/publications/policy/good_scientific_practice.html) [Accessed 19 August 2008]. 2006. Biotechnology and Biological Sciences Research Council (BBSRC).  
Reference Type: Electronic Citation  
Abstract: BBSRC statement on ensuring good scientific practice in research.
  
11. The British Sociological Association. Available: <http://www.britsoc.co.uk/> [Accessed 19 August 2008]. 2008. The British Sociological Association.  
Reference Type: Electronic Citation  
Abstract: Guidelines on conduct, ethical practice and related issues.
  
12. British Psychological Society. The Code of Ethics and Conduct. Available: [http://www.bps.org.uk/downloadfile.cfm?file\\_uuid=5084A882-1143-DFD0-7E6C-F1938A65C242&ext=pdf](http://www.bps.org.uk/downloadfile.cfm?file_uuid=5084A882-1143-DFD0-7E6C-F1938A65C242&ext=pdf) [Accessed 19 August 2008]. 2006. British Psychological Society.  
Reference Type: Electronic Citation
  
13. Health and Safety Executive (HSE) . Available: <http://www.hse.gov.uk/> [Accessed 19 August 2008]. 2008. Health and Safety Executive (HSE).  
Reference Type: Electronic Citation  
Abstract: Government agency responsible for ensuring health and safety work
  
14. Implementation of Peer Review. Available: <http://www.amrc.org.uk/homepage/?Nav=814,484,990> [Accessed 19 August 2008]. 2005. Association of Medical Research Charities.  
Reference Type: Electronic Citation
  
15. Cancer Research UK & UCL Cancer Trials Centre. Available: <http://www.ucl.ac.uk/cancertrials/> [Accessed 19 August 2008]. 2002. Cancer Research UK & UCL Cancer Trials Centre  
Reference Type: Electronic Citation
  
16. Institute of Physics. Available: <http://www.iop.org/> [Accessed 19 August 2008]. 2002. Institute of Physics (IOP).  
Reference Type: Electronic Citation  
Abstract: Offers a range of training courses for physics researchers
  
17. The Market Research Society. Available: <http://www.marketresearch.org.uk/> [Accessed 19 August 2008]. 2008. The Market Research Society.  
Reference Type: Electronic Citation  
Abstract: Site includes Code of Conduct, MRS's best practice guides including employee research, qualitative research, data collection, and research with children and young people.

### B2.3 Clinical Trials

1. Medicines for Human Use (Clinical Trials) Regulations 2004. Available: <http://www.opsi.gov.uk/si/si2004/20041031.htm> [Accessed 17 August 2008]. 2004. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 Available: <http://www.opsi.gov.uk/si/si2006/20061928.htm> [Accessed 17 August 2008]. 2006. Office of Public Sector Information.  
Reference Type: Electronic Citation
3. The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006. Available: <http://www.opsi.gov.uk/SI/si2006/20062984.htm> [Accessed 17 August 2008]. 2006. Office of Public Sector Information.  
Reference Type: Electronic Citation
4. The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008. Available: [http://www.opsi.gov.uk/si/si2008/uksi\\_20080941\\_en\\_1](http://www.opsi.gov.uk/si/si2008/uksi_20080941_en_1) [Accessed 17 August 2008]. 2008. Office of Public Sector Information.  
Reference Type: Electronic Citation
5. Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 1996 - Statutory Rule 1996 No. 250. Available: [http://www.opsi.gov.uk/sr/sr1996/Nisr\\_19960250\\_en\\_1.htm](http://www.opsi.gov.uk/sr/sr1996/Nisr_19960250_en_1.htm) [Accessed 17 August 2008]. 1996. Office of Public Sector Information.  
Reference Type: Electronic Citation  
Abstract: Laboratories that intend carrying out genetic modification are required to register with the Health and Safety Executive.
6. EU directive on Good Clinical Practice in clinical trials. Available: <http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf> [Accessed 17 August 2008]. 2001. European Organisation for Research and Treatment of Cancer.  
Reference Type: Electronic Citation
7. European Union Pharmaceutical Legislation. Volume 10. Available: [http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10\\_en.htm](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm) [Accessed 17 August 2008]. 2008. European Union.  
Reference Type: Electronic Citation  
Abstract: Volume 10 of the publication "The rules governing medicinal products in the European Union" contains guidance documents applying to clinical trials.
8. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Available: <http://www.ich.org/> [Accessed 17 August 2008]. 2002. The ICH Secretariat.  
Reference Type: Electronic Citation  
Abstract: 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)
9. Research Governance in Health and Social Care: NHS permission for R&D involving NHS Patients. Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4122563](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4122563) [Accessed 17 August 2008]. 2004. Department of Health  
Reference Type: Electronic Citation
10. Inspection: The United Kingdom Good Laboratory Practice Monitoring Authority (UK GLP

MA). Available:  
<http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007566.pdf>  
[Accessed 17 August 2008]. 2002. Medicines and Healthcare products Regulatory Agency.  
Reference Type: Electronic Citation

11. Clinical trials: Arrangements for trials which had an exemption or certificate. Available:  
<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Trialsapprovedbefore1May2004/index.htm> [Accessed 17 August 2008]. 2004. Medicines and Healthcare Products Regulatory Agency.  
Reference Type: Electronic Citation

12. Radiation. Available:  
<http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebContentAreaLanding/Page/1153822623782?p=1153822623782> [Accessed 17 August 2008]. 2002. Health Protection Agency.  
Reference Type: Electronic Citation  
Abstract: Chemical and environmental division provides laboratory and technical services; runs training courses; provides expert information and has a significant advisory role in the UK.

13. Approval for Research Involving Ionising Radiation. Available:  
<http://www.nres.npsa.nhs.uk/EasysiteWeb/getresource.axd?AssetID=4781&type=Full&servicetype=Attachment> [Accessed 17 August 2008]. 2006. National Research Ethics Service.  
Reference Type: Electronic Citation

14. Health and Safety Executive. Available: <http://www.hse.gov.uk/index.htm> [Accessed 17 August 2008]. 2002. Health and Safety Executive.  
Reference Type: Electronic Citations  
Abstract: Laboratories that intend carrying out genetic modification are required 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 at H&SE.

15. The Approved List of Biological Agents Available:  
<http://www.hse.gov.uk/pubns/misc208.pdf> [Accessed 17 August 2008]. 2004. Health and Safety Executive.  
Reference Type: Electronic Citation  
Abstract: Institutions/Departments proposing to accommodate projects involving the use of dangerous pathogens must comply with the safeguards recommended.

### **B2.3.1 Registration of Trials**

1. International Clinical Trials Registry Platform (ICTRP). Available:  
<http://www.who.int/ictpr/network/trds/en/index.html> [Accessed 29 August 2008]. 2008. World Health Organisation (WHO)  
Reference Type: Electronic Citation

2. UK PubMed Central. Available:  
<http://www.nihr.ac.uk/files/pdfs/OpenAccessPolicyStatement.pdf> [Accessed 29 August 2008]. 2007. Department of Health.  
Reference Type: Electronic Citation  
Abstract: In association with a number of other UK biomedical funders, the Department of Health is a partner in an initiative led by the Wellcome Trust to establish a UK version of PubMedCentral (UKPMC) [www.ukpmc.ac.uk](http://www.ukpmc.ac.uk) . Launched in January 2007, the aim of this initiative is to create a stable, permanent and free-to-access digital archive of the full text, peer-reviewed research publications (and datasets) that arise from research funded through the National Institute for Health Research (NIHR) by the DH, the Wellcome Trust and other members of the UKPMC Funders Group.

3. UKCRN Portfolio Database. Available: <http://portal.nihr.ac.uk/Pages/Portfolio.aspx> [Accessed 18 August 2008]. 2008. National Institute for Health Research.  
Reference Type: Electronic Citation
4. NRES project to improve public reporting of clinical trials underway. Available: <http://www.nres.npsa.nhs.uk/news-and-publications/news/project-to-improve-public-reporting-of-clinical-trials-underway/> [Accessed 27 August 2008]. 2008. NRES  
Reference Type: Electronic Citation  
Abstract: NRES, the James Lind Alliance and the Department of Health have launched a project to reconcile the NRES Research Ethics Database with the two public clinical trial registers (International Standard Randomised Controlled Trial Number Register and ClinicalTrials.gov) to contribute to improving public reporting of clinical trials
5. Registration of Randomised Clinical Trials. Available: <http://www.controlled-trials.com/> [Accessed 17 August 2008]. 2008. Current Controlled Trials.  
Reference Type: Electronic Citation  
Abstract: Registration of RCTs 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 metaRegister contains details of some 6000 trials supported by 18 agencies.
6. ClinicalTrials.gov. Available: <http://clinicaltrials.gov> [Accessed 17 August 2008]. 2002. Clinical Trials.gov.  
Reference Type: Electronic Citation  
Abstract: In the USA, ClinicalTrials.gov provides patients, families and the public with information about clinical research studies.
7. Guidance for Industry - Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions. Available: <http://www.fda.gov/cder/guidance/4856FNL.PDF> [Accessed 17 August 2008]. 2002. Food and Drug Administration.  
Reference Type: Electronic Citation
8. Reporting of Trials. Available: <http://www.ama-assn.org> [Accessed 17 August 2008]. 2008. The Journal of the American Medical Association.  
Reference Type: Electronic Citation  
Abstract: Trials should be reported according to principles laid out in the CONSORT statement
9. The CONSORT statement. Available: <http://www.consort-statement.org/> [Accessed 17 August 2008]. 2008. The CONSORT statement.  
Reference Type: Electronic Citation  
Abstract: Reporting of Trials - Trials should be reported according to principles laid out in the CONSORT statement

#### **B2.4 General Practice**

1. Royal College of General Practitioners Good Medical Practice for General Practitioners Available: [http://www.rcgp.org.uk/PDF/GMP\\_web.pdf](http://www.rcgp.org.uk/PDF/GMP_web.pdf) [Accessed 28 August 2008]. 2008. Royal College of General Practitioners.  
Reference Type: Electronic Citation  
Abstract: This was updated in 2008. Research is covered in the probity section

#### **B2.5 Social Care and Science Research**

1. Health and Social Care Act 2008. Available:



- [http://www.opsi.gov.uk/acts/acts2008/ukpga\\_20080014\\_en\\_1](http://www.opsi.gov.uk/acts/acts2008/ukpga_20080014_en_1) [Accessed 18 August 2008]. 2008. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. Report from the Planning Group on Ethics Review in Social Care Research, Jan Pahl, with link to DH response at end of section  
Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_081429](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081429) [Accessed 27 August 2008]. 2007. Department of Health.  
Abstract: This report outlines the recommendations of the Planning Group on Ethics Review in Social Care Research set up by the Department of Health  
Reference Type: Electronic Citation
  3. National Social Care Research Ethics Committee  
Available: [http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/Researchgovernance/DH\\_081435](http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/Researchgovernance/DH_081435) [Accessed 27 August 2008]. 2007. Department of Health.  
Abstract: The Research Governance Framework for Health and Social Care (RGF) sets out principles of good practice and summarises the responsibilities of the partners in research across health and social care. It draws attention to systems that care organisations and others should establish. A care organisation requires evidence that any study affecting its duties has the favourable opinion of an appropriate research ethics committee.  
Reference Type: Electronic Citation
  4. Research Register for Social Care. Available: <http://www.researchregister.org.uk/> [Accessed 29 August 2008]. 2008.  
Reference Type: Electronic Citation
  5. Research in social care: guidelines for researchers  
Available: <http://www.rdinfo.org.uk/SCFlowchart/FlowchartSC.html> [Accessed 27 August 2008]. 2007. National Institute for Health Research.  
Reference Type: Electronic Citation
  6. Economic and Social Research Council Research Funding Guide  
Available: [http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/opportunities/research\\_funding/](http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/opportunities/research_funding/) [Accessed 17 August 2008]. 2008. Economic and Social Research Council.  
Reference Type: Electronic Citation  
Abstract: The ESRC's funding regulations including not only details required under ESRC funding but also useful guidance on research ethics and confidentiality.
  7. Social Services Research Group  
Available: <http://www.ssrq.org.uk> [Accessed 17 August 2008]. 2008.  
Reference Type: Electronic Citation  
Abstract: The Social Services Research Group website: the network for research, information, planning & evaluation in social, housing & health services, including Guidelines for Good Practice in Research and Collaborative Research.

## B2.6 Samples and collections

1. Human Tissue Act 2004. Available:  
Available: [http://www.opsi.gov.uk/acts/acts2004/ukpga\\_20040030\\_en\\_1](http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1) [Accessed 17 August 2008]. 2004. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. The Human Organ Transplants Act 1989. Available:  
Available: [http://www.opsi.gov.uk/acts/acts1989/ukpga\\_19890031\\_en\\_1](http://www.opsi.gov.uk/acts/acts1989/ukpga_19890031_en_1) [Accessed 17 August 2008]. 1989. Office of Public Sector Information.  
Reference Type: Electronic Citation
3. The Anatomy Regulations 1988  
Available: [http://www.opsi.gov.uk/si/si1988/Uksi\\_19880044\\_en\\_1.htm](http://www.opsi.gov.uk/si/si1988/Uksi_19880044_en_1.htm) [Accessed 17 August 2008]. 1988.  
Reference Type: Electronic Citation  
Abstract: Legislation covering human cadavers donated to departments of anatomy in British Medical Schools for the study or teaching of, or for research into, anatomy.
4. Code of Practice – Post mortem examination.  
Available:  
[http://www.hta.gov.uk/db/documents/2006-07-04\\_Approved\\_by\\_Parliament\\_-\\_Code\\_of\\_Practice\\_3\\_-\\_Post\\_Mortem.pdf](http://www.hta.gov.uk/db/documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_3_-_Post_Mortem.pdf) [Accessed 17 August 2008]. 2006. Human Tissue Authority  
Reference Type: Electronic Citation
5. Code of Practice – The removal, storage and disposal of human organs and tissue.  
Available: [http://www.hta.gov.uk/db/documents/2006-07-04\\_Approved\\_by\\_Parliament\\_-\\_Code\\_of\\_Practice\\_5\\_-\\_Removal.pdf](http://www.hta.gov.uk/db/documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_5_-_Removal.pdf) [Accessed 17 August 2008]. 2006. Human Tissue Authority  
Reference Type: Electronic Citation
6. Medical Research Council  
Human Tissue and Biological Samples for use in Research - Operational and Ethical guidelines Available:  
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420> [Accessed 17 August 2008]. 2008. Medical Research Council.  
Reference Type: Electronic Citation  
Abstract: MRC guidance on ethical, legal and management issues concerning human tissue and biological samples for use in research.
7. 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
8. Nuffield Council on Bioethics  
Available: <http://www.nuffieldbioethics.org/home/> [Accessed 17 August 2008]. 2008.  
Nuffield Council on Bioethics.  
Reference Type: Electronic Citation  
Abstract: Human Tissue: Ethical and Legal Issues - Report published in April 1995. Conclusions and recommendations available on the website
9. UK National Culture Collection  
Available: <http://www.ukncc.co.uk/> [Accessed 17 August 2008]. 2008.  
Reference Type: Electronic Citation  
Abstract: 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.



10. European Collection of Cell Cultures  
Available: <http://www.ecacc.org.uk/> [Accessed 17 August 2008]. 2008.  
Reference Type: Electronic Citation  
Abstract: ECACC provides quality cell cultures to the academic community and industry, provides guidance on culture deposition and access.

## **B2.7 Statistics**

1. National Statistics  
White Paper "Building Trust in Statistics" (Stationery Office 0-10-144122-3)  
Abstract: 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.
2. Royal Statistical Society  
Code of professional conduct for its Fellows. Available:  
<http://www.rss.org.uk/main.asp?page=1875> [Accessed 17 August 2008]. 1993.  
Reference Type: Electronic Citation
3. Royal Statistical Society and the UK Data Archive (2002)  
Preserving & Sharing Statistical Material Available:  
<http://www.rss.org.uk/PDF/Archiving.pdf> [Accessed 17 August 2008]. 2002.  
Reference Type: Electronic Citation
4. American Statistical Association  
Ethical Guidelines for Statistical Practice  
Available: <http://www.amstat.org/profession/index.cfm?fuseaction=ethicalstatistics>  
[Accessed 17 August 2008]. 1999.  
Reference Type: Electronic Citation

## **B3 Other Established Standards**

### **B3.1 Sources of Research Information**

1. National Institute for Health Research  
National Institute for Health Research (NIHR) provide the support and facilities the NHS needs for first class Key facilities, including:
  - [Clinical research networks for England](#)
  - [Research Centres](#)
  - [Biomedical Research Units](#)
  - [Experimental medicine facilities](#)
  - [Technology platforms](#)
  - [Research Design Services](#)
  - [Collaborations for Leadership in Applied Health Research and Care \(CLAHRC\) \(previously known as Academic Health Centres of the Future\)](#)
  - [Flexibility and Sustainability Funding \(FSF\)](#)  
<http://www.nihr.ac.uk/infrastructure.aspx> [Accessed 26 August 2008]
2. Collaborating on Research Grants. Available:  
<http://www.epsrc.ac.uk/Business/OurApproach/WhoWorkWith.htm> [Accessed 17 August 2008]. 2002. The Engineering and Physical Sciences Research Council.  
Reference Type: Electronic Citation  
Abstract: Over 2000 organisations are collaborating on research or training funded by us. We work closely with other research councils on issues that cut across our remits, and

often jointly-fund activities. Research Councils UK has a steering group on knowledge transfer and economic impact to provide a consistent approach and sharing of best practice.

3. Equipment and Facilities. Available: <http://www.bbsrc.ac.uk/science/facilities/Welcome.html> [Accessed 17 August 2008]. 2002. Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation  
Abstract: National Facilities Supported by BBSRC, Equipment, Genomics database networks supported by funding from the GAIT initiative, Resources for the Investigating Gene Function initiative
4. ESRC Research Resources. Available: <http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/research/> [Accessed 17 August 2008]. 2001. Economic & Social Research Council.  
Reference Type: Electronic Citation
5. Funding Guide. Available: <http://www.epsrc.ac.uk/CMSWeb/Downloads/Publications/Other/FundingGuideApril2008.pdf> [Accessed 17 August 2008]. 2008. The Engineering and Physical Sciences Research Council.  
Reference Type: Electronic Citation
6. How to get funding. Available: <http://www.bbsrc.ac.uk/funding/index.html> [Accessed 17 August 2008]. 2002. Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation
7. Oasis Database. Available: <http://www.bbsrc.ac.uk/science/grants/> [Accessed 17 August 2008]. 2008. Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation  
Abstract: Oasis contains information on all research funded by the BBSRC at BBSRC sponsored Institutes, Universities and Higher Education Institutes and other research institutions. This database contains details of:  
Research Grants (for specified projects in universities, research institutes and research centres), Postgraduate studentships, Fellowships, Research Projects (at BBSRC-sponsored Institutes, Horticulture Research International and at the Edward Jenner Institute for Vaccine Research). These are funded by BBSRC's Competitive Strategic Grant (CSG) to the Institute and are listed on this database as CSG projects, and BBSRC-sponsored Institute staff publications (from 1987 onwards)
8. Research Grant Areas. Available: <http://www.bbsrc.ac.uk/funding/grants/index.html> [Accessed 17 August 2008]. 2008. Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation
9. Research Funding. Available: <http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/opportunities/> [Accessed 17 August 2008]. 2008. Economic & Social Research Council.  
Reference Type: Electronic Citation
10. Research Funding Guide. Available: <http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/opportunities/midcareer/fundingrules/> [Accessed 17 August 2008]. 2008. Economic & Social Research Council.  
Reference Type: Electronic Citation
11. ESRC Society Today Awards and Outputs Database. Available: <http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/AdvancedSearchPage2.aspx> [Accessed 22 August 2008]. 2008. Economic & Social Research Council.

Reference Type: Electronic Citation

Abstract: Previously Regard - An ERSC funded database service for social science research is archived here.

### **B3.2 Training for Research**

1. Education, Training and Development. Available: <http://www.dh.gov.uk/en/Managingyourorganisation/Humanresourcesandtraining/EducationTrainingandDevelopment/index.htm> [Accessed 17 August 2008]. 2008. Department of Health.  
Reference Type: Electronic Citation  
Abstract: This page contains a listing of the training available to NHS staff.
2. UK GRAD Programme. Available: <http://www.grad.ac.uk/> [Accessed 17 August 2008]. 2008. UK GRAD Programme.  
Reference Type: Electronic Citation
3. New training programmes for scientists conducting early drug studies in man  
From April 2008, the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom is enrolling scientists in the pharmaceutical industry, universities and regulatory authorities who have an interest in early clinical drug development. Available: <http://www.fpm.org.uk/humanpharm/> [Accessed 28 August 2008]  
Reference Type: Electronic Citation
4. NRES Researcher Training Day  
NHS Research Applications - Gaining Expertise, Understanding Expectation. Available: <http://www.nres.npsa.nhs.uk/news-and-publications/news/researcher-training-days-2008-2009/> [Accessed 28 August 2008]. 2008. NRES.  
Reference Type: Electronic Citation

### **B3.3 Other useful contacts**

1. Research Centres. Available: <http://www.bbsrc.ac.uk/organisation/institutes/> [Accessed 17 August 2008]. 2008. Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation  
Abstract: As well as funding research in universities, BBSRC provides funding for a number of research centres around the UK. BBSRC sponsors eight strategic research institutes, has set up six structural biology centres, and funds a number of other research centres.

## C. INFORMATION

### C1 Legislation and Regulation

1. Freedom of Information Act 2000 . Available:  
[http://www.opsi.gov.uk/acts/acts2000/ukpga\\_20000036\\_en\\_1](http://www.opsi.gov.uk/acts/acts2000/ukpga_20000036_en_1) [Accessed 16 August 2008]. 2000. Office of Public Sector Information..  
Reference Type: Electronic Citation  
Abstract: This Act sets out the requirements on public bodies (including Institutes of Higher Education) to provide information in response to requests from the public.
2. UKCRC Regulatory and Governance Advice Service. Available: <http://www.ukcrc-rgadvice.org/> [Accessed 29 August 2008]. 2008. UK Clinical Research Collaboration (UKCRC)  
Reference Type: Electronic Citation

### C2 Other Department of Health Requirements

1. UK PubMed Central. Available:  
<http://www.nihr.ac.uk/files/pdfs/OpenAccessPolicyStatement.pdf> [Accessed 29 August 2008]. 2007. Department of Health.  
Reference Type: Electronic Citation  
Abstract: In association with a number of other UK biomedical funders, the Department of Health is a partner in an initiative led by the Wellcome Trust to establish a UK version of PubMedCentral (UKPMC) [www.ukpmc.ac.uk](http://www.ukpmc.ac.uk) . Launched in January 2007, the aim of this initiative is to create a stable, permanent and free-to-access digital archive of the full text, peer-reviewed research publications (and datasets) that arise from research funded through the National Institute for Health Research (NIHR) by the DH, the Wellcome Trust and other members of the UKPMC Funders Group.
2. UK Clinical Research Network Portfolio Database. Available:  
[http://www.ukcrn.org.uk/index/clinical/portfolio\\_new.html](http://www.ukcrn.org.uk/index/clinical/portfolio_new.html) [Accessed 16 August 2008]. 2008.  
Reference Type: Electronic Citation
3. Collaboration in R&D between the NHS and other research funders. Available:  
[http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/NationalNHSRDFunding/DH\\_4001925](http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/NationalNHSRDFunding/DH_4001925) [Accessed 22 August 2008]. 2007. Department of Health.  
Reference Type: Electronic Citation  
Abstract: NHS Support for Science, NHS Priorities and Needs R&D Funding and Information to support NHS R&D funding systems. 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.
4. The National Research Register (Archived)  
<https://portal.nihr.ac.uk/Pages/NRRArchive.aspx> [Accessed 16 August 2008]. 2007. Update Software Ltd.  
Reference Type: Electronic Citation  
Abstract: National Research Register has been archived.

## C3 Other Established Standards

### C3.1 Research Data, Documentation and Archiving

1. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guideline, 1996. Available: <http://www.ich.org/LOB/media/MEDIA482.pdf> [Accessed 16 August 2008]. 2002. ICH.  
Reference Type: Electronic Citation  
Abstract: 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.
2. MRC Guidelines for Good Clinical Practice in Clinical Trials, 1998. Available: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416> [Accessed 16 August 2008]. 1998. Medical Research Council (MRC).  
Reference Type: Electronic Citation  
Abstract: 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.
3. Qualitative Data Service (Qualidata). Available: <http://www.esds.ac.uk/qualidata/about/introduction.asp> [Accessed 16 August 2008]. 2002. Economic and Social Data Service  
Reference Type: Electronic Citation  
Abstract: ESRC qualitative data archive resource centre (Qualidata). These guidelines relate to the preparation of qualitative data and any associated documentation for deposit in a repository via 'Qualidata'.
4. UKOLN. Available: <http://www.ukoln.ac.uk/projects/ebank-uk/docs/scientific-practice.doc> [Accessed 16 August 2008]. 1998. UKOLN  
Reference Type: Electronic Citation  
Abstract: A joint statement by the Director General of the Research Councils and the Chief Executives of the UK Research Councils  
Issued on 18 December 1998.
5. UK Data Archive. Available: <http://www.data-archive.ac.uk> [Accessed 16 August 2008]. 2008. University of Essex.  
Reference Type: Electronic Citation  
Abstract: The UK Data Archive (UKDA) is a resource centre that acquires, disseminates, preserves, and promotes the largest collection of digital data in the social sciences and humanities in the United Kingdom. Its primary aim is to support secondary use of quantitative and qualitative data for research and learning.  
The UKDA also houses two specialist units: the History Data Service (HDS) and Qualidata  
- Qualitative Data Service, and provides access to international data through cooperative agreements and memberships with archives around the world.

### C3.2 Publication

1. Intellectual Property. Available: [http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH\\_4002178](http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH_4002178) [Accessed 16 August 2008]. 2007. NHS Executive.  
Reference Type: Electronic Citation  
Abstract: Intellectual property issues are dealt with by The NHS as an Innovative Organisation: A Framework and Guidance on the Management of Intellectual Property in the NHS and three associated documents: The Management of Intellectual Property and Related Matters, Handling Inventions and Other Intellectual Property, and HSC 1998/106: Policy Framework for the Management of Intellectual Property Within the NHS Arising from Research and Development.
2. Commercialisation. Available:

- <http://www.bbsrc.ac.uk/business/commercialisation/> [Accessed 16 August 2008]. 2008. Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation  
Abstract: The BBSRC provide a range of links for researchers to explore the commercial exploitation opportunities for their research.
3. Walker, D. Heroes of dissemination. Available: [http://www.esrc.ac.uk/ESRCInfoCentre/Images/Heroes%20of%20dissemination\\_tcm6-5965.pdf](http://www.esrc.ac.uk/ESRCInfoCentre/Images/Heroes%20of%20dissemination_tcm6-5965.pdf) [Accessed 16 August 2008]. 2001. Economic & Social Research Council.  
Reference Type: Electronic Citation  
Abstract: Communication Best Practice Guide
  4. Guidelines 2000: Scientific Advice and Policy Making. Available: <http://www.berr.gov.uk/dius/science/page15432.html> [Accessed 16 August 2008]. 2000. Department for Business Enterprise and Regulatory Reform (BERR)  
Reference Type: Electronic Citation
  5. The Health Technology Assessment Programme. Available: <http://www.ncchta.org/research/index.shtml> [Accessed 16 August 2008]. 2008. National Coordinating Centre for Health Technology Assessment.  
Reference Type: Electronic Citation  
Abstract: The NCCHTA sets out standards for the reporting and publication of research funded through the NHS HTA Programme.
  6. The NHS Centre for Reviews and Dissemination. Undertaking systematic reviews of research on effectiveness. CRD Report No 4 (2nd edition) February 2001. Available: <http://www.york.ac.uk/inst/crd/publications.htm> [Accessed 16 August 2008]. 2008. NHS Centre for Reviews and Dissemination.  
Reference Type: Electronic Citation  
Abstract: This report is the CRD's guidance for carrying out or commissioning reviews. It contains guidance about reporting systematic reviews.
  7. The CONSORT Statement . Available: <http://www.consort-statement.org/> [Accessed 16 August 2008]. 2002. The CONSORT Group.  
Reference Type: Electronic Citation  
Abstract: The CONSORT statement is an important research tool that takes an evidence based approach to improve the quality of reports of randomised trials. CONSORT comprises a checklist and flow diagram to help improve the quality of reports of randomised controlled trials. It offers a standard way for researchers to report trials.

## D. HEALTH, SAFETY & EMPLOYMENT

### D1 Legislation and Regulation

1. UKCRC Regulatory and Governance Advice Service. Available: <http://www.ukcrc-rgadvice.org/> [Accessed 29 August 2008]. 2008. UK Clinical Research Collaboration (UKCRC)  
Reference Type: Electronic Citation

#### D1.1 General

1. Contract Research Report 268: Workplace Consultation on Health and Safety (Prepared by the Institute for Employment Studies). CRR 268/2000. 2000. HSE.  
Reference Type: Report
2. Council Directive 91/383/EEC of 25 June 1991 supplementing the measures to encourage improvements in the safety and health at work of workers with a fixed-duration employment relationship or a temporary employment relationship. 1991. LEGE.  
Reference Type: Generic
3. Employee Involvement in Health and Safety: Some Examples of Good Practice. 2001. HSL.  
Reference Type: Generic  
Notes: Document Number: WPS/00/03
4. Employers' policy statements for health and safety at work. Guidance Notes. 1981. HSENI .  
Reference Type: Generic  
Notes: Document Number: HSA 11
5. Health and Safety (Training for Employment) Regulations 1990. 1990. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1990/1380
6. Health and Safety Policy Statement and Guidance For Managers and Staff in the Department of Health. 1997. Department of Health.  
Reference Type: Generic  
Notes: Document Number: PS(CS)
7. HELA Local Authority Circular 84/2: Training - The Health and Safety (Training for Employment) Regulations 1990. 2000. HSE.  
Reference Type: Generic
8. HELA Local Authority Circular 38/3: HSW - Written Health and Safety Policy Statement. 2000. HSE.  
Reference Type: Generic  
Notes: Document Number: LAC 38/3
9. Proposal for a Council Recommendation concerning the Application of Legislation Governing Health and Safety at Work to Self-employed Workers. 2002. LEGE.  
Reference Type: Generic  
Notes: Document Number: COM (2002) 166 final
10. Department for Business Enterprise and Regulatory Reform (BERR). Available: <http://www.berr.gov.uk/> [Accessed 14 August 2008]. 2008. Department for Business Enterprise and Regulatory Reform (BERR)  
Reference Type: Electronic Citation



Abstract: DTI's guide to regulations including advice to small firms, employment rights and regulations affecting the biotechnology and chemical industry.

## D1.2 Specifics

### D1.2.1 Health and Safety

1. The Fire Precautions (Workplace) Regulations 1997 [SI 1997 No.1840]. Available: <http://www.opsi.gov.uk/si/si1997/19971840.htm> [Accessed 14 August 2008]. 1997. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. The Fire Precautions (Workplace) (Amendment) Regulations 1999 [SI 1999 No 1877]. Available: <http://www.opsi.gov.uk/si/si1999/19991877.htm> [Accessed 14 August 2008]. 1999. Office of Public Sector Information.  
Reference Type: Electronic Citation
3. Bradley, K. The point of law: Health and Safety at Work etc. Act 1974 explained. 2001. London, Office of Public Sector Information.  
Reference Type: Generic  
Abstract: A guide, in jargon free language, to the Health and Safety at Work Act 1974. Includes: the full text of each section of the Act with each sub section explained in plain English; annotations which discuss the application of the statute in practice; and an analysis of the impact of the recent legal decisions upon the interpretation of the Act. Also included are the Management of Health and Safety at Work Regulations 1999 that follow on from the Act. Aimed at health and safety managers and other professionals who have some responsibility for health and safety in the workplace.
4. Health and Safety Guidance for Managers and Staff in the Department of Health. 1997. Department of Health.  
Reference Type: Generic  
Notes: Document Number: MISC(97)42
5. Health and Safety Executive Health and Safety at Work etc Act 1974. Available: <http://www.hse.gov.uk/legislation/hswa.pdf> [Accessed 14 August 2008]. 2002. Health and Safety Executive.  
Reference Type: Electronic Citation  
Abstract: Site includes guides on law, regulations and employer's liability
6. Legislation Owned and Enforced by HSE and Local Authorities. Available <http://www.hse.gov.uk/legislation/enforced.htm> [Accessed 14 August 2008]. 2008. Health and Safety Executive.  
Reference Type: Electronic Citation
7. Guide to occupational health and safety management systems. Available: <http://www.bsi-global.com/en/Shop/Publication-Detail/?pid=000000000030087399> [Accessed 14 August 2008]. 2000. British Standards Institution.  
Reference Type: Electronic Citation  
Abstract: Provides non-certifiable guidance based on OH & S management systems, their design, implementation and integration within the overall management system based on risk management.  
Notes: Standard Number: OHSAS 18002:2000
8. Managing Safety the Systems Way. Available: <http://www.bsi-global.com/en/Shop/Publication-Detail/?pid=000000000030117212> [Accessed 14 August 2008]. 2004. British Standards Institution.  
Reference Type: Electronic Citation  
Abstract: Focuses on delivering OHSAS 18001: Occupational health and safety systems - specification, using BS 8800 and OHSAS 18002 (guidelines for 18001). Explains how the



various elements in developing an OH&S management system can be tackled and integrated into day-to-day management arrangements, and how the system can be maintained as OH&S evolves, responding to internal and external influences.

Notes: Standard Number: BIP 2050:2004

9. Occupational health and safety management systems. Specification. Available: <http://www.bsi-global.com/en/Shop/Publication-Detail/?pid=000000000030084888> [Accessed 14 August 2008]. 2004. British Standards Institution.  
Reference Type: Electronic Citation  
Notes: Standard Number: BS 8800:2004
10. Occupational health and safety management systems. Guidelines for the implementation of OHSAS 18001. Available: <http://www.bsi-global.com/en/Shop/Publication-Detail/?pid=000000000030180551> [Accessed 14 August 2008]. 2007. British Standards Institution.  
Reference Type: Electronic Citation  
Abstract: OHSAS 18002 seeks to explain the underlying principles of OHSAS 18001. It describes the intent, typical inputs, processes and typical outputs, against each requirement of OHSAS 18001, to aid in the understanding and implementation of OHSAS 18001. It does not create additional requirements to those specified in OHSAS 18001 nor does it prescribe mandatory approaches to the implementation of OHSAS 18001. It is intended to address occupational health and safety (OH&S) rather than product and services safety.  
Notes: Standard Number: OHSAS 18001:2007

### **D1.2.2 Good Laboratory Practice**

1. The Good Laboratory Practice Regulations 1999. Available: Available: <http://www.opsi.gov.uk/si/si1999/19993106.htm> [Accessed 14 August 2008]. 1999. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. Guide to UK GLP Regulations 1999. Available: <http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007566.pdf> [Accessed 14 August 2008]. 2000. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Compliance with the principles of Good Laboratory Practice (GLP) is a legal requirement for test facilities that undertake health and environmental safety studies, and some other testing, that will be submitted to regulatory authorities for the purposes of risk assessment. The principles of GLP, and the procedures implemented within the United Kingdom to monitor GLP compliance are contained within Statutory Instrument No. 1999/3106, the Good Laboratory Practice Regulations 1999 (the GLP Regulations). This Guide has been produced by the UK's GLP Monitoring Authority (GLPMA) and provides additional information on the UK GLP compliance programme. It should be read in conjunction with the GLP Regulations.
3. Laboratory fume cupboards. Recommendations for selection, use and maintenance. Available: <http://www.bsi-global.com/en/Shop/Publication-Detail/?pid=00000000000326516> [Accessed 14 August 2008]. 1994. British Standards Institution.  
Reference Type: Electronic Citation  
Notes: Standard Number: BS 7258-3:1994
4. Department of Health. The GLP Pocket-Book. London: Medicines Control Agency, 2000.  
Abstract: A pocket-sized publication containing the Good Laboratory Practice (GLP) Regulations 1999 and the Guide to the GLP Regulations, called The GLP Pocket-Book, is now available. This is a useful and valuable aid in applying the principles of GLP.

### D1.2.3 COSHH

1. Assessing and Managing Risks at Work from Skin Exposure to Chemical Agents - Guidance for Employers and Health and Safety Specialists. 2001. HSE.  
Reference Type: Generic  
Notes: Document Number: HSG 205
2. COSHH a brief guide to the regulations. Available:  
<http://www.hse.gov.uk/pubns/indg136.pdf> [Accessed 14 August 2008]. 2002. Health & Safety Executive.  
Reference Type: Electronic Citation
3. Health and Safety - The Notification of Installations Handling Hazardous Substances Regulations 1982. 1982. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1982/1357
4. Health and Safety - The Notification of New Substances Regulations 1993. 1993. LEGUK.  
Reference Type: Generic  
Notes: Document Number:SI 1993/3050
5. Health and Safety - The Health and Safety at Work etc. Act 1974 (Application to Environmentally Hazardous Substances) Regulations 1996. 1996. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1996/2075
6. Health and Safety - The Control of Substances Hazardous to Health (Amendment) Regulations 1996. 1996. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1996/3138
7. Health and Safety - The Control of Substances Hazardous to Health (Amendment) Regulations 1997. 1997. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1997/11
8. Health and Safety - The Control of Substances Hazardous to Health (Amendment) Regulations 1998. 1998. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1998/1357
9. Health and Safety - The Health and Safety at Work etc. Act 1974 (Application to Environmentally Hazardous Substances) (Amendment) Regulations 1999. 1999. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1999/40
10. Health and Safety - The Control of Substances - Hazardous to Health Regulations 1999. 1999. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1999/437
11. Health and Safety - The Notification of New Substances (Amendment) Regulations 2001. 2001. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 2001/1055
12. Health and Safety - The Batteries and Accumulators (Containing Dangerous Substances) (Amendment) Regulations 2001. 2001. LEGUK.  
Reference Type: Generic  
Notes: Document Number:SI 2001/2551

13. Health and Safety - The Notification of New Substances (Amendment) Regulations 2002. 2002. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 2002/2176
14. Health and Safety - The Health and Safety at Work etc. Act 1974 (Application to Environmentally Hazardous Substances) Regulations 2002. 2002. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 2002/282
15. Proposals for amending the Control of Substances Hazardous to Health Regulations 2002.  
Available: <http://www.hse.gov.uk/consult/condocs/cd184.pdf> [Accessed 14 August 2008].  
2002. Health & Safety Executive.  
Reference Type: Electronic Citation  
Abstract: This consultative document is issued by the Health and Safety Commission in compliance with its duty to consult, under sections 16(2) and 50(3) of the Health and Safety at Work etc. Act 1974, bodies which appear to it to be appropriate before submitting proposals for the making of Regulations and the issue of Approved Codes of Practice.

#### **D1.2.4 Genetically modified organisms**

1. Contained use of genetically modified organisms. Available: <http://www.hse.gov.uk/biosafety/gmo/> [Accessed 14 August 2008]. 2002. Health & Safety Executive.  
Reference Type: Electronic Citation
2. Health and Safety - The Genetically Modified Organisms (Contained Use) Regulations 2000. 2000. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 2000/2831
3. Health and Safety - The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002. 2002. LEGUK.  
Reference Type: Generic  
Notes: Document Number:SI 2002/63
4. Health & Safety Executive. Contained use of genetically modified organisms. Available: <http://www.hse.gov.uk/pubns/indg357.pdf> [Accessed 14 August 2008]. 2002. Health & Safety Executive.  
Reference Type: Electronic Citation

#### **D1.2.5 Radiation**

1. Safety Policy Directorate. Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR). Available: <http://www.hse.gov.uk/radiation/ionising/reppir.htm> [Accessed 14 August 2008]. 2002. Health & Safety Executive.  
Reference Type: Electronic Citation

## D2 Other DH Requirements

### D2.1 Pathogens

1. Dangerous Pathogens. Available: <http://www.advisorybodies.doh.gov.uk/acdp/index.htm> [Accessed 14 August 2008]. 2002. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Advice on working with dangerous pathogens, including infection hazards arising from the use of research animals
2. Health and Safety (Dangerous Pathogens) Regulations 1981. 1981. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 1981/1011

### D2.2 Radiation

1. Health and Safety – The Ionising Radiation (Medical Exposure) Regulations 2000. Available: <http://www.opsi.gov.uk/si/si2000/20001059.htm> [Accessed 14 August 2008]. 2001. Office of Public Sector Information.  
Reference Type: Electronic Citation
2. Health and Safety – The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006. Available: <http://www.opsi.gov.uk/si/si2006/20062523.htm> [Accessed 14 August 2008]. 2006. Office of Public Sector Information.  
Reference Type: Electronic Citation
3. Health and Safety - The Radiation (Emergency Preparedness and Public Information) Regulations 2001. 2001. LEGUK.  
Reference Type: Generic  
Notes: Document Number: SI 2001/2975
4. Radioactive Waste Management Advisory Committee. Available: <http://www.defra.gov.uk/rwmac/index.htm> [Accessed 14 August 2008]. 2004. Department for Environmental, Food and Rural Affairs.  
Reference Type: Electronic Citation  
Abstract: 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.

## D3 Other Established Standards

1. A Code of Practice for the Safety of Social Researchers. Available: [http://www.the-sra.org.uk/documents/word/safety\\_code\\_of\\_practice.doc](http://www.the-sra.org.uk/documents/word/safety_code_of_practice.doc) [Accessed 14 August 2008]. 2002. Social Research Association.  
Reference Type: Electronic Citation
2. Institution of Occupational Safety and Health (IOSH). Available: <http://www.iosh.co.uk/> [Accessed 14 August 2008]. 2002. Institution of Occupational Safety and Health (IOSH).  
Reference Type: Electronic Citation  
Abstract: 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.
3. Organisations concerned with Health and Safety Information. Available: <http://www.hse.gov.uk/org/> [Accessed 14 August 2008]. 2008. Health & Safety Executive.  
Reference Type: Electronic Citation

4. Safety in health service laboratories: the labelling, transport and reception of specimens. 1986. HSC.  
Reference Type: Generic  
Notes: Document Number: UNIQUE 004857
5. Safety in Health Service Laboratories - Safe Working and the Prevention of Infection in Clinical Laboratories. 1991. HSC.  
Reference Type: Generic  
Notes: Document Number: UNIQUE 001255
6. Safety in Health Service Laboratories - Safe Working and the Prevention of Infection in the Mortuary and Post-Mortem Room. 1991. HSC.  
Reference Type: Generic  
Notes: Document Number: UNIQUE 001256
7. Safety in Health Service Laboratories - Safe Working and the Prevention of Infection in Clinical Laboratories: Model Rules for Staff and Visitors. 1991. HSC.  
Reference Type: Generic  
Notes: Document Number: UNIQUE 001300

## **E. FINANCE & INTELLECTUAL PROPERTY RIGHTS**

### **E1 Legislation and Regulation**

1. UKCRC Regulatory and Governance Advice Service. Available: <http://www.ukcrc-rgadvice.org/> [Accessed 29 August 2008]. 2008. UK Clinical Research Collaboration (UKCRC)  
Reference Type: Electronic Citation

### **E2 Other DH Requirements**

#### **E2.1 Financial Management**

1. The Department of Health Finance Manual. Available: <http://www.info.doh.gov.uk/doh/finman.nsf> [Accessed 22 August 2008]. 1999. Department of Health.  
Reference Type: Electronic Citation.  
Abstract: 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.

#### **E2.2 NHS Trusts' Financial Governance**

1. The Department of Health Finance Manual. Available: <http://www.info.doh.gov.uk/doh/finman.nsf> [Accessed 22 August 2008]. 1999. Department of Health.  
Reference Type: Electronic Citation.  
Abstract: 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.

#### **E2.3 Primary Care Trust Corporate Governance**

1. The Department of Health Finance Manual. Available: <http://www.info.doh.gov.uk/doh/finman.nsf> [Accessed 22 August 2008]. 1999. Department of Health.  
Reference Type: Electronic Citation.  
Abstract: The Primary Care Group Corporate Governance section of the NHS Finance Manual outlines the responsibilities of PCTs with respect to Financial Governance.
2. Model Standing Orders, Reservation and Delegation of Powers and Standing Financial Instructions. Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4132059](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4132059) [Accessed 22 August 2008]. 2006. Department of Health.  
Reference Type: Electronic Citation.  
Contains Model Standing Orders, Reservation and Delegation of Powers and Standing Financial Instructions for the NHS, SHA and PCT.
3. UK Statutory Instruments - available from the Office of Public Sector Information.
  - 3.1 Statutory Instrument 2002 No. 555 The Primary Care Trusts (Functions) (England) Amendment Regulations 2002. Available: <http://www.opsi.gov.uk/si/si2002/20020555.htm> [Accessed 22 August 2008]. 2002. Office of Public Sector Information.  
Reference Type: Electronic Citation.
  - 3.2 Statutory Instrument 2001 No. 745 The Primary Care Trusts (Functions) (England) Amendment Regulations 2001. Available:

- <http://www.opsi.gov.uk/si/si2001/20010745.htm> [Accessed 22 August 2008]. 2001. Office of Public Sector Information.  
Reference Type: Electronic Citation.
- 3.3 Statutory Instrument 2000 No. 695 The Primary Care Trusts (Functions) (England) Regulations 2000. Available:  
<http://www.opsi.gov.uk/si/si2000/20000695.htm> [Accessed 22 August 2008]. 2000. Office of Public Sector Information.  
Reference Type: Electronic Citation.
4. UK Statutory Instruments - available from the Office of Public Sector Information website
- 4.1 Statutory Instrument 2002 No. 1405 The Primary Care Trusts (Establishment) Amendment Order 2002. Available: <http://www.opsi.gov.uk/si/si2002/20021405.htm> [Accessed 26 August 2008]. 2002. Office of Public Sector Information.  
Reference Type: Electronic Citation.
- 4.2 Statutory Instrument 2002 No. 557 The Primary Care Trusts (Membership, Procedure and Administration Arrangements) Amendment (No. 2) (England) Regulations 2002. Available: <http://www.opsi.gov.uk/si/si2002/20020557.htm> [Accessed 22 August 2008]. 2002. Office of Public Sector Information.  
Reference Type: Electronic Citation.
- 4.3 Statutory Instrument 2002 No. 38 The Primary Care Trusts (Membership, Procedure and Administration Arrangements) Amendment (No. 3) (England) Regulations 2002. Available: <http://www.opsi.gov.uk/si/si2002/20020038.htm> [Accessed 22 August 2008]. 2002. Office of Public Sector Information.  
Reference Type: Electronic Citation.
- 4.4 Statutory Instrument 2001 No. 3787 The Primary Care Trusts (Membership, Procedure and Administration Arrangements) Amendment (No. 2) (England) Regulations 2001. Available: <http://www.opsi.gov.uk/si/si2001/20013787.htm> [Accessed 22 August 2008]. 2002. Office of Public Sector Information.  
Reference Type: Electronic Citation.
- 4.5 Statutory Instrument 2001 No. 2631 The Primary Care Trusts (Membership, Procedure and Administration Arrangements) Amendment (England) Regulations 2001. Available: <http://www.opsi.gov.uk/si/si2001/20012631.htm> [Accessed 22 August 2008]. 2001. Office of Public Sector Information.  
Reference Type: Electronic Citation.
- 4.6 Statutory Instrument 2000 No. 89 The Primary Care Trusts (Membership, Procedure and Administration Arrangements) Regulations 2000. Available:  
<http://www.opsi.gov.uk/si/si2000/20000089.htm> [Accessed 22 August 2008]. 2000. Office of Public Sector Information.  
Reference Type: Electronic Citation.
5. Primary Care Information. Available:  
<http://www.dh.gov.uk/en/Healthcare/Primarycare/Primarycaretrusts/index.htm> [Accessed 26 August 2008]. 2008. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Contains links to key documents including Primary care trust model standing orders, reservation and delegation of powers and standing financial instructions – August 2006 and Financial Framework.



## E3 Other Established Standards

### E3.1 Controls Assurance

1. The Department of Health Finance Manual. Available: <http://www.info.doh.gov.uk/doh/finman.nsf> [Accessed 22 August 2008]. 1999. Department of Health.  
Reference Type: Electronic Citation.  
Abstract: 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.
2. Standards for Better Health. Available: [http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh\\_4086665](http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4086665) [Accessed 29 August 2008]. 2006. Department of Health.  
Reference Type: Electronic Citation  
Note: The Department of Health no longer requires Trusts to report centrally to control assurance. Key elements of the Controls Assurance Standards will be incorporated into the new *Standards for Better Health*.

### E3.2 Fraud Prevention

1. Her Majesty's Treasury Managing the risk of fraud good practice guide. Available: [http://www.hm-treasury.gov.uk/media/2/8/Managing\\_the\\_risk\\_fraud.pdf](http://www.hm-treasury.gov.uk/media/2/8/Managing_the_risk_fraud.pdf) [Accessed 1 October 2008]. 2008. Her Majesty's Treasury.  
Reference Type: Electronic Citation
2. Counter Fraud & Security Management Service Division. Available: <http://www.cfsms.nhs.uk/> [Accessed 12 August 2008]. 2008.  
Reference Type: Electronic Citation  
Abstract: Guidance on countering fraud and corruption in NHS Trust

### E3.3 NHS IM & T Procurement

1. The Department of Health Publications. Available: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsProcurement/DH\\_4008340](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsProcurement/DH_4008340) [Accessed 12 August 2008]. 2000. Department of Health.  
Reference Type: Electronic Citation  
Abstract: Contains a review of NHS IM & T procurement and is designed to assist local health communities in IM&T procurement activities.

### E3.4 Economic Potential of Public Sector Research

1. Her Majesty's Treasury (HMT) Available: [http://www.hm-treasury.gov.uk/documents/enterprise\\_and\\_productivity/research\\_and\\_enterprise/ent\\_res\\_scps.cfm](http://www.hm-treasury.gov.uk/documents/enterprise_and_productivity/research_and_enterprise/ent_res_scps.cfm) [Accessed 12 August 2008]. 2008. Her Majesty's Treasury.  
Reference Type: Electronic Citation  
Abstract: 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.

### E3.5 Intellectual Property

1. Commentary on 'Handling Inventions and Other Intellectual Property: A Guide for NHS

- Researchers'. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4008102](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008102) [Accessed 12 August 2008]. 2002. Department of Health.  
Reference Type: Electronic Citation
2. Policy Framework for the Management of Intellectual Property within the NHS arising from Research and Development (HSC 1998/106). Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecircul ars/DH\\_4004971](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecircul ars/DH_4004971) [Accessed 26 August 2008] 1998. NHS Executive.  
Reference Type: Electronic Citation
  3. The Management of Intellectual Property and Related Matters, An Introductory Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4003101](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4003101) [Accessed 26 August 2008]. 1998. NHS Executive.  
Reference Type: Electronic Citation
  4. Handling Inventions and other Intellectual Property, A Guide for NHS Researchers. 1998. NHS Executive.  
Reference Type: Generic
  5. Intellectual Property Framework and Guidance. Available:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4002660](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4002660) [Accessed 12 August 2008]. 2002. NHS Innovations.  
Reference Type: Electronic Citation  
Abstract: The Framework and Guidance is aimed at encouraging the NHS to become a more innovative organisation, capturing innovations which can lead to new products, improved interventions and services for health and social care. It supports the delivery of the NHS Plan.
  6. 2000 White Paper 'Excellence and Opportunity' - a Science and Innovation Policy for the 21st Century'. Available: <http://www.berr.gov.uk/files/file12002.pdf> [Accessed 26 August 2008]. 2000. Department for Business Enterprise and Regulatory Reform.  
Reference Type: Electronic Citation
  7. Research and Enterprise. Baker Report. Available: [http://www.hm-treasury.gov.uk/Documents/Enterprise\\_and\\_Productivity/Research\\_and\\_Enterprise/ent\\_s me\\_baker.cfm](http://www.hm-treasury.gov.uk/Documents/Enterprise_and_Productivity/Research_and_Enterprise/ent_s me_baker.cfm) [Accessed 26 August 2008]. 1999. Her Majesty's Treasury.  
Reference Type: Electronic Citation
  8. Research and Enterprise. Government response to the Baker Report. Available: <http://www.hm-treasury.gov.uk/media/6/9/57.pdf> [Accessed 26 August 2008]. 1999. Her Majesty's Treasury.  
Reference Type: Electronic Citation
  9. Intellectual Property in Government Research Contracts. Guidelines for Public Sector Purchasers of Research and Research Providers. Available:  
<http://www.ipo.gov.uk/ipresearch.pdf> [Accessed 26 August 2008]. 2000. Intellectual Property Office.  
Reference Type: Electronic Citation
  10. Intellectual Property. Available:  
<http://www.epsrc.ac.uk/Business/Guidance/IP.htm> [Accessed 12 August 2008]. 2007. The Engineering and Physical Sciences Research Council.  
Reference Type: Electronic Citation  
Abstract: EPSRC positively encourages the exploitation of the results of research it sponsors, as a contribution to enhanced quality sustainability and competitiveness for the U.K. This publication provides information on EPSRC's policy and approach to intellectual property.

11. Intellectual property policy statement and exploitation plan. Available: <http://www.hse.gov.uk/research/iprights.pdf> [Accessed 12 August 2008]. 2002. Health & Safety Executive.  
Reference Type: Electronic Citation  
Abstract: The Cabinet Office publication 'Intellectual Property Rights in the Public Sector Research Base' (HMSO, September 1992) recommended that Government Departments should publish an intellectual property exploitation plan. The Health and Safety Executive also has a requirement to report to the Office of Science and Technology in respect of its policy on managing intellectual property rights for the commercial exploitation of its research results. In response to these requirements, the Health and Safety Executive has produced this document which sets out its policy and exploitation plans for that intellectual property which originates from HSE's research activities.
12. Commercialisation. Available: <http://www.bbsrc.ac.uk/business/ip/Welcome.html> [Accessed 12 August 2008]. 2002. Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation  
Abstract: Commercialisation guidance and details of Intellectual Property Workshops can be found here.
13. 2000 White Paper 'Excellence and Opportunity' - a Science and Innovation Policy for the 21st Century'. Available: <http://www.berr.gov.uk/files/file12002.pdf> [Accessed 26 August 2008]. 2000. Department for Business Enterprise and Regulatory Reform.  
Reference Type: Electronic Citation

### **E3.6 Department for Business Enterprise and Regulatory Reform**

1. Department for Business Enterprise and Regulatory Reform.  
Available: <http://www.berr.gov.uk> [Accessed 26 August 2008]. 2008.  
Reference Type: Electronic Citation

### **E3.7 Her Majesty's Treasury (HMT)**

1. Selling into Wider Markets: A Policy Note for Public Bodies. Available: [http://www.hm-treasury.gov.uk/media/0/D/New\\_WM\\_Guidance.pdf](http://www.hm-treasury.gov.uk/media/0/D/New_WM_Guidance.pdf) [Accessed 26 August 2008]. 2002.  
Reference Type: Electronic Citation  
Abstract: 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.

### **E3.8 Professional Standards**

1. The Institute of Chartered Accountants in England and Wales. Available: <http://www.icaew.co.uk> or <http://www.icaew.com/index.cfm?route=1283> for members. [Accessed 26 August 2008]. 2008.  
Reference Type: Electronic Citation  
Abstract: 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.

### **E3.9 Other Standards**

1. Intellectual property management and exploitation. Available: [http://www.bbsrc.ac.uk/publications/policy/intellectual\\_property\\_policy.pdf](http://www.bbsrc.ac.uk/publications/policy/intellectual_property_policy.pdf) [Accessed 12 August 2008]. 2002. Biotechnology and Biological Sciences Research Council.  
Reference Type: Electronic Citation