Annex 7

Regulatory and Governance

This annex describes:

- Implemented initiatives to streamline the regulatory and governance environment in the UK
- The organisations that are involved in the regulatory and governance processes
- Regulations, stating the UK nations where these regulations are applicable

Implemented initiatives to streamline the R&G environment

	England	Northern Ireland	Scotland	Wales
UKCRC R&G Advice Service	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK
Integrated Research Application System (IRAS)	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK
Research Passport	Being implemented through the CLRNs in England	Will be taken forward by a joint HSC/University working group	Now fully in place in most Health Boards, although some still in the process of implementation. All Boards will have full implementation by September 2009.	Implementation of Research Passport system in secondary care is almost complete. Primary Care Research Management and Governance Office will take responsibility for the implementation of the Research Passport in primary care
Model Clinical Trial Agreement (mCTA) and Guidance Notes	mCTA England plus Guidance Notes which cover the four versions of the agreement	mCTA Northern Ireland plus Guidance Notes which cover the four versions of the agreement	mCTA Scotland plus Guidance Notes which cover the four versions of the agreement	mCTA Wales plus Guidance Notes which cover the four versions of the agreement

	England	Northern Ireland	Scotland	Wales
Clinical Research Organisation model Clinical Trial Agreement (CRO mCTA) and Guidance Notes	CRO mCTA England plus Guidance Notes which cover the four versions of the agreement	CRO mCTA Northern Ireland plus Guidance Notes which cover the four versions of the agreement	CRO mCTA Scotland plus Guidance Notes which cover the four versions of the agreement	CRO mCTA Wales plus Guidance Notes which cover the four versions of the agreement
Model Clinical Investigations Agreement (mCIA) and Guidance Notes	mCIA England plus Guidance Notes which cover the four versions of the agreement	mCIA Northern Ireland plus Guidance Notes which cover the four versions of the agreement	mCIA Scotland plus Guidance Notes which cover the four versions of the agreement	mCIA Wales plus Guidance Notes which cover the four versions of the agreement
Clinical Research Organisation model Clinical Investigation Agreement (CRO mCIA) and Guidance Notes	CRO mCIA England plus Guidance Notes which cover the four versions of the agreement	CRO mCIA Northern Ireland plus Guidance Notes which cover the four versions of the agreement	CRO mCIA Scotland plus Guidance Notes which cover the four versions of the agreement	CRO mCIA Wales plus Guidance Notes which cover the four versions of the agreement
Model Agreement for Non-Commercial Research in the Health Service (mNCA)	mNCA plus Guidance Notes. This agreement is intended for non-NIHR Portfolio studies in England	mNCA plus Guidance Notes	mNCA plus Guidance Notes. In use for studies involving Scotland	mNCA plus Guidance Notes
Centralised health service permissions	NIHR Coordinated System for gaining NHS Permission (NIHR CSP)	Northern Ireland Integrated Sign-Off Process	Full in place through NHS Research Scotland (NRS)	Primary Care Office launched in April 2009. Primary and Secondary Care to be combined and launched in April 2010.
PCT Permission form for Industry Trials	Applicable in England	N/A	N/A	N/A

	England	Northern Ireland	Scotland	Wales
Single REC Opinion – only one application is needed, however many sites are involved	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK
NRES Central Allocation System (CAS) – a telephone booking service for applications to RECs	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK
Transfer of Site Specific Assessment (SSA) to NHS / HSC hosts for NHS / HSC sites support by IRAS	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK	Rolled out across the UK

Organisations involved in the R&G process

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
UKCRC R&G Project Group	The UKCRC Board oversees the work of the R&G Project Group	To continue in current format until the end of 2009; will then be superseded by the UKCRC R&G Forum	To facilitate high quality clinical research in the UK by promoting a regulatory and governance environment that protects the rights, dignity and safety of patients and is free of unnecessary obstacles that inhibit research without producing any societal benefit. The UKCRC Project Group associated with this Activity brings together individuals from the UKCRC Partner organisations and other key stakeholder organisations engaged on regulatory and governance issues.	Yes	Yes	Yes	Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
The Administration of Radioactive Substances Advisory Committee (ARSAC) **www.arsac.org.uk**	Committee was set up as part of Regulation 2 of the Medicines (Administrations of Radioactive Substances) Regulations 1978 (MARS Regulations 1978) which states that doctors/dentists wanting to administer radioactive medicinal products to humans need a certificate issued by Health Ministers. Regulations also est. a committee to advise ministers on applications	Advisory Organisation	Advise Health Ministers with respect to the grant, renewal, suspension, revocation & variation of certificates & generally in connection with systems prior to authorisation	Yes	Yes	Yes	Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Department of Health (DH) www.dh.gov.uk	Branch of the UK Government	Provides strategic leadership to the NHS and social care organisations but does not run them	Improve health and well being of population of England	Yes			
Chief Scientist Office (CSO) www.sehd.scot.nhs.uk/cso	Directorate of the Scottish Government	Supports and promotes high quality research aimed at improving the services offered by NHS Scotland	Aims to secure lasting improvements to the health of the people in Scotland			Yes	
Public Health Agency, HSC Research and Development, Northern Ireland www.publichealth.hscni.net	Directorate of the Northern Ireland Health & Social Services Central Health Agency	Established to promote, coordinate & support R&D within the HSC. The R&D Office has a dual strategic & operational role	Remit encompasses the research needs of the HSC R&D Office and all sectors of Health & Social within Northern Ireland		Yes		

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Welsh Office of Research & Development for health and social care (WORD) www.word.wales.gov.uk	A branch of the strategy unit	WORD develops policy to reflect the health & social care priorities of the National Assembly for Wales	Strategic aim is to ensure that policy & practice in health & social care in Wales are underpinned by evidence, for the benefit of patients & the public				Yes
Equality and Human Rights Commission www.equalityhumanrights.com	Est. in October 2007. Combines the responsibilities of the 3 previous equality commissions	Independent Advocate	Aims to reduce inequality, eliminate discrimination, strengthn good relations between people, and promote & protect human rights	Yes		Yes	Yes
Equality Commission for Northern Ireland www.equalityni.org	Independent public body est under Northern Ireland Act 1998	Promoting awareness of & enforcing anti-discrimination law	Advance equality, promote equality of opportunity to encourage good relations & challenge discrimination through promotion, advice & enforcement		Yes		

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Gene Therapy Advisory Committee (GTAC) **www.dh.gov.uk/ab/GTAC/index.htm**	1992 Report of Committee for the Ethics of Gene Therapy - recognised gene therapy should be limited to life threatening diseases or disorders. GTAC est. in 1993 to oversee & implement this	Advisory Organisation	Consider & advise on acceptability of proposals for gene therapy research on humans (on ethical grounds). Works with other agencies that have responsibilities in this field. Provide advice to UK Health Ministers on developments in therapy research & their implications	Yes	Yes	Yes	Yes
Health and Safety Executive (HSE) **www.hse.gov.uk**	Sponsored by Department of Work and Pensions - accountable to Parliamentary Under Secretary for Work & Pensions	Regulatory Organisation - responsible for the regulation of almost all risks to health & safety arising from work activity in Britain	To protect people's health & safety by ensuring risks in the changing workplace are properly controlled. Merged with the Health and Safety Commission (HSC) in April 2008	Yes		Yes	Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Health Inspectorate Wales **www.hiw.org.uk**	Promotes continuous improvement in the quality and safety of patient care in NHS Wales	Regulator of independent healthcare which has full delegated authority for its regulatory decisions	HIW inspects NHS bodies and service providers against national standards, agreements and clinical governance guidance. HIW also assesses the management arrangements in place to deliver clinical and NHS services as well as assessing the quality of NHS services across agencies/ sector				Yes
Home Office **www.homeoffice.gov.uk**	Department of UK Government	Regulatory Organisation	Main areas of responsibility - Law & Order, Immigration & Nationality and General public well-being & safety	Yes	Yes	Yes	Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Human Genetics Commission (HGC) **www.hgc.gov.uk**	Reports to the UK Government	Advisory Body	Give the govt advice on human genetics - focusing on social, ethical & legal issues. Key role - promote, debate & listen to what public & stakeholders have to say / Inspecting NHS bodies and service providers against national standards, agreements and clinical governance guidance	Yes	Works within the context of devolution settlements for NI, Scotland & Wales		
Human Fertilisation & Embryology Authority (HFEA) **www.hfea.gov.uk**	Non departmental govt body. Est. in 1991 following passing of the Human Fertilisation & Embryology Act in 1990	Regulatory Organisation	Regulates and inspects all UK clinics providing IVF, donor insemination or the storage of eggs, sperm or embryos. Licenses & monitors all human embryo research being conducted in the UK	Yes	Yes	Yes	Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Human Tissue Authority (HTA) **www.hta.gov.uk**	Human Tissue Act of 2004 est. the HTA to advise on & oversee compliance with the Act. (Human Tissue (Scotland) Act 2006)	Role to inform the public & Secretary of State about issues within its remit	Issue codes of practice covering consent, donation, post-mortem, removal & anatomical examination. License a number of activities & will inspect to ensure compliance with Human Tissue Act & licence conditions	Yes	Yes	Yes	Yes
The Information Commissioner's Office (ICO) **www.ico.gov.uk**	The Information Commissioner is an independent official appointed by the Crown	Regulatory Organisation to oversee the Data Protection Act 1998. Freedom of Information Act 2000, Environmental Information Regulations 2004	Promoting public access to official information & protecting your personal information	Yes	Yes – has 3 regional offices (NI, Scotland, Wales) as a direct response to the devolution process		

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Medicines and Healthcare products Regulatory Agency (MHRA) www.mhra.gov.uk	Executive Agency of DH		Protect & promote public health & patient safety. Ensures that medicines, healthcare products & medical equipment meet appropriate standards of safety, quality performance & effectiveness & are used safely	Yes	Yes	Yes	Yes
NHS Research Scotland (NRS) http://nhsgrampian.org/nhsgrampian/nrscc.jsp?pContentID=6574&p_applic=CCC&p_service=Content.show&	Through an Oversight Board chaired by CSO and comprising representatives of Scottish Health Boards		To manage the efficient approval of multi-centre research in Scotland; and provide a forum for progressing other Scotland-wide co-ordinated activities			Yes	

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
NHS Trusts	England is split into 10 strategic health authorities (SHAs). Within each SHA, the NHS is split into various types of trusts that take responsibility for running the different NHS Services in your local area	Trusts take responsibility for running different NHS services in the local area	Set up in 2002 to develop plans for improving health services in their local areas & to make sure their local NHS organisations were performing well	Yes			
NHS Boards (Scotland) **www.show.scot.nhs.uk**	Run by the NHS in Scotland. There are 14 Health Boards with 4 very research active ones that conduct 94% of the Scottish NHS research		Responsible for local health planning & improvement for the delivery of hospital, community and primary care services. There are 14 Health Boards with 4 very research active ones which conduct 94% of the Scottish NHS research			Yes	
NHS Trusts (Wales) **www.wales.nhs.uk**	Wales split into 13 trusts		Provides health services in Wales				Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Local Health Boards (Wales) www.wales.nhs.uk/catorgs.cfm#5	There are 22 Local Health Boards in Wales		Commissioners of Health Service in Wales				Yes
Health Boards (Northern Ireland)	4 Area Boards in Northern Ireland		Responsible for assessing the needs of their respective populations & commissioning services to meet those needs. Charged with the establishment of key objectives to meet the health & social needs of their population and the development of policies & priorities to meet those objectives		Yes		
National Research Ethics Service (NRES) www.nres.npsa.nhs.uk	Works on behalf of the Department of Health. Part of the National Patient Safety Agency	Advisory Organisation	Provides help and leadership for RECs & the REC system - safeguard rights, dignity & welfare of people participating in research in the NHS. Also advises DH re EUCTD & if need to review policy & operational guidance relating to RECs	Yes	Works within the context of devolution settlements for NI, Scotland & Wales		

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
NHS R&D Forum www.rdforum.nhs.uk	Network for R&D management in health & social care	Network	Aims to improve the environment for research in health & social care by facilitating & encouraging sharing of best practice & working with other organisations	Yes			
FORWARD (the Forum of NHS Wales for R&D Management in Health and Social Care) www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=32877	Network for R&D management in health & social care	Network	Aims to enhance the research environment to facilitate further developments in evidence based practice and improved service delivery for the benefit of participants, recipients and the research community				Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
National Offender Management Service (NOMS; Ministry of Justice) http://noms.justice.gov.uk/about-us/	NOMS is part of the Ministry of Justice. The NOMS board, which includes the Director General of HM Prison Service and the Director of Probation, supports the Chief Executive in establishing NOMS as an organisation where we commission and provide the highest quality correctional services		NOMS is the system through which we commission and provide the highest quality correctional services and interventions in order to protect the public and reduce re-offending. NOMS gives permission to conduct health research involving prisoners	Yes			Yes
NHS Quality Improvement Scotland (QIS) www.nhshealthquality.org/nhsgis/43.html	A special health board accountable to the Scottish Government	Advisory Organisation with non statutory regulatory role	Works with members of the public, patients and healthcare staff to translate the latest scientific research, expert opinion and patient experience into practical improvements that can be implemented in the health service			Yes	

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
UK Stem Cell Bank **www.ukstemcellbank.org.uk**	Funded by MRC & BBSRC with the full backing of the UK Government. Hosted by NIBSC - National Institute for Biological Standards Control		Works with & for the scientific & clinical community to assure the quality of human stem cell lines used in research & therapy. Operates in accordance with strict principles laid down by high level Steering Committee	Yes	Yes	Yes	Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
National Information Governance Board for Health and Social Care (NIGB) **www.nigb.nhs.uk**	Health and Social Care Act 2008 established the NIGB as a statutory body. From Jan-09 the NIGB's functions include administration of applications under section 251 of the NHS Act 2006 which allows the common law duty of confidentiality to be set aside in specific circumstances. This function was formerly carried out by PIAG which was abolished on 31 Dec 08	Statutory Body	Role of NIGB is to support improvements to information governance practice in health and social care	Yes			Yes

Organisation	How managed	Status of organisation	Remit	England	Northern Ireland	Scotland	Wales
Care Quality Commission **www.cqc.org.uk**	Established by government legislation in April 09. Before April 09 this work was carried out by the Healthcare Commission, the Mental Health Act Commission and the Commission for Social Care Inspections	Independent Regulator	Regulate health and adult social care services in England and protects the rights of people detained under the Mental Health Act. Its work brings together independent regulators of health, mental health and adult social care	Yes			

National Regulations

Full Title	Year	England	Northern Ireland	Scotland	Wales	Comments
Adults with Incapacity (Scotland) Act 2000	2000			Yes		
Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002, as amended 2007	2002, 2007			Yes		
Age of Legal Capacity (Scotland) Act 1991	1991			Yes		
Age of Majority (Northern Ireland) 1969	1969		Yes			
Age of Majority (Scotland) 1969	1969			Yes		
Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006	2006			Yes		
Children Act (Northern Ireland) 1995	1995		Yes			

Full Title	Year	England	Northern Ireland	Scotland	Wales	Comments
Children Act (Scotland) 1995	1995			Yes		
Children Act 1989	1989	Yes	Yes	Yes	Yes	Only childminding and day care in Part X apply in Scotland
COSHH (Control of Substances Hazardous to Health Regulations 2002) Amendments 2003 and 2004	2002, 2003, 2004	Yes	Yes	Yes	Yes	
Data Protection Act 1998	1998	Yes	Yes	Yes	Yes	
Disability Discrimination Act 1995	1995	Yes	Yes	Yes	Yes	
Disability Discrimination Act 2005	2005	Yes		Yes	Yes	
Freedom of Information (Scottish) Act 2002	2002			Yes		
Freedom of Information Act 2000	2000	Yes	Yes	Yes	Yes	2002 Scottish Act covers largely the same issues

Full Title	Year	England	Northern Ireland	Scotland	Wales	Comments
Good Laboratory Practice Regulations 1999 Good Laboratory Practice (Codification Amendments Etc) Regulations 2004	1999, 2004	Yes	Yes	Yes	Yes	
Health Service (Control of Patient Information) Regulations 2002	2002	Yes			Yes	
Health and Social Care Act 2001 – Section 60	2007	Yes			Yes	
Human Fertilisation and Embryology Act 1990 (the 1990 Act)	1990	Yes	Yes	Yes	Yes	
Human Fertilisation and Embryology (Disclosure of Information) Act 1992	1992	Yes	Yes	Yes	Yes	
Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2009	2009	Yes	Yes	Yes	Yes	
Human Reproductive Cloning Act 2001	2001	Yes	Yes	Yes	Yes	
Human Rights Act 1998, 2001	1998, 2001	Yes	Yes	Yes	Yes	

Full Title	Year	England	Northern Ireland	Scotland	Wales	Comments
Human Tissue Act 2004	2004	Yes	Yes	Yes	Yes	Only a few subsections apply to Scotland
Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006	2006	Yes	Yes		Yes	
Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006	2009	Yes	Yes	Yes	Yes	
Human Tissue (Scotland) Act 2006	2006			Yes		
Independent Health Care Regulations (Northern Ireland) 2005	2005		Yes			
The Ionising Radiation (Medical Exposure) Regulations 2000 and Amendment Regulations 2006	2000, 2006	Yes	Yes	Yes	Yes	
Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000	2000		Yes			

Full Title	Year	England	Northern Ireland	Scotland	Wales	Comments
Medical Devices Regulations 2002 and the Medical Devices (Amendment) Regulations 2003 and the Medical Devices (Amendment) Regulations 2007	2002, 2003, 2007	Yes	Yes	Yes	Yes	
Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1994 (SI 1994/102) as amended by the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995 (SI 1995/309) and amended by the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 2006	1994, 1995, 2006	Yes	Yes	Yes	Yes	
Medicines for Human Use (Clinical Trials) Regulation 2004 and Amendment Regulations 2006	2004, 2006	Yes	Yes	Yes	Yes	
Mental Capacity Act 2005	2005	Yes	Yes	Yes	Yes	Only 2 paragraphs in a schedule apply to Scotland
Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006	2006	Yes				
Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007	2007				Yes	

Full Title	Year	England	Northern Ireland	Scotland	Wales	Comments
Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007	2007	Yes				
Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007	2007				Yes	
Mental Health Act 1983, 2007	1983, 2007	Yes	Yes		Yes	
Nursing and Midwifery Council (Midwives) Rules of Order Council 2004	2004	Yes	Yes	Yes	Yes	
Nursing Homes Regulations (Northern Ireland) 2005	2005		Yes			
Private and Voluntary Health Care (England) Regulations 2001	2001	Yes				
Private and Voluntary Health Care (Wales) Regulations 2002	2002				Yes	
Public Interest Disclosure Act 1998	1998	Yes	Yes	Yes	Yes	

Full Title	Year	England	Northern Ireland	Scotland	Wales	Comments
Radioactive Substances Act 1993	1993	Yes	Yes	Yes	Yes	
Residential Care Homes Regulations (Northern Ireland) 2005	2005		Yes			
The Welsh Language Act 1993	1993				Yes	
The NHS Wales Act 2006	2006				Yes	Paragraph 17 of schedule 2