



RESEARCH GOVERNANCE POLICY

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Documents to read alongside this Policy , Procedure etc (delete as necessary)	<i>Research Governance Framework for Health and Social Care in Wales 2nd edition 2009; R&D related Standard Operating Procedures of relevance to the reader</i>
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Version Number	Date of Review Approved	Date Published	Summary of Amendments

Research Governance Policy

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GLOSSARY OF TERMS

- Chief Investigator (CI) - The investigator with overall responsibility for the research. In a multi site study, the CI has coordinating responsibility for research at all sites.
- Investigational Medicinal Product (IMP) - A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial including a medicinal product which has a marketing authorisation but is, for the purposes of the trial, being used or assembled (formulated or packaged) in a way different from the approved form, or being used for an unapproved indication or when used to gain further information about an approved use.
- Participant - Patient, service user, carer, relative of the patient or deceased, professional carer, other employee, or member of the public, who consents to take part in a research study (in law, participants in clinical trials involving IMPs are known as subjects).
- Principal Investigator (PI) - The investigator responsible for the research site where the study involves specified procedures requiring site-specific assessment. For multi site studies, there should be one PI for each research site. In the case of a single site study, the CI and the PI will normally be the same person.
- Research - An attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. Research may be aimed at understanding the basis and mechanism of disease, improving the diagnosis and treatment of a disease or designing better ways of delivering healthcare.
- Researchers - Those conducting the research.
- Research Ethics Committee (REC) - Committee established to provide participants, researchers, funders, sponsors, employers, care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognised ethical standards. For clinical trials involving medicines, the reviewing REC must be one recognised by the United Kingdom Ethics Committee Authority.
- Sponsor - Individual, organisation or group taking responsibility for securing the arrangements to initiate, manage and/or finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively,

they make arrangements to allocate all the responsibilities identified in the Research Governance Framework for Health and Social Care in Wales 2nd Edition, 2009 (Research Governance Framework) (1) and/or the Medicines for Human Use (Clinical Trials) Regulations 2004 (2) and their Amendments (3,4) that are relevant to the study.

- Student Research – Any research performed as part of an educational qualification.

1.0 INTRODUCTION

1.1 Research is essential to the successful promotion and protection of health and wellbeing and also to modern, effective health and social care services. At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and wellbeing of the research participants. Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent and fully informed decision making processes, clear allocation of responsibilities and robust monitoring arrangements in healthcare research.

1.2 The Research Governance Framework (1) sets out a framework for the governance of research in health and social care. The standards in the Research Governance Framework apply to all research that relates to the responsibilities of the Welsh Government, that is, research concerned with the protection and promotion of public health and research undertaken in or by the Welsh Government, or Welsh Government-sponsored public bodies and the NHS. It applies to clinical and non-clinical research, research undertaken by NHS or social care staff, research carried out in the Primary Care setting, research undertaken by NHS staff using NHS resources, and research undertaken by industry, charities, the research councils, universities and local government within the health and social care systems.

2.0 POLICY STATEMENT

2.1 Cardiff and Vale University Health Board (UHB) considers that the governance of research and development (R&D) activity involving its patients, staff and resources to be of paramount importance. The UHB is committed to research that is managed appropriately to ensure patient dignity, rights, safety and wellbeing, that research is of high quality, complies with the law, is relevant and that financial probity is maintained.

3.0 SCOPE

- 3.1** The scope of this Policy extends to all research activity, both commercial and non-commercial, involving the UHB including:
- Research using patients, carers, volunteers and members of staff at the UHB and in Primary Care settings;
 - Research using patient tissue, organs or data;
 - Research taking place on UHB premises or involving UHB resources, including non-clinical and laboratory based research;
 - Research being undertaken as part of an educational qualification.
- 3.2** The UHB will ensure that all research activity outlined in section 3.1 complies with the law and with the standards outlined in the Research Governance Framework (1).

4.0 AIM

The aim of this Policy is to provide a framework for research, which complies with the law and good practice, without unnecessarily restricting the freedom of individual researchers to develop ideas which can improve clinical care.

5.0 OBJECTIVES

- 5.1** To ensure that R&D is of the highest quality and that researchers operate within the same quality framework as the services which the research is aimed at improving.
- 5.2** To ensure that all R&D is carried out lawfully, properly and sensitively, respecting the rights, dignity, wellbeing and safety of participants.
- 5.3** To clearly identify the responsibilities that fall to individuals involved in the R&D.

6.0 PRINCIPLES

- 6.1** Explicit written approval from the UHB's Director of Research and Development must be obtained prior to commencing research.
- 6.2** To obtain UHB R&D approval the research must be reviewed in accordance with the UHB's R&D approval process and in accordance with the National Institute for Social Care and Health Research Permissions Co-ordinating Process (NISCHR-PCP).
- 6.3** Written evidence of a favourable opinion from the appropriate NHS Research Ethics Committee must be obtained prior to commencing research on any research involving:
- Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient's or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions;
 - Individuals identified as potential research participants because of their status as relatives, or carers of patients and users of the NHS, as defined above;
 - Access to data, organs or other bodily material of past and present NHS patients;
 - Foetal material and in vitro fertilisation involving NHS patients;
 - The recently deceased in NHS premises;
 - The use of, or potential access to, NHS premises or facilities;
 - NHS staff recruited as research participants by virtue of their professional role.
- 6.4** For clinical trials involving an Investigational Medicinal Product (CTIMP), a Clinical Trial Authorisation from the Medicines and Healthcare Products Regulatory Agency (MHRA) must be obtained prior to the study commencing.
- 6.5** All research must be conducted in accordance with Good Clinical Practice (GCP) which means the principles and practices for the conduct of a study as provided for by the Medicines for Human Use (Clinical Trials) Regulations 2004 (2) and its Amendments (3,4), and the Research Governance Framework (1).
- 6.6** All research involving an Investigational Medicinal Product (IMP) undertaken within the UHB (whether university or NHS based) must adhere to the Procedure for the Safe Handling of Clinical Trial Medicines within Cardiff and Vale University Health Board. (5).
- 6.7** All investigators must be trained in compliance with the Good Clinical Practice Training Policy for Personnel Undertaking Clinical Research (6).
- 6.8** All agreements and indemnity documents relating to research projects must be submitted through the R&D Office and signed by an authorised

signatory. Independent practitioners in the Primary Care setting are responsible for their own agreements and indemnity documents.

7.0 ROLES AND RESPONSIBILITIES

7.1 Responsibilities – Chief Executive

The Chief Executive is responsible for ensuring that there are adequate arrangements in place for the governance of research involving the UHB.

The authorised signatory for agreements involving financial transactions is the Chief Executive or authorised deputy, except service level agreements as per section 7.3. The Association of the British Pharmaceutical Industry (ABPI) indemnity documents relating to clinical trials involving UHB patients must be signed by the UHB Chief Executive or by their authorised deputy.

7.2 Responsibilities - Medical Director

The overall responsibility for this Policy rests with the Medical Director as Executive Lead for R&D.

7.3 Responsibilities – Research and Development Director

The UHB Research and Development Director has delegated responsibility for the conduct, governance and strategic direction of research within the UHB which includes (but is not limited to):

- The approval of all research involving the UHB;
- Signing, on behalf of the UHB, all contracts for research where there is no financial component, non-disclosure agreements and Service Level Agreements of a small value with other local NHS organisations.
- Ensuring that the R&D Office meets the responsibilities detailed in section 7.5 and that the Office is appropriately resourced to do so.

7.4 Responsibilities – Management

7.4.1 Divisional Directors are responsible for:

- Establishing systems at Divisional level that facilitate compliance with the Research Governance Framework;
- Ensuring that all researchers working within their Division hold either a full or honorary UHB contract of employment in accordance with UHB Procedures, or a letter of access where appropriate.
- Appointment of Divisional R&D Leads.

7.4.2 Divisional R&D Leads are responsible for:

- Ensuring that research governance issues raised by the UHB Research Governance Group are communicated to their Division and that any relevant Divisional research governance issues are brought to the Research Governance Group.

7.4.3 Directorate R&D Leads are responsible for:

- Establishing systems at Directorate level to comply with the R&D Approval processes of the UHB and for ensuring research governance issues are communicated throughout the Directorate.
- Reporting to Divisional R&D Leads and Clinical Directors.

7.4.4 Clinical Directors are responsible for:

- Appointment of Directorate R&D Leads.
- Ensuring that, subject to section 7.8.1, in the event of the PI leaving the UHB and the study being terminated, the R&D Office is notified and, where applicable, appropriate arrangements are made to archive the study documents and data for closed studies ensuring it is still accessible. Study documents and source data must be retained in accordance with NHS Policy and in accordance with the UHB R&D Standard Operating Procedure RD02: Research Study Files, Filing and Archiving (21).

7.5 Responsibilities - Research and Development Office

The UHB R&D Office is responsible for:

- Developing and establishing systems for the management of research involving the UHB including systems to ensure that the UHB can meet the responsibilities of a Sponsor under the Clinical Trials Regulations and the Research Governance Framework;
- Ensuring the UHB R&D approval process meets the requirements of the Welsh Government;
- Maintaining a record of all research being conducted within the UHB including student research;
- Ensuring, where necessary, that an appropriate NHS REC has approved the research;
- Assessing applications for the UHB to act as research Sponsor to individual studies;
- Arranging for written agreements to be put in place, where necessary, for research involving an external partner, funder and/or Sponsor;
- In relation to commercial research, costing commercial research studies, negotiating contracts, developing and establishing systems to ensure financial probity in collaboration with the UHB Finance Department;
- Providing training in basic research methodology and governance;
- Monitoring and audit of research practices across the UHB;
- Permitting and assisting with any monitoring, auditing or inspection required by relevant authorities;
- Assisting with the development of the UHB R&D Strategy;

- Assisting with the identification of intellectual property arising from research and development;
- Compiling and submitting the UHB R&D Annual Report to the Welsh Government;
- Compiling and submitting research governance reports to the Research Governance Group and Quality and Safety Committee;
- Taking action in accordance with relevant UHB policies upon receipt of any report of suspected research fraud or misconduct;
- Taking relevant action in accordance with the UHB policies and procedures on reporting research related adverse events (15-18) upon receipt of any serious adverse event report.

7.6 Responsibilities – Researchers

7.6.1 All research staff, including those holding an Honorary Contract with the UHB, have the responsibility of being familiar with the principles of GCP in accordance with the UHB GCP Training Policy for Personnel Undertaking Clinical Research (6) and as described in the Research Governance Framework and, where applicable, the Clinical Trial Regulations, and must conduct their role accordingly.

7.6.2 Researchers who do not hold a substantive employment contract with the UHB must obtain an Honorary Research Contract or Letter of Access (as deemed appropriate by the UHB) if they wish to undertake research activity in the UHB which involves:

- direct or indirect contact with patients/service users;
- access to identifiable or anonymised patient data derived from health records;
- access to identifiable or anonymised patient samples, tissues or organs;
- working on UHB premises;
- direct contact with UHB staff; access to identifiable or anonymised staff data.

7.6.3 Researchers are responsible for ensuring that:

- The research is conducted in accordance with the following:
 - The current version of the study Protocol (REC and UHB approved)
 - The Research Governance Framework (1)
 - The Clinical Trials Regulations (where relevant) (2-4)
 - The Data Protection Act (1998) (7) and Common Law requirement
 - Confidentiality Code of Practice for Health and Social Care in Wales (8)
 - Health and Safety at Work etc Act (1974)(9)
 - The Human Tissue Act (2004) (10)
 - The Mental Capacity Act (2005) (11)

- The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007 (12)
 - The Mental Capacity Act Code of Practice (13)
 - Freedom of Information Act 2000 (14)
 - All relevant UHB Policies and Procedures
- The appropriate care professionals are informed of a subject's participation in research (with patient permission, where applicable).
 - The integrity and confidentiality of clinical and other records and data generated by the research is protected in accordance with Data Protection Legislation (7) and the Caldicott Principles (15).
 - Any failures in conducting the study in accordance with the above are reported as appropriate.
 - All relevant adverse events are recorded and reported in accordance with the UHB policies and procedures on reporting research related adverse events (16-19).
 - Suspected fraud or misconduct is reported in accordance with UHB policies and procedures.
 - Informed consent is taken in accordance with UHB policies and procedures.

7.7 Responsibilities - Chief Investigator (CI)

- 7.7.1** The CI must be a senior individual, with appropriate experience, expertise and training to either:
- undertake the design, conduct, analysis and reporting of the study to the standards set out in the Research Governance Framework or;
 - lead and manage others who have been delegated responsibility for some of these aspects.

7.7.2 The CI has overall responsibility for the conduct of the research and is accountable to their employer, and, through them, to the Sponsor(s) of the research. If the research is taking place at more than one site, the CI takes on personal responsibility for the design, management and reporting of the study, and co-ordinating the Principal Investigators at other sites.

- 7.7.3** The CI is responsible for ensuring that:
- The research team gives priority at all times to the dignity, rights, safety and well-being of participants;
 - The study complies with all legal and ethical requirements;
 - The research is carried out to the standards required within the Research Governance Framework;
 - All members of the research team/trial site team are trained in accordance with the UHB's Good Clinical Practice Training Policy for Personnel Undertaking Clinical Research (6);
 - For CTIMP studies each member of the research team, including those at collaborating sites, is qualified by education, training and

experience to discharge their role in the study, and their qualifications are documented and retained in the Investigator Site Files at site;

- All researchers involved in CTIMP studies are aware of their legal duties;
- Students and new researchers have adequate supervision, support and training;
- A suitable Sponsor is secured and agreements are in place detailing the responsibilities of all parties involved in the research;
- R&D approval is obtained from each care organisation involved prior to commencing the study at that care organisation;
- The Protocol is submitted for ethics review to an NHS REC, the study does not start without a favourable opinion, and the research team acts on any conditions attached to the ethics opinion;
- Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant REC, the UHB R&D Office and the Sponsor(s)¹;
- Substantial amendments to the project are re-submitted for ethical review, for UHB R&D approval and Sponsor(s) agreement (and MHRA approval where appropriate) in accordance with UHB Standard Operating Procedures(20,21). With the exception of urgent safety measures, these amendments are implemented only when approved²;
- When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate (unless exemption has been given by a REC), and they confirm their agreement to retain overall responsibility for their care;
- When the research involves a service user or carer or a child looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person (and/or their carer) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information;
- Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate;
- Unless participants or the NHS REC opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research;
- For clinical trials involving medicines, the research follows any conditions imposed by the UK Regulatory Authority (the MHRA);

¹ For clinical trials involving medicines, it is a legal requirement to follow the protocol approved by the licensing authority (the Medicines and Healthcare products Regulatory Agency).

² Also, for clinical trials involving medicines, to the licensing authority (MHRA)

- Procedures are in place to ensure collection of high quality, accurate data and to maintain the integrity and confidentiality of data during processing and storage³;
- Arrangements are in place for the management of financial and other resources provided for the study;
- Arrangements are in place for the management of any intellectual property arising from the research;
- Reports on the progress and outcomes of the work required by the UHB R&D Office, the Sponsor(s), funders, MHRA or others with a legitimate interest are produced on time and to an acceptable standard;
- The findings from the work are open to critical review through the accepted scientific and professional channels;
- They accept a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs. Once established, findings from the work are disseminated promptly and fed back as appropriate to participants;
- There are appropriate arrangements to archive the data when the research has finished, and to ensure it is still accessible. Study documents and source data must be retained in accordance with NHS Policy and the UHB R&D Standard Operating Procedure RD02: Research Study Files, Filing and Archiving (22);
- All data and documentation associated with the study are made available at the request of the inspection and auditing authorities.

7.7.4 Where the CI delegates responsibilities to members of the research team, this must be clearly documented in a study delegation log or similar, and kept in the Trial Master File or similar for each study. The CI remains accountable for the actions of his/her research team.

7.8 Responsibilities - Principal Investigator (PI)

7.8.1 The PI is the individual responsible for the research site where the study involves specified procedures requiring site-specific assessment. For multi site studies, there should be one PI for each research site. In the case of a single site study, the CI and the PI will normally be the same person. In this case the CI must assume the PI responsibilities detailed in this policy in addition to the CI responsibilities.

7.8.2 The PI is responsible for the conduct of the study at the study site and must ensure that:

- The research team give priority at all times to the dignity, rights, safety and well-being of participants;
- The study complies with all legal and ethical requirements;
- The research is carried out to the standards in the Research Governance Framework;

³ Also, for clinical trials involving medicines, procedures to comply with legal requirements concerning Good Clinical Practice during the trial, and Good Manufacturing Practice in manufacturing investigational medicinal products.

- All members of the research team/trial site team are trained in accordance with the UHB's GCP Training Policy for Personnel Undertaking Clinical Research (6);
- Each member of the local research team is qualified by education, training and experience to discharge his/her role in the study, and their qualifications are documented and retained in the Investigator Site File;
- All local researchers involved in a clinical trial of IMPs are aware of their legal duties and expressly agree to accept their tasks and roles on an individual study basis, with the PI required to sign the Standard Conditions of Management Approval for Clinical Trials of Investigational Medicinal Products (23);
- Students and new researchers have adequate supervision, support and training;
- UHB R&D approval is obtained prior to commencing the study;
- Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, by the UHB R&D Office and by the Sponsor⁴;
- Substantial amendments to the protocol or proposal are submitted for ethical review, for UHB R&D approval and Sponsor(s) agreement in accordance with UHB Standard Operating Procedures (20,21). With the exception of urgent safety measures these amendments are implemented only when approved⁵;
- When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and they confirm their agreement to retain overall responsibility for their care;
- When the research involves a service user or carer or a child looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person (and/or their carer) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information;
- Unless participants or the ethics opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research;
- For clinical trials involving IMPs, the research follows any conditions imposed by the Regulatory Authority (the MHRA);
- Procedures are in place to ensure collection of high quality, accurate data and for the integrity and confidentiality of data during processing and storage⁶;
- Arrangements are in place for the management of financial and other resources provided for the study;

⁴ For clinical trials involving medicines, it is a legal requirement to follow the protocol approved by the licensing authority (MHRA).

⁵ Also, for clinical trials involving medicines, to the licensing authority (MHRA).

⁶ Also, for clinical trials involving medicines, procedures to comply with legal requirements concerning Good Clinical Practice during the trial, and Good Manufacturing Practice in manufacturing investigational medicinal products.

- Arrangements are in place for the management of any intellectual property.
- Reports on the progress and outcomes of the work required by the CI, the UHB R&D Office, the Sponsor(s), funders, MHRA or others with a legitimate interest are produced on time and to an acceptable standard;
- The findings from the work are open to critical review through the accepted scientific and professional channels;
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants;
- There are appropriate arrangements to archive the data when the research has finished, and to ensure it is still accessible. Study documents and source data must be retained in accordance with the NHS Policy and in accordance with the UHB R&D Standard Operating Procedure RD02: Research Study Files, Filing and Archiving (22);
- All data and documentation associated with the study are made available at the request of the inspection and auditing authorities;
- In the event that the PI's position at the UHB is terminated that either (a) an appropriate individual assumes the role of PI and the Sponsor(s), REC, MHRA, CI and the R&D Office are informed and approve of the change in PI or (b) the study is terminated. The PI must ensure that information is provided to the Clinical Director so that the responsibilities in section 7.4.4 can be discharged

7.8.3 The PI must ensure that the R&D Office is involved in arranging agreements relating to the UHB's responsibilities in conducting research involving an external partner, funder and/or Sponsor and that these are authorised through the R&D Office in accordance with section 7.5

7.8.4 In relation to commercial research, the PI must:

- Refer all commercial research to the R&D Office at the earliest opportunity prior to the research commencing;
- Ensure that commercial research is performed under a written agreement between the UHB and the commercial company. This agreement must be signed by the Chief Executive of the UHB.

7.9 Responsibilities – All staff

Before agreeing to their patients or service users being approached, all staff must satisfy themselves that the research has been approved by the UHB R&D Office and, where necessary, the appropriate REC.

8.0 RESOURCES

- 8.1** The UHB R&D Office has responsibility for monitoring and auditing of research. This helps to ensure that the UHB's legal responsibilities in relation to the conduct of R&D can be met.
- 8.2** It is a legal requirement for all staff involved in studies covered by the Clinical Trials Regulations to work to the principles of GCP. There will be ongoing resource implications for ensuring all relevant staff have up to date training in GCP. Where necessary to comply with the UHB's GCP Training Policy for Personnel Undertaking Clinical Research, such training will also need to be provided to researchers involved in non-CTIMPs. This should be funded from the NISCHR R&D allocation to the UHB.
- 8.3** Research will not be undertaken unless there is appropriate resource identified.

9.0 TRAINING

- 9.1** Divisional R&D Leads will ensure that the relevant staff within their Division are aware of the Research Governance Policy and the implications for their practice.
- 9.2** The existence of the Research Governance Policy and its implications for researchers will be covered during UHB R&D training events.
- 9.3** Ongoing support of research staff will be provided via the UHB R&D Office.

10.0 IMPLEMENTATION

All staff undertaking R&D within the UHB together with those who have a specific responsibility within this policy are responsible for its implementation.

11.0 EQUALITY

The UHB is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups. We have undertaken an Equality Impact Assessment and received feedback on this policy and the way it operates. We wanted to know of any possible or actual impact that this policy may have on any groups in respect of gender (including maternity and pregnancy as well as marriage or civil partnership issues), race, disability, sexual orientation, Welsh language, religion or belief, transgender, age or other protected characteristics. The assessment found that there was no impact to the equality groups mentioned.

12.0 AUDIT

12.1 The UHB Research Governance Group is responsible for overseeing the operational management of research governance and for providing assurance of robust research governance arrangements in the UHB. It will be necessary to ensure that research projects hosted by the UHB are being carried out in accordance with this Policy.

12.2 Routine audits of research projects will be carried out by the R&D Office to ensure that all processes comply with the Policy. Compliance with the Policy will also be checked during any other audits undertaken by the R&D Office. Similarly, clinical trial monitoring visits will assess awareness of and compliance with the Policy. Audit findings will be reported to the Research Governance Group and to the UHB Quality and Safety Committee where appropriate.

13.0 DISTRIBUTION

The document will be available via the UHB Intranet and Cardiff University Internet site

14.0 REVIEW

The Policy will be reviewed every 3 years, or more regularly if new legislation so requires.

REFERENCES

- (1) Research Governance Framework for Health and Social Care in Wales 2nd Edition (2009). Wales Office of Research and Development for Health and Social Care (now NISCHR), Welsh Assembly Government, Cardiff.
- (2) The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031) and amendments. The Medicines and Healthcare products Regulatory Agency
<http://www.legislation.gov.uk/ukxi/2004/1031/contents/made>
- (3) The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (Statutory Instrument 2006/1928). The Medicines and Healthcare products Regulatory Agency (2006).
<http://www.hmsa.gov.uk/si/si2006/20061928.htm>
- (4) The Medicines for Human Use (Clinical Trials) Amendment (No. 2) Regulations 2006 (Statutory Instrument 2006/2984). The Medicines and Healthcare products Regulatory Agency (2006).

(<http://www.hmso.gov.uk/si/si2006/20062984.htm>)

- (5) Procedure for the Safe Handling of Clinical Trial Medicines within Cardiff and Vale University Health Board
- (6) Good Clinical Practice Training Policy for Personnel Undertaking Clinical Research (UHB015) Version 1.0 (November 2010).
- (7) The Data Protection Act (1998). HM Stationery Office, London (1998).
- (8) Confidentiality Code of Practice for Health and Social Care in Wales
<http://www.wales.nhs.uk/sites3/Documents/783/Confidentiality%20CodeofPractice.pdf>
- (9) Health and Safety at Work Act (1974)
<http://www.hse.gov.uk/legislation/hswa.htm>
- (10) The Human Tissue Act (2004). Available from the Office of Public Sector Information:
<http://www.opsi.gov.uk/acts/acts2004/20040030.htm>
- (11) The Mental Capacity Act (2005). Available from the Office of Public Sector Information:
<http://www.opsi.gov.uk/acts/acts2005/20050009.htm>
- (12) Welsh Statutory Instrument 2007 No.837 (W.72) The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007
- (13) The Mental Capacity Act 2005 Code of Practice
http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpgacop_20050009_en.pdf
- (14) Freedom of Information Act (2000)
<http://www.legislation.gov.uk/ukpga/2000/36/contents>
- (15) NHS Executive. Caldicott Guardians. HSC 1999/012 (1999).
- (16) Policy for Reporting Research-Related Adverse Events. Reference No. 164 (2005) (under review)
- (17) Procedure for Reporting Research-Related Adverse Events for Cardiff and Vale UHB Sponsored Clinical Trials of Investigational Medicinal Products (to be approved)
- (18) Procedure for Reporting Research-Related Adverse Events for Clinical Trials of Investigational Medicinal Products Hosted by Cardiff and Vale University Health Board (to be approved).

- (19) Procedure for Reporting Research-Related Adverse Events in Research studies (excluding Clinical Trials of Investigational Medicinal Products) (to be approved)
- (20) Amendments to a Clinical Trial of an Investigational Medicinal Product: Standard Operating Procedure (UHB 027)
- (21) Amendments to a study which is not a Clinical Trial of an Investigational Medicinal Product: Standard Operating Procedure (UHB 028)
- (22) Standard Operating Procedure RD02: Research Study Files, Filing and Archiving, Version 1.1 (April 2006) (under review).
- (23) Standard Conditions of Management Approval for Clinical Trials of Investigational Medicinal Products (R&D Office, A-CM-001)