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RESEARCH GOVERNANCE STANDARD OPERATING PROCEDURE

Introduction and Aim

Research Governance can be defined as the broad range of regulations, principles and standards of good practice that ensure high quality research. The Research Governance Standard Operating Procedure (the Procedure) underpins the Research Governance Policy. The Procedure should ensure that through outlining the responsibilities that fall to individuals involved in R&D that high quality research is carried out in accordance with the law and best practice.

Objectives

- 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.
- To ensure that all R&D is carried out lawfully, properly and sensitively, respecting the rights, dignity, wellbeing and safety of participants.
- To clearly identify the responsibilities that fall to individuals involved in research

Scope

The Procedure 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, satellite sites and authorised external organisations, or involving UHB resources, including non-clinical and laboratory based research;
- Research being undertaken as part of an educational qualification.

Equality and Health Impact Assessment	*An Equality and Health Impact Assessment (EHIA) has been completed on the Research Governance Policy under which this Research Governance Standard Operating Procedure falls and this found there to be no negative impact.*
Documents to read alongside this Procedure	*See Reference section.* *All R&D related SOPs as listed in the supporting documents section of the Research Governance Policy as they apply to*

	the type of research being undertaken
Approved by	*Research Governance Group*

Accountable Executive or Clinical Board Director	*Medical Director*
Author(s)	*Research and Development Manager*

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	30.04.2019	15.07.2019	This is a new Procedure. In compliance with the UHB Policy and Procedure templates, the previous version of the Research Governance Policy (UHB 099) has been rewritten as a separate short Research Governance Policy (UHB 099) underpinned by this Research Governance Procedure

Research Governance Standard Operating Procedure

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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.

- **Medicines and Healthcare products Regulatory Agency (MHRA)** – regulates medicines, medical devices and blood components for transfusion in the UK.

- **Participant** - Patient, service user, carer, relative of the patient or deceased, professional carer, other employee, or member of the public, who takes part in a research study (in law, participants in clinical trials involving IMPs are known as subjects).

- **Principal Investigator (PI)** – an individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single site study, the chief investigator and the PI will normally be the same person.

- **Research** - An attempt to derive generalisable or transferable 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.

- **Research team**- 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 legal and 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 UK policy framework for health and social care research (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 BACKGROUND

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, legal and 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 UK policy framework for health and social care research (1) sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards. These principles apply to all research that relates to the responsibilities of the Welsh Government and the other devolved administrations in the UK. 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 PRINCIPLES

2.1 Explicit written confirmation of capacity and capability from the UHB's Director of Research and Development must be obtained prior to commencing clinical research activity at the UHB for any research which requires capacity and capability to be confirmed.

2.2 To obtain confirmation of capacity and capability the research must be reviewed in accordance with the UHB's R&D processes and in accordance with the Health and Care Research Wales Support Centre policies and procedures

2.3 Where required, written evidence of a favourable opinion from the appropriate NHS Research Ethics Committee must be obtained prior to commencing research. The requirements for ethical review by Research Ethics Committees are set out in the harmonised UK-wide edition of the Governance Arrangements for Research Ethics Committees (GAfREC, 2018), (5) and include:
(i) Requirements for ethical review of research under legislation applying to the UK as a whole or particular countries of the UK
(ii)Requirements for ethical review under the policy of the UK Health Departments, where research relates to the services for which they are responsible

2.4 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 trial commencing. For Device studies a notice of no objection is required prior to the study commencing.

2.5 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 UK policy framework for health and social care research (1).

2.6 All research involving an Investigational Medicinal Product (IMP) undertaken within the UHB (whether University or NHS based) must adhere to UHB040 Investigational Medicinal Product (IMP) Management Standard Operating Procedure (7).

2.7 All intrusive research (which is not a CTIMP) for which consent is required and which may include participants who lack the mental capacity to agree to taking part must comply with the Mental Capacity Act 2005.

2.8 All investigators must be trained in compliance with the Research Training requirements including Good Clinical Practice (GCP) Training – SOP(UHB 317) (8).

2.9 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.

3.0 ROLES AND RESPONSIBILITIES

3.1 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 3.3. 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.

3.2 Responsibilities - Medical Director

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

3.3 Responsibilities –Director of Research and Development

The UHB Director of Research and Development 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 Sponsorship or confirmation of capacity and capability 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 3.5 and that the Office is appropriately resourced to do so.

3.4 Responsibilities – Management

3.4.1 Clinical Board Directors are responsible for:

- Establishing systems at Clinical Board level that facilitate compliance with the UK policy framework for health and social care research;
- Ensuring that all researchers working within their Clinical Board hold either a full or honorary UHB contract of employment in accordance with UHB Procedures, or a letter of access where appropriate.
- Appointment of Clinical Board R&D Leads.

3.4.2 Clinical Board R&D Leads are responsible for:

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

3.4.3 Directorate R&D Leads are responsible for:

- Undertaking Directorate review of projects submitted for consideration for R&D approval/capacity and capability confirmation and informing the R&D Office whether the Directorate is able to support the proposed research activity. This should include scientific review where appropriate.
- Establishing systems at Directorate level to comply with the R&D Approval/capacity and capability confirmation processes of the UHB and for ensuring research governance issues are communicated throughout the Directorate.
- Reporting to Clinical Board R&D Leads and Clinical Board Directors.

3.4.4 Clinical Directorate Directors are responsible for:

- Appointment of Directorate R&D Leads and Deputy R&D Leads.

- Ensuring that, subject to section 3.8.1, 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 R&D Standard Operating Procedures UHB 121 Archiving of Clinical trial and Research Study Data (9) and UHB 139 Data Management in Clinical Trials SOP (10)

3.5 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 UK policy framework for health and social care research ;
- Ensuring the UHB R&D approval/confirmation of capacity and capability process meets the requirements of the Welsh Government;
- Maintaining a record of all clinical research being conducted within the UHB
- 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 advice relating to in basic research methodology and governance;
- Monitoring and audit of research practices across the UHB to include ensuring receipt of monitoring reports where appropriate;
- 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, Safety and Experience 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 Safety Reporting in CTIMPs SOP (UHB 253) (11) upon receipt of any serious adverse event report.

3.6 Responsibilities – Researchers

3.6.1 All research staff, including those holding an Honorary Contract with the UHB, have the responsibility of being familiar with clinical research training requirements in accordance with the UHB Research Training requirements including Good Clinical Practice (GCP) Training – SOP (UHB 317) (8) and as described in the UK policy framework for health and social care research and, where applicable, the Clinical Trial Regulations and the Mental Capacity Act 2005, and must conduct their role accordingly.

3.6.2 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.

3.6.3 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 UK policy framework for health and social care research (1)
  - The Clinical Trials Regulations (where relevant) (2-4)
  - The Data Protection Act (2018) and General Data Protection regulations (GDPR) (12)
  - Confidentiality Code of Practice for Health and Social Care in Wales (13)
  - Health and Safety at Work Act (1974)(14)
  - The Human Tissue Act (2004) (15)
  - The Mental Capacity Act (2005) (16)
  - The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007 (17)
  - The Mental Capacity Act Code of Practice (18)
  - Freedom of Information Act 2000 (19)
  - Medical Devices Legislation (20-22)

  - 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 (12) and the Caldicott Principles (23).
- 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 Safety Reporting in CTIMPs SOP (UHB 253) (11).
- Suspected fraud or misconduct is reported in accordance with UHB policies and procedures.
- Complying with Managing breaches of GCP or the Protocol SOP in accordance with SOP (UHB 235) (24)
- Informed consent is taken in accordance with UHB policies and procedures and the Mental Capacity Act 2005 is followed where appropriate.

3.7 Responsibilities - Chief Investigator (CI)

3.7.1 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 UK policy framework for health and social care research or;
- lead and manage others who have been delegated responsibility for some of these aspects.

3.7.2 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.

3.7.3 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 UK policy framework for health and social care research;

- All members of the research team/trial site team are trained in accordance with the UHB's Research Training requirements including Good Clinical Practice (GCP) Training – SOP (UHB 317) (8);
- 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;
- 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;
- Ensuring robust scientific review is obtained where applicable
- The study is registered as per IRAS requirements
- R&D confirmation of capacity and capability is obtained from each care organisation involved prior to commencing the study at that care organisation;
- The Protocol is, where required, submitted for review by a 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 HRA/HCRW approval (where required), and Sponsor(s) agreement (and MHRA approval where appropriate) in accordance with UHB procedures (25, 26). With the exception of urgent safety measures, these amendments are implemented only when approved[2];
- 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

[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)

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 studies involving medicines and/or devices, the research follows any conditions imposed by the UK Regulatory Authority (the 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 storage[3];
- Recruitment data uploads entered by participating sites on national databases are checked. In circumstances where central upload of recruitment data is mandated, to accept responsibility for the upload of all participant recruitment data onto the national database.
- 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 R&D Standard Operating Procedures UHB 121 Archiving of Clinical trial and Research Study Data (9) and Data Management in Clinical Trials SOP (UHB 139) (10). All data and documentation associated with the study are made available at the request of the inspection and auditing authorities.

[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.

3.7.4 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.

3.8 Responsibilities - Principal Investigator (PI)

3.8.1 The PI is the individual responsible for the research site where the study involves specified procedures requiring capacity and capability 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 procedure in addition to the CI responsibilities.

3.8.2 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 UK policy framework for health and social care research;
- All members of the research team/trial site team are trained in accordance with the Research Training requirements including Good Clinical Practice (GCP) Training – SOP (UHB 317)(8);
- 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
- Students and new researchers have adequate supervision, support and training;
- UHB R&D approval/confirmation of capacity and capability 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 Sponsor[4];

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

- 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 and or devices , 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 storage[5];
- 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.
- 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 in accordance with Sponsor arrangements 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 R&D Standard Operating Procedures UHB 121 Archiving of Clinical Trial and Research Study Data (9) and UHB 139 Data management in Clinical Trials SOP (10)

[5] 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 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 3.4.4 can be discharged

3.8.3 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 3.5

3.8.4 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 or delegated deputy and must have been checked for authorisation by the R&D office.

3.8.5 The PI is responsible for ensuring that recruitment data for the site is uploaded onto the Local portfolio management System (ReDA3 in a timely manner, as instructed by the UHB R&D Office

3.8.6 The PI is responsible for ensuring they provide the R&D office with sufficient information on each study for completion of the mandatory minimum data set required by Welsh Government

3.9 Responsibilities – All UHB 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 and regulatory authorities. All staff have a responsibility to act within the limitations of their role, their training and competence. Staff must be supported to meet the required standards of the UHB in relation to skills training and competence assessment both prior to, and for the duration of their time working on the research study.

4.0 RESOURCES

4.1 The UHB R&D Office has responsibility for ensuring arrangements are in place 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.

4.2 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 training as per the Clinical Research Training requirements including Good Clinical Practice (GCP) Training – SOP (UHB 317) (8) This should be funded from the Health and Care Research Wales allocation to the UHB.

4.3 Research will not be undertaken unless there is appropriate resource identified.

5.0 TRAINING

5.1 Clinical Board R&D Leads will ensure that the relevant staff within their Clinical Board are aware of the Research Governance Policy and this Research Governance Procedure and the implications for their practice.

5.2 The existence of the Research Governance Policy and Procedure and its implications for researchers will be covered during UHB R&D training events.

5.3 Ongoing support of research staff will be provided via the UHB R&D Office.

6.0 IMPLEMENTATION

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

7.0 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 and Health Impact Assessment on the Research Governance Policy under which this Procedure falls and received feedback on the Policy and the way it operates. We wanted to know of any possible or actual impact that the Policy or Procedure 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.

8.0 AUDIT

8.1 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 the Research Governance Policy and Procedure..

8.2 Risk-based audit of a small selection of research projects will be carried out in compliance with the Research Audit SOP (UHB 236) to ensure that processes comply with this procedure. Similarly, for selected UHB Sponsored studies, audit visits will assess awareness of and compliance with this procedure. Audit findings will be reported to the Research Governance Group and to the UHB Quality, Safety and Experience Committee where appropriate. Principal Investigators may also be expected to carry out self-audit under the guidance of the R&D Office.

9.0 DISTRIBUTION

The document will be available via the UHB Intranet and on the R&D Internet pages once reconfigured in partnership with Health and Care Research Wales Support Centre.

10.0 REVIEW

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

REFERENCES

(1) UK policy framework for health and social care research v3.3 7/11/17. https://www.healthandcareresearch.gov.wales/uploads/Policy%20%26%20Strategy/Research%20Governance/uk-policy-framework-health-social-care-research.pdf

(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/uksi/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.hmso.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) GAfREC is available at https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures/

(6) HRA guidance on requirements for ethical review https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/

(7) Investigational Medicinal Product (IMP) management Standard Operating Procedure. (UHB 040)

(8) Research Training requirements including Good Clinical Practice (GCP) Training – SOP (UHB 317)

(9) Archiving of Clinical Trial and Research Study Data SOP (UHB 121)

(10) Data Management in Clinical Trials SOP (UHB 139)

(11) Safety Reporting in CTIMPs SOP (UHB 253)

(12) The Data Protection Act (2018) and General Data Protection Regulation (GDPR) *https://ico.org.uk/for-organisations/guide-to-data-protection/introduction-to-data-protection/about-the-dpa-2018/*

(13) Confidentiality Code of Practice for Health and Social Care in Wales http://www.wales.nhs.uk/sites3/Documents/950/CodeofPractice.pdf

(14) Health and Safety at Work Act (1974) http://www.hse.gov.uk/legislation/hswa.htm

(15) The Human Tissue Act (2004). http://www.legislation.gov.uk/ukpga/2004/30

(16) The Mental Capacity Act (2005). http://www.legislation.gov.uk/ukpga/2005/9

(17) Welsh Statutory Instrument 2007 No.837 (W.72) The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007

(18) The Mental Capacity Act 2005 Code of Practice http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpgacop_20050009_en.pdf

(19) Freedom of Information Act (2000) http://www.legislation.gov.uk/ukpga/2000/36/contents

(20) Medical Devices Regulations 2002 http://www.legislation.gov.uk/uksi/2002/618/introduction/made

(21) The EU Regulation on Medical Devices 2017/745 https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN

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