GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board	**Reference Number: UHB099** **Version Number: 4** **Date of Next Review: 06/07/2025** **Previous Trust/LHB Reference Number: 296**

RESEARCH GOVERNANCE POLICY

Policy Statement

Research Governance can be defined as the broad range of regulations, principles and standards of good practice that ensure high quality research. Cardiff and Vale University Health Board (UHB) considers the governance of research and development (R&D) activity involving its patients, staff and resources to be of paramount importance. We are committed to high quality, relevant research that is managed appropriately to ensure patient dignity, rights, safety and wellbeing. We will ensure that all research complies with the law and that financial probity is maintained.

Policy Commitment

The UHB is committed to providing 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.

Supporting Procedures and Written Control Documents

This Policy and the supporting procedures listed below aim 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
- Ensure that all R&D is carried out lawfully, properly and sensitively respecting the rights, dignity, wellbeing and safety of patients
- Clearly identify the responsibilities of individuals involved in R&D

Other supporting documents are:

Research Governance Procedure (UHB 457)
Governance & Compliance Audit of Human Tissue For Research Purposes (UHB 134)
Financial Procedure for supporting Non-Commercial Research (UHB 487)
Archiving of Clinical Trial and Research Study Data SOP (UHB 121)
Informed Consent in Clinical Research (UHB 147)
Investigating and Handling Allegations of Research Misconduct Procedure (UHB145)
Research Audit SOP (UHB 236)
Managing Breaches of Good Clinical Practice or the Study Protocol SOP (UHB 235)
Oversight and Monitoring in Research SOP (UHB 247)
Data Management for Clinical Trials SOP (UHB 449)

Safety Reporting in CTIMPs SOP (UHB 253)
Clinical Research Training requirements including Good Clinical Practice (GCP) Training – SOP (UHB 317)
Applying for Cardiff and Vale UHB NHS Sponsorship SOP (UHB 453)
Reporting requirements for Cardiff and Vale UHB Sponsored Research SOP (UHB 406)
Managing amendments for Sponsored Research SOP (UHB 302)
Obtaining Capacity and Capability Confirmation for Research to Start (UHB 448)
UK Policy Framework for Health and Social Care Research

Scope

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, 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 Impact Assessment (EqIA) was completed on Version 1 and 2 and this found there to be no impact. This EqIA has been updated with new references to form an EHIA. The changes to the Policy (see below) would not impact on the outcome of the EHIA.

Policy Approved by	Quality, Safety and Experience Committee Chair
Group with authority to approve procedures written to explain how this policy will be implemented	Research Governance Group
Accountable Executive or Clinical Board Director	Medical Director

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 Review Approved	Date Published	Summary of Amendments
2	Review by Research Governance Group 26/04/2016	1/11/2016	The document has been updated to reflect the current Clinical Board and committee structure of the UHB, the changes to Health and Care Research Wales and updated internal UHB documents. The Mental Capacity Act has been highlighted in certain sections. The Audit section has been changed to reflect alignment with the current Research Audit SOP
3	Review by QSE Committee	26/09/2019	In line with UHB requirements, this Policy now follows the Policy template of UHB. UHB Policy has been replaced by a Policy and a Procedure and has been updated to reflect the replacement of the Research Governance Framework for Health and Social Care in Wales with the UK Policy Framework for Health and Social Care Research.
4	Review by Research Governance Group		EHIA assessment reviewed and no issues noted to be changed. All references to the R&D office have been updated to JRO. Links checked and updated.

Equality & Health Impact Assessment for

Research Governance Policy

1.	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	Research Governance Policy
2.	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Joint Research Office, Medical Director's Office, Executive Clinical Board Research and Development Manager, Joint research Office, Floor 2, Old Lakeside Building
3.	Objectives of strategy/ policy/ plan/ procedure/ service	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 • Ensure that all R&D is carried out lawfully, properly and sensitively respecting the rights, dignity, wellbeing and safety of participants • Clearly identify the responsibilities of individuals involved in R&D

4.	Evidence and background information considered. For example • population data • staff and service users data, as applicable • needs assessment • engagement and involvement findings • research • good practice guidelines • participant knowledge • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages Population pyramids are available from Public Health Wales Observatory[1] and the UHB's 'Shaping Our Future Wellbeing' Strategy provides an overview of health need[2].	Previous EQIA performed on the previous version of the Research Governance Policy. Comments from those involved in the designing and development stages Good practice guidelines Based on content of the UK Policy Framework for Health and Social Care Research which underwent extensive consultation at the UK wide level at staff and service user level.
5.	Who will be affected by the strategy/ policy/ plan/ procedure/ service	Staff and service users involved in Research and Development

[1] http://nww2.nphs.wales.nhs.uk:8080/PubHObservatoryProjDocs.nsf
[2] http://www.cardiffandvaleuhb.wales.nhs.uk/the-challenges-we-face

6. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.**
6.1 Age For most purposes, the main categories are: • under 18; • between 18 and 65; and • over 65	The policy applies equally to all research participants and all those involved in the research study. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application process and the guidance for information sheets and their content. The guidance available from NRES (HRA) ensures that vulnerable adults and children have special protection and the oversight provided by monitoring and audit by sponsors ensures that this is implemented. Its application requires strict adherence to legal obligations, regulations and guidance in		

	respect of information governance management. The evidence suggests that it has no impact on this equality group.		
6.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	Yes Documents are not automatically published in Braille or languages other than English. The primary source of circulation is via the intranet. Software which will read the policy for the reader is now very common therefore documents should generally be accessible to those with a visual impairment. The Disability Discrimination Act requires that information should be made accessible for those with disabilities. In addition, recommendations on accessibility in terms of reading age, form part of the ethical review undertaken of all research taking place within the NHS and are contained in the NRES guidance referenced at the end of this section. Where specific groups with a particular disability are part of a research group under study then as part of the ethical review, arrangements for taking informed consent in an appropriate way and with appropriate skills/tools will be a mandatory part of the review and approval process. The Health Research Authority together with the Medical Research Council ‘Consent and Patient Information Sheet preparation Guidance’ http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/ highlights the requirement for information to be made available in appropriate ways to allow equality of access to research studies for all.		

	Governance arrangements for Research Ethics Committees available at Governance arrangements for Research Ethics Committees - Health Research Authority (hra.nhs.uk)		
6.3 People of different genders: Consider men, women, people undergoing gender reassignment **NB** Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender	The policy applies equally to all research participants and all those involved in the research study. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application process and the guidance for information sheets and their content. The guidance available from NRES (HRA) ensures that vulnerable adults and children have special protection and the oversight provided by monitoring and audit by sponsors ensures that this is implemented. Its application requires strict adherence to legal obligations, regulations and guidance in respect of information governance management. The evidence suggests that it has no impact on this equality group.		

6.4 People who are married or who have a civil partner.	The policy applies equally to all research participants. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application process and the guidance for information sheets and their content. The guidance available from NRES (HRA) ensures that vulnerable adults and children have special protection and the oversight provided by monitoring and audit by sponsors ensures that this is implemented. Its application requires strict adherence to legal obligations, regulations and guidance in respect of information governance management. The evidence suggests that it has no impact on this equality group.		
6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	There are potential risks to the unborn child in including women of child bearing age in early phase drug studies. In the past this meant that only men were recruited. However, women are now included in these studies with very careful control of pregnancy testing before during and after the study and follow up and reporting of all pregnancy outcomes to the Medicine and Healthcare products Regulatory Agency. As part of the ethical review that all research studies undergo aspects of equality of access will be closely examined Governance arrangements for Research Ethics Committees available at Governance arrangements for Research Ethics Committees - Health Research Authority (hra.nhs.uk)		

6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers	The policy applies equally to all research participants and all those involved in the research study. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application process and the guidance for information sheets and their content. The guidance available from NRES (HRA) ensures that vulnerable adults and children have special protection and the oversight provided by monitoring and audit by sponsors ensures that this is implemented. Its application requires strict adherence to legal obligations, regulations and guidance in respect of information governance management. The evidence suggests that it has no impact on this equality group. Issues around cultural and language are dealt with extensively as part of the ethical review that all research projects undergo before getting approval to be undertaken. Evidence has been gathered from the National Research Ethics Service(NRES) website guidance document http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/. In particular it is a requirement as part of ethical approval that if translation is required to enable an individual to consider taking part in a research project then translation must be provided by an independent translator provided by the organisation. There is a specific section in the NRES/IRAS application which highlights the fact that family members must not be used to ensure that there is no coercion. Governance arrangements for Research Ethics Committees available at		

	Governance arrangements for Research Ethics Committees - Health Research Authority (hra.nhs.uk)		
6.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief	The policy applies equally to all research participants and all those involved in the research study. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application process and the guidance for information sheets and their content. The guidance available from NRES (HRA) ensures that vulnerable adults and children have special protection and the oversight provided by monitoring and audit by sponsors ensures that this is implemented. Its application requires strict adherence to legal obligations, regulations and guidance in respect of information governance management. The evidence suggests that it has no impact on this equality group.		
6.8 People who are attracted to other people of: • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual)	The policy applies equally to all research participants and all those involved in the research study. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application process and the guidance for information sheets and their content. The guidance available from NRES (HRA) ensures that vulnerable adults and children have special protection and the oversight provided by monitoring and audit by sponsors ensures that this is implemented. Its application requires strict adherence to legal obligations, regulations and guidance in		

	respect of information governance management. The evidence suggests that it has no impact on this equality group. Evidence has been gathered from the NMC which highlights the responsibility of all nurses/midwives to treat [people] fairly irrespective of race, disability, age, sexual orientation, religion or belief and gender. Available at http://www.nmc-uk.org/About-us/Equality-and-diversity/Equality-and-diversity-about-us/		
6.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design Well-being Goal – A Wales of vibrant culture and thriving Welsh language	In respect of communication the UHB will need to ensure that people who wish to communicate in the Welsh medium have a means to do so as referred to in our Welsh Language Scheme. This can be found on the UHB website Welsh Language in Healthcare - Cardiff and Vale University Health Board (nhs.wales)		
6.10 People according to their income related group:	The policy applies equally to all research participants and all those involved in the research study. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application		

Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health	process and the guidance for information sheets and their content. The guidance available from NRES (HRA) ensures that vulnerable adults and children have special protection and the oversight provided by monitoring and audit by sponsors ensures that this is implemented. Its application requires strict adherence to legal obligations, regulations and guidance in respect of information governance management. The evidence suggests that it has no impact on this equality group.		
6.11 People according to where they live: Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities	The policy applies equally to all research participants and all those involved in the research study. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application process and the guidance for information sheets and their content. The guidance available from NRES (HRA) ensures that vulnerable adults and children have special protection and the oversight provided by monitoring and audit by sponsors ensures that this is implemented. Its application requires strict adherence to legal obligations, regulations and guidance in respect of information governance management. The evidence suggests that it has no impact on this equality group.		
6.12 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service	No further additions required		

7. HIA / How will the strategy, policy, plan, procedure and/or service impact on the health and well-being of our population and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people and on the impact on our population. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts and any particular groups affected**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate** Make reference to where the mitigation is included in the document, as appropriate
7.1 People being able to access the service offered: Consider access for those living in areas of deprivation and/or those experiencing health inequalities Well-being Goal - A more equal Wales	The policy applies equally to all research participants and all those involved in the research study. The strict regulatory framework which governs the conduct of research within the NHS has at its heart equality of access to research for all potential participants. This is enshrined in the application process and the guidance for information sheets and their content.		

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts and any particular groups affected**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate** Make reference to where the mitigation is included in the document, as appropriate
7.2 People being able to improve /maintain healthy lifestyles: Consider the impact on healthy lifestyles, including healthy eating, being active, no smoking /smoking cessation, reducing the harm caused by alcohol and /or non-prescribed drugs plus access to services that support disease prevention (eg immunisation and vaccination, falls prevention). Also consider impact on access to supportive services including smoking cessation services, weight management services etc. Well-being Goal – A healthier Wales	There is potentially a positive impact in this area as some research conducted in accordance with this policy may address how various interventions relating to changing lifestyle to more healthier choices can improve well being		

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts and any particular groups affected**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate** Make reference to where the mitigation is included in the document, as appropriate
7.3 People in terms of their income and employment status: Consider the impact on the availability and accessibility of work, paid/ unpaid employment, wage levels, job security, working conditions Well-being Goal – A prosperous Wales	This policy has little impact in this area		
7.4 People in terms of their use of the physical environment: Consider the impact on the availability and accessibility of transport, healthy food, leisure activities, green spaces; of the design of the built environment on the physical and mental health of patients, staff and visitors; on air quality, exposure to pollutants; safety of neighbourhoods,	This policy has little impact in this area. However some research conducted under this policy may produce results which show that certain interventions on physical environment may have a positive impact on health and well-being.		

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts and any particular groups affected**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate** Make reference to where the mitigation is included in the document, as appropriate
exposure to crime; road safety and preventing injuries/accidents; quality and safety of play areas and open spaces Well-being Goal – A resilient Wales			
7.5 People in terms of social and community influences on their health: Consider the impact on family organisation and roles; social support and social networks; neighbourliness and sense of belonging; social isolation; peer pressure; community identity; cultural and spiritual ethos Well-being Goal – A Wales of cohesive communities	Researchers are encouraged to seek input from the lay community/patient support groups when designing research studies. This can have a positive impact on the sense of belonging and 'community' identity.		

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts and any particular groups affected**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate** Make reference to where the mitigation is included in the document, as appropriate
7.6 People in terms of macro-economic, environmental and sustainability factors: Consider the impact of government policies; gross domestic product; economic development; biological diversity; climate Well-being Goal – A globally responsible Wales	High quality relevant research as outlined in this policy can have a positive impact on influencing government policy and guidelines		

Please answer question 8.1 following the completion of the EHIA and complete the action plan

8.1 Please summarise the potential positive and/or negative impacts of the strategy, policy, plan or service	A policy which commits to the UHB carrying out high quality research in a safe and lawful manner has the potential to positively impact on the patient community by providing opportunities for patients to receive new and innovate treatments and diagnostic procedures and ensure UHB retains a positive reputation for undertaking high quality research

Action Plan for Mitigation / Improvement and Implementation

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
8.2 What are the key actions identified as a result of completing the EHIA?	On reviewing the previous policy and writing the latest policy and procedure and completing the EHIA, there appear to be no negative impacts of the Policy. Therefore no key actions have been identified.			

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
8.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment required? This means thinking about relevance and proportionality to the Equality Act and asking: is the impact significant enough that a more formal and full consultation is required?	As no negative impact has been identified, it is considered unnecessary to undertake a more detailed assessment.			

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
8.4 What are the next steps? Some suggestions:- • Decide whether the strategy, policy, plan, procedure and/or service proposal: ○ continues unchanged as there are no significant negative impacts ○ adjusts to account for the negative impacts ○ continues despite potential for adverse impact or missed opportunities to advance equality (set out the justifications for doing so) ○ stops. • Have your strategy, policy, plan, procedure and/or service proposal approved • Publish your report of this impact assessment • Monitor and review	On reviewing this policy and rewriting as a policy and procedure in line with UHB guidelines, the EQIA has been revisited and an EHIA now completed. The policy and procedure have been approved by Research Governance Group. When this policy is next reviewed, this EHIA will form part of that consultation exercise. This EHIA will be reviewed 3 years after approval unless changes to terms and conditions, legislation or best practice determine that an earlier review is required			