Part A: Preparation and Assessment of Relevance and Priority

Part A is a three step process which will help you to prioritise work and prepare for EqIA.

Step 1 - Preparation:
identify the title of the Policy/function/strategy, the main aims and the key contributors
(see **Form 1**)

Step 2 - Gather Evidence:
collect, but do not analyse information at this stage - just see what evidence is available
(see **Form 2**)

Step 3 - Assessment of Relevance and Priority:
determine whether or not the evidence demonstrates high, medium, low, or no relevance and priority across the core dimensions of the equality duties, by each of the equality strands
(see **Form 3**)
(see Form 3)

Form 1: Preparation

Part A must be completed at the beginning of a Policy/function/strategy development or review, and for every such occurrence. (Refer to the Step-by-Step Guide for additional information).

Step 1 - Preparation		
1.	**Title of Policy** - what are you equality impact assessing?	**Procedure for the Safe Handling of Clinical Trial Medicines within Cardiff and Vale University Health Board**
2.	**Policy Aims and Brief Description** - what are its aims? Give a brief description of the Policy (The What, Why and How?)	This procedure sets out the standards required for the management of clinical trial medicines at Cardiff and Vale University Health Board. To inform potential investigators of the requirements for safe, ethical and legal trials management for Investigational Medicinal Products. Provide details of activities which need to be completed before a trial is undertaken and responsibilities of pharmacy and investigators during the trial. Safe, ethical and legal practice in accordance with Good Clinical Trials Practice (MHRA)
3.	**Who Owns/Defines the Policy?** - who is responsible for the Policy/work?	The Pharmacy Clinical Trials Group is responsible for developing this policy. The Research Governance Group is responsible for approving this policy. The Directorate of Pharmacy and Medicines Management and the UHB Research and Development Department are responsible for implementing the policy.

Step 1 - Preparation		
4.	**Who is Involved in undertaking this EqIA? -** who are the key contributors to the EqIA and what are their roles in the process?	Kathryn Murray, Clinical Trials Pharmacist undertook the EqIA
5.	**Other Policies** - Describe where this Policy/work fits in a wider context. Is it related to any other policies/activities that could be included in this EqIA?	Links with relevant UHB Pharmacy Clinical Trials and R&D procedures, including CT19 'Supply storage and monitoring of IMP held outside of pharmacy', CT17 'Maintenance of Active Trials', CT3 'Preparing for Cardiff and Vale University Health Board Research Review Service Meetings' , ' (UHB adopted) Trust Research Governance Policy (ref 296) September 2007' and 'Standard conditions of management approval for clinical trials of investigational medicinal products'
6.	**Stakeholders** - Who is involved with or affected by this Policy?	Directorate of Pharmacy and Medicines Management, UHB Research and development department, Investigators

Step 1 - Preparation		
7.	**What factors may contribute to the outcomes of the Policy? What factors may detract from the outcomes?** These could be internal or external factors.	Compliance with this policy will ensure that IMP management for clinical trials performed in the UHB is safe and ethical and in accordance with legal practice in accordance with Good Clinical Trials Practice (MHRA)

Form 2: Evidence Gathering

Equality Strand	Evidence Gathered	Does the evidence apply to the following with regard to this Policy/work? Tick as appropriate.									
		Eliminating Discrimination and Eliminating Harassment		Promoting Equality of Opportunity		Promoting Good Relations and Positive Attitudes		Encouraging participation in Public Life		Take account of difference even if it involves treating some individuals more favourably*	
Race	No evidence found after undertaking a search of procedure undertaken by other NHS organisations. (google search performed 21/9/15 by Kathryn Murray)		x		x		x		x		
Disability	No evidence found after undertaking a search of procedure undertaken by other NHS organisations. (google search performed 21/9/15 by Kathryn Murray)		x		x		x		x		x
Gender	No evidence found after undertaking a search of procedure undertaken by other NHS organisations. (google search performed 21/9/15 by Kathryn Murray)		x		x		x		x		
Sexual Orientation	No evidence found after undertaking a search of procedure undertaken by other NHS organisations. (google search performed 21/9/15 by Kathryn Murray)		x		x		x		x		
Age	No evidence found after undertaking a search of procedure undertaken by other NHS organisations. (google search performed 21/9/15 by Kathryn Murray)		x		x		x		x		
Religion or Belief	No evidence found after undertaking a search of procedure undertaken by other NHS organisations. (google search performed 21/9/15 by Kathryn Murray)		x		x		x		x		
Welsh	No evidence found after undertaking a search of		x		x		x		x		

Language	**procedure undertaken by other NHS organisations. (google search performed 21/9/15 by Kathryn Murray)**																		
People have a human right to: life; not to be tortured or treated in a degrading way; to be free from slavery or forced labour; to liberty; to a fair trial; not to be punished without legal authority; to respect for private and family life, home and correspondence; to freedom of thought, conscience and religion; to freedom of expression and of assembly; to marry and found a family and to not be discriminated against in relation to any of the rights contained in the European Convention.																			
Human Rights	**This procedure takes into account the legislation- e.g no inhumane treatment, respecting people, consent and privacy.**																		

*** This column relates only to Disability due to the specific requirement in the DDA 2005 to treat disabled people more favourably to achieve equal outcomes. This is not applicable to the other equality strands.**

Form 3: Assessment of Relevance and Priority

Equality Strand	Evidence: Existing evidence to suggest some groups affected. Gathered from Step 2. (See Scoring Chart A)	Potential Impact: Nature, profile, scale, cost, numbers affected, significance. Insert one overall score (See Scoring Chart B)	Decision: Multiply 'evidence' score by 'potential impact' score. (See Scoring Chart C)
Race	**1**	**0**	**0**
Disability	**1**	**0**	**0**
Gender	**1**	**0**	**0**
Sexual Orientation	**1**	**0**	**0**
Age	**1**	**0**	**0**
Religion or Belief	**1**	**0**	**0**
Welsh Language	**1**	**0**	**0**
Human Rights	**1**	**0**	**0**

Scoring Chart A: Evidence Available

3	Existing data/research
2	Anecdotal/awareness data only
1	No evidence or suggestion

Scoring Chart B: Potential Impact

-3	High negative
-2	Medium negative
-1	Low negative
0	No impact
+1	Low positive
+2	Medium positive
+3	High positive

Scoring Chart C: Impact Decision

-6 to -9	High Impact (H)
-3 to -5	Medium Impact (M)
-1 to -2	Low Impact (L)
0	No Impact (N)
1 to 9	Positive Impact (P)

FORM 4: (Part A) Outcome Report

Policy Title:	**Procedure for the Safe Handling of Clinical Trial Medicines within Cardiff and Vale University Health Board**
Organisation:	Cardiff and Vale University Health Board
Name: **Title:** **Department:**	Kathryn Murray Clinical Trials Pharmacist Pharmacy Department, University Hospital of Wales
Summary of Assessment:	We have undertaken an Equality Impact Assessment and received feedback on this procedure and the way it operates. We wanted to know of any possible or actual impact that this 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.
Decision to Proceed to Part B Equality Impact Assessment:	**No** **Please record reason(s) for decision** **As there was no impact there is no reason to proceed to Part B**

Action Plan

You are advised to use the template below to detail any actions that are planned following the completion of Part A or Part B of the EqIA Toolkit. You should include any remedial changes that have been made to reduce or eliminate the effects of potential or actual adverse impact, as well as any arrangements to collect data or undertake further research.

	Action(s) proposed or taken	**Reasons for action(s)**	**Who will benefit?**	**Who is responsible for this action(s)?**	**Timescale**
1. What **changes** have been made as a result of the EqIA?	None				
2. Where a Policy may have differential impact on certain groups, state what arrangements are in place or are proposed to **mitigate** these impacts?	N/A				

3. **Justification**: For when a policy may have adverse impact on certain groups, but there is good reason not to mitigate.	N/A				
4. Describe any **mitigating actions** taken?	N/A				
5. Provide details of any actions planned or taken to **promote equality**.	N/A				

Date:	21/9/15
Monitoring Arrangements:	Regular review during meetings of Pharmacy Clinical Trials Group and Research Governance Group. Pharmacy and R&D clinical governance audits during life of policy
Review Date:	2020

Signature of all Parties:	You will have to sign a hard copy as well as 'electronically' signing a copy (choose a signature font) for when it gets published on both the intranet and the internet.