King's Health Partners Clinical Trials Office
Amendment assessment form

Study Short Title:	
Chief Investigator:	
(Co)Sponsor(s):	
EudraCT Number:	
IRAS Number:	
MATTS Number:	

Amendment ID: *(title or date etc.)*			
Justification: *(Describe changes and reason for changes)*			
Implementation: *(Give details on how the changes will be managed and implemented)*			
Documents that will change as a result of the amendment *(list not exhaustive; other documents may require amendments which should be listed here)*			
Documents that will submitted		**Current version & date**	**Amended version & date**
☐	**Protocol**		
☐	**IB**		
☐	**IMPD**		
☐	**PIS**		
☐	**ICF**		
☐	**GP letter**		
☐	**IMP labels**		
☐	**Other**		
Internal Trial Documents not for submission			
☐ **CRF/eCRF**		☐ **Lab Manual**	☐ **Source Data Location List**
☐ **Contracts**		☐ **Pharmacy Documents**	☐ **Statistical Analysis Plan**
☐ **Data Management Plan**		☐ **Risk Assessment**	☐ **Other** *(please specify)*:
☐ **Monitoring Plan**		☐ **Source Data Worksheets**	
Substantiality Review:			
		Substantial	**Non-Substantial**
MHRA		☐	☐
REC		☐	☐
HRA		☐	☐
Competent Authority Data set *(Completed in IRAS or EudraCT)*			
Update required?		☐ **Yes**	☐ **No**	☐ **Updates required but non-substantial and will not be submitted until next substantial amendment.**

If multinational, countries for which CA info will be updated:		☐ **N/A**
Parties to be notified of the amendment: *(list not exhaustive; there may be others which need to be listed here)*		
☐ **Pharmacy,**	☐ **Data Managers**	☐ **eCRF/Database Provider**
☐ **Clinical Research Facility**	☐ **External CTU/King's CTU**	☐ **Randomisation Service**
☐ **PIs**	☐ **ESMS/unblinding service**	☐ **Labs**
☐ **R&D**	☐ **Contracts team**	☐ **Other** *(please specify)**:***
Matts Updated?		
☐ **Yes**	☐ **No** *(please justify)*:	

Clinical Research Associate preparing amendment:	**Name:**
Clinical Quality Manager or Delegate Authorisation:	**Name:**
	Signature:
	Date:

(Signed copy to be filed in KHP-CTO Sponsor file)