Checklist of documents required for R&D review

The following documents are required for R&D approval:

Documents to be submitted	Further Information	Tick
All research studies require Trust R&D approval. **IRAS Form** If a study involves service users and carers external ethical approval is required. To obtain this an on-line Research application form is required via the Integrated Research Application System application form (IRAS) Please check on the National Research ethics Service website if your study requires ethical approval – some studies don't. However all research studies require Trust R&D approval	You will need to complete the IRAS electronic research application - IRAS. This is accessed via the IRAS website www.myresearchproject.org.uk Ensure the filter page is correctly completed as the pages thereafter only relate to the information entered in the filter page. The IRAS website advises on all aspects of undertaking research within the NHS HRA website If a study only involves staff, an IRAS application is **not** required.	
Site Specific Information Form (SSI Form)	The Declaration should be signed by the PI. All signatures are now electronic.	
Research Participant Information Sheet	(With version number and date)	
Research Participant Consent Form	(With version number and date)	
For guidance on Patient Information Sheets and Consent Forms please see the website http://www.bing.com/search?q=ethics+and+patient+information+sheets+consent+form+guidance&src=IE-SearchBox&FORM=IE8SRC		
Research Protocol	(with version number and date)	
Questionnaires (if non validated)		
Interview Schedules (if applicable)	(with version number and date)	
Summary CV for CI/Local PI	Submit the CV of the researcher who will conduct the research locally	
REC Letter showing favourable opinion (if applicable) **or** Written Confirmation from the REC that ethical review is not required	If your study involves service users and carers you will normally need external ethical approval. However in a few cases it is possible that a research study does not require ethical review. In this case you must submit written confirmation from the REC - an email is acceptable.	

Checklist continued.

Documents to be Submitted	Further information	Tick
Evidence of independent Peer Review	This is normally provided via the University hosting the research	
Gantt Chart R&D department will be able to issue a template if required	Brief breakdown of main milestones – eg planned recruitment schedule, write up, submission deadline, etc.	
Details of any **staff time** needed to support the study	Brief outline of what is expected from staff to support the study.	
Summary of the study for the R&D publications	This will be placed on the Trust website and needs to be in an easy read format. It should give a brief outline of the project, any inclusion/exclusion criteria and what is involved for potential participants.	

For Student Research only, please submit:		
Summary CV for Research Supervisor Template available from R&D department if required	Professional CV – eg work address and contact details rather than personal details.	
Evidence of University ethical approval (sign off)	Normally a letter of approval.	

For Clinical Trials of Investigational Medicinal Products (CTIMPs) only, please submit:		
Clinical Trial Agreement (CTA): Including contract/financial agreement, and statement of indemnity (Individual CTAs for each participating Trust).	For commercially contracted trials, the model Clinical Trial Agreement should be used. http://www.dh.gov.uk	
MHRA Approval – Clinical Trial Authorisation	http://www.mhra.gov.uk	
EudraCT Number	(European Clinical Trials Database) http://eudract.emea.eu.int	

If you have any queries, please contact the R&D department.
Please email documents to Karen.bruce@merseycare.nhs.uk