NHS
Mersey Care
NHS Foundation Trust

Community and Mental Health Services

Checklist of documents required for R&D review

All research studies to be carried out within the trust require Trust R&D review.

Documents to be submitted	Further Information	Tick
Copy of IRAS form Combined REC & R&D form as submitted for HRA approval If your study involves service users and carers, independent ethical approval will need to be sought. IRAS is a single system for applying for permissions and approvals for health and social care research in the UK. Please visit the IRAS website. The IRAS form will help you determine which review body approvals are required. To check if your study requires ethical approval: http://www.hra-decisiontools.org.uk/ethics/. The decision tool provides a decision certificate**	You will need to complete an on-line research ethics application form via the Integrated Research Application System (IRAS) www.myresearchproject.org.uk Ensure the filter page is correctly completed as this will determine the following pages and will only relate the information entered in the filter page. If a study only involves staff ethical approval is not required.	
Copy of REC Letter	Showing favourable opinion (if applicable) or REC confirmation that ethical approval is not required**	
Copy of Initial HRA Assessment letter	If issued	
HRA Approval letter HRA is the new process of approval for the NHS in England and brings together the assessment of governance and legal compliance alongside the independent Research Ethics Committee Service. HRA approval replaces the need for local NHS checks, and trusts now focus on assessing, arranging and confirming capacity to deliver the study.	Please visit the HRA website which offers guidance and FAQs regarding the review and approvals process http://www.hra.nhs.uk	
• **Research Protocol**	showing version number and date	
• **Participant Information Sheet(s)**	showing version number and date	
• **Participant Consent Form(s)**	showing version number and date	
Patient information sheet and consent form guidance: http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/		
• **Summary CV** Chief Investigator; Local Principal Investigator and researcher(s) conducting study.	Please contact the R&D Department to discuss access paperwork for the research team if attending trust premises. Link to template.	

Further documentation to be submitted		
• **Questionnaires**	Copies of non-validated questionnaires	
• **Interview Schedules**	with version number and date	
• **Amendments**	Details of any amendments made to Protocol and documentation receiving ethical approval	
• **HRA Statement of Activities** • **Schedule of Events**	*For non-commercial studies only* Please visit the HRA website for advice and/or contact theTrust's R&D dept. Example : Statement(s) of Activities and Schedule(s) of Events	
• **Relevant model agreement**	Please discuss with the R&D department if an agreement is required.	
• **Any other documents**	The sponsor can provide further documentation to support review, set up and delivery of the project.	
• **Study summary**	Details of your study may be placed on the Trust's website and/or internal intranet site. Please submit an easy read summary, providing a brief outline of the project in layman's terms approx. A5 paper size.	

For Student Research please submit:		
• **Summary CV** for Research Supervisor	Professional CV including work/university address and contact details rather than personal details. http://www.hra.nhs.uk/resources/applying-for-reviews/applying-for-approvals-template-documents/	
• **Evidence of University Ethical approval or Sponsorship**	Please provide written evidence that the study has University ethical approval or does not require ethical review, and/or confirmation of University sponsorship.	

For student studies involving *single* site and *staff* only		
• Protocol; • Information sheet and consent forms; • Evidence of University sponsorship/approval • Non-validated questionnaires and any interview schedules. • Summary cv for yourself and research supervisor.	If your educational study only involves staff and is on one site, an IRAS application is **not** required and the study can be reviewed outside of HRA (if a single site study). However, if your study involves more than one NHS site, HRA approval will be required.	
• Research passport or NHS to NHS confirmation of employment	Please discuss with the R&D department access paperwork and whether you require an Honorary Research Contract or Letter of Access.	

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, Research & Development Assistant
Karen.bruce@merseycare.nhs.uk or Tel: 0151 471 2638

Please see the R&D process flowchart which is on the trust's website or request a copy from the R&D dept.