Mersey Care
NHS Foundation Trust

Community and Mental Health Services

Research Review Process

for *all* research projects to be carried out in the Trust

Consider the research question: Discuss your research project idea with your line manager and/or academic supervisor, taking into account the Trust's R&D and Perfect Care priorities.

Developing the Research proposal –The Trust considers it is good practice to have your study peer reviewed. Additionally, you should involve service users and/or carers in all stages of the research project, particularly in the development of the proposal and the methodology. Service user and carer perspective is invaluable because they are experts by experience. If you need help and advice please contact the R&D dept. For useful Researcher Briefing notes on how to involve members of the public, please visit: http://www.invo.org.uk/resource-centre/resource-for-researchers.

Decide if your study is research as defined by the UK Policy Framework for Health and Social Care Research. by clicking on the interactive link: http://www.hra-decisiontools.org.uk/research/index.html

Documentation: Since the introduction of the General Data Protection Regulation (GDPR), the HRA has provided guidance for information sheets and consent forms. Please see recommended wording that can be incorporated into your Participant Information Sheet. https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-public-sector/

R&D notification: The Trust recommends that you contact the R&D team to provide details of your study, before or during submission to ethics so your project can be logged for review.
Service notification/review: Please make contact with the relevant service(s)/team managers well in advance of submission to ethics. The teams will need to have a clear understanding of the study and how much staff time is needed to support the project. Please visit the trust website or R&D Team if you are unsure who to contact.

Ethical approval: If your study involves service users and/or carers, you will need to apply for independent ethical approval via an on-line research application form. Please visit the Integrated Research Application System (IRAS) website https://www.myresearchproject.org.uk The website offers free e-learning modules to help you familiarise yourself with IRAS, application forms and process. Care should be taken when completing the application's filter page because this populates the following pages. If your study involves service users and carers, you will not be able to start the study until a copy of the ethical approval letter has been provided to the R&D team and a letter of support issued.
Verification of IRAS submission – *before* you submit to IRAS. When you have completed the IRAS form, uploaded all documents (with date and version numbers) and collected the required authorisations, you will need to complete the verification tool. This saves time and reduces the REC requesting additional information.
https://www.myresearchproject.org.uk/help/hlpverificationtool.aspx

Health Research Authority (HRA) approval:
If your study is to be led from England and involves the NHS, the study will require HRA approval. Trusts focus on assessing capacity and capability – looking at feasibility and facilitation.
HRA sits alongside ethical approval and trust review.
HRA approval is granted *after* ethical approval (if applicable) and *before* Trust confirmation of Capacity and Capability.
For further guidance please visit:
www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval.

For **Clinical Trials** going through HRA approval, the NIHR has introduced metrics and targets which trusts and researchers are asked to work together to meet. Your study is a clinical trial if you have chosen one of the below options in IRAS filter page,

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

If your study is a clinical trial, please contact the R&D team as soon as possible to discuss performance metrics

Student studies involving only staff:	**Non student studies involving only staff:**
Please notify the R&D team of your study. They may be able to link you to a key member of staff within the service(s). If the study is only taking place in **one** organisation (Mersey Care NHS Foundation Trust) then it can be reviewed outside of ethics and HRA approval process and an IRAS application is **not** required. If the study involves more than one trust, then you will need HRA approval via IRAS. Please see the attached Checklist of documents.	This type of study does **not** require ethical approval, but if it involves NHS sites led from England you will need to obtain HRA approval via IRAS. Please notify the R&D Team of your study and they may be able to link you with a key member of staff within the service(s). The project will be logged for review once HRA approval has been granted. These studies will require HRA approval but not ethics. Please see the attached Checklist of documents.

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Trust review:

NHS review is sometimes referred to as 'Local Set Up' or 'Assess, Arrange and Confirm'.
Before or during submission to HRA, please contact the R&D Team to make them aware of your study.
A local information pack (Checklist of Documents) should be sent by email to the R&D Team.
Receipt of the documents will activate trust review.
During this time contracts may need to be agreed and exchanged, supplies of any medicinal products will need to be ordered and provided to the trust and site initiation visits may take place. .
The study will be logged and issued with a trust identification number and the department and services will look at the practicalities and feasibility of carrying out your study.
Once all regulatory approvals are in place and R&D department has received confirmation of support from the relevant teams/service involved in the study, the R&D department will issue an email of Confirmation of Capacity and Capability (CCC). CCC provides proof that the study can commence. You may be asked to complete a form explaining the research in layman's terms which will be placed in R&D newsletter and/or Trust website.

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External researchers accessing the Trust: All external researchers should discuss with the R&D Team the need for Research Passports, Honorary Research Contracts or Letters of Access *before* any project starts.
Proof of a DBS checks may be required and you may need to attend Trust inductions for certain sites.
Further information concerning these issues can be obtained from the R&D Team.

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Recruitment data target: If your study is an 'adopted' study and eligible for NIHR adoption, you will be expected to upload monthly recruitment figures to the Central Portfolio Management System.
Please discuss with your local Clinical Research Network (CRN).
Providing recruitment data and updates is a condition of ethical and HRA approval. Please see HRA guidance.
If you are struggling to achieve your recruitment target within the given timeframe, please inform the R&D team as soon as possible.

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Amendments: If you plan to make an amendment to your research study, you will need to determine whether you need to notify the review bodies and inform the R&D team.
Please see the amendment guidance on the IRAS and HRA websites:
https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx
https://www.hra.nhs.uk/approvals-amendments/amending-approval

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Annual monitoring and recruitment data: All studies will be monitored annually.
It is a condition of ethical and HRA approval that feedback is provided.

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Completion and dissemination: At the end of your study the trust will ask you to complete a short feedback form.
The research findings will be shared with the relevant service(s).
Dissemination to research participants It is good practice to disseminate the results of research to research participants, who have kindly given up their time to be involved, and contributed to the study.
Research findings may be disseminated in article, report or presentation form; the format should be accessible and appropriate for all participants, and in a timely manner after the study has finished.
Please refer to the HRA guidance on information at the end of study.

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And FINALLY, thank you for choosing Mersey Care NHS Foundation Trust to be part of your research.
Research&developmentteam@merseycare.nhs.uk