

Cheshire and Wirral Partnership NHS Foundation Trust Research and Evaluations – Approval Guide

This document outlines an approval guide for research projects and evaluations being carried out at Cheshire and Wirral Partnership NHS Foundation Trust. As each project is slightly different, please contact the Research Office (philelliott@nhs.net) at the earliest opportunity so that a timely approval pathway can be facilitated.

The pathway is similar for research projects and evaluations, though research studies may require ethical and other additional approvals. Please note that decisions reached by project leads using the Health Research Authority algorithm for distinguishing between research and evaluations may not be upheld by the Trust, due to its potential for individual interpretation. This is especially the case for studies involving service users and carers. In such instances, the Trust will consult the Health Research Authority for a definitive decision. The Trust approval process is able to commence when all other approvals have been confirmed – for example, by the Health Research Authority, NHS ethics committees, and university ethics as appropriate.

All research studies require Health Research Authority approval. At present, the only exceptions are studies carried out at a single site (Trust) where the primary aim is to achieve an educational qualification. This is at the Trust's discretion (which is accepted at Cheshire and Wirral Partnership NHS Foundation Trust), on the understanding that Health Research Authority principles in research will be upheld. Evaluations would not require Health Research Authority/NHS ethics committee approvals in the majority of cases.

As a general guide, NHS ethics committee approval will also be required for research studies involving service users and/or carers, plus selected other studies where there may be added considerations such as vulnerability of participants. All studies taking place at, or involving, a university or similar institution will require university ethics approval, which vary from place to place, although usually similar.

When these approvals are obtained, the following documents would be required by the Trust's research office, as appropriate:

- Project proposal, with version and date
- Information sheet and consent form (version and date, with appropriate logo (i.e. university))
- Data collection tools, i.e. questionnaire, interview topic guide
- Health Research Authority and NHS ethics committee approval where appropriate
- University ethics application and approval as appropriate
- Signed and dated CV from project lead(s), plus from tutor for educational studies

A summary of the study will then be emailed by the research office to the appropriate clinical director(s) to ask if they have any concerns or queries, and if they would be willing for the study to proceed. The aim is to be as supportive as possible, and a reply is requested within seven working days, leave permitting. For educational studies, an email is also sent to tutors regarding working together with the aim of ensuring updates will be forthcoming when requested.

Following confirmation of approval, a formal letter will be issued alongside information about good practice in research, plus an approval acceptance form outlining approval terms and conditions. Once this has been signed, data collection may commence. For external researchers and project leads carrying out studies on Trust premises, a letter of access will also be issued upon receipt of confirmatory checks by the employer or educational institution.