Research Process Map

Research is now a key component of the Trust Strategy, being placed at 'the heart of what we do'.
To get involved, follow this process map:

The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust

START: All RJAH researchers **MUST** submit a hand-signed CV and GCP certificate every 2 years to conduct research. Sent it to rjah.researchoffice@nhs.net once complete.
GCP e-Learning: Good Clinical Practice | NIHR (for new researchers) or GCP refresher

Do you want to develop your own research idea?

Research study design and development

YES = Sponsored study pathway
Determine if your study is classified as research
Use this tool: Is my study research?

E-mail rjah.researchoffice@nhs.net to access support services for conducting 'home-grown' research at RJAH

Conduct a literature review to identify gaps in your topic of interest and further develop your research question
Guidance: The RJAH Library and Knowledge Service

Write a research protocol and sent it to rjah.researchoffice@nhs.net
Template and guidance: Protocol - Health Research Authority

NO = Hosted study pathway
E-mail rjah.researchoffice@nhs.net to register your interest in becoming involved in a research project

The Research Department will monitor research studies from external organisations that are potentially suitable to be undertaken at RJAH

The research project will be assigned to a Project Manager who will take it to a C&C (Capacity & Capability) meeting to discuss feasibility

Study set up

If feasible and suitable, the Research Department will seek Trust approval to undertake research at RJAH

If feasible and suitable, the Research Department will contact relevant researchers to establish interest in conducting the study. Once a researcher is identified the Project Manager will submit an expression of interest

Once selected as a study site, the Project Manager will accept the LIP (Local Information Pack) with essential study documents

The Project Manager will liaise with Research Governance to review the following documents (in draft for Sponsored studies):

- IRAS (Integrated Research Application System) form
- Essential study documents, including participant facing documents, study agreements and costings

Key:
- Sponsored study pathway
- Hosted study pathway
- Applicable to all studies

Written by Rebecca Davies, Research Dept

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Study set up

The study Chief (CI, lead study site) or Principal Investigator (PI, participating site) **MUST** complete a CI/ PI declaration and read the relevant Research SOPs (standard operating procedures) every 2 years

You must submit the reviewed IRAS form and associated study documents for ethical and regulatory approvals to conduct research in the UK

The Research Department will set up a research study site file with suggested investigator site file contents | NIHR

SIV (Site Initiation Visit) to be attended by the relevant research staff who will complete a Delegation Log

If all study set up activity has been completed, the Research Department and Governance will give the study the Green Light

Study conduct

Research screening - appropriately delegated individuals (study dependant) find participants that match study eligibility criteria

Research approach - appropriately delegated individuals (study dependant) can inform participants and give them a Participant Information Sheet (PIS)

Informed Consent conducted by appropriately delegated individuals (study dependant) - Training available from NIHR

Safety Reporting requirements are study specific, but generally protocol defined adverse events (AEs) will be submitted to the organisation responsible for study conduct

For sponsored studies, AEs will be submitted to RJAH

For hosted studies, AEs will be submitted to the external organisation

Conduct of study activity according to the protocol

Modifications are required when changes are needed to study conduct and run and must be re-reviewed by the Health Research Authority (HRA)

End of study

Database lock and statistical analysis by statistician

End of study declaration and final report submission to the HRA (Health Research Authority) by the Chief Investigator (may be external to RJAH for Hosted studies)

Dissemination of research results to research participants and the wider research community (publication and presentations)

The Research Department prepares the research for archiving to place in long-term storage

The Research Department securely destroys the research once the retention period has lapsed

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