



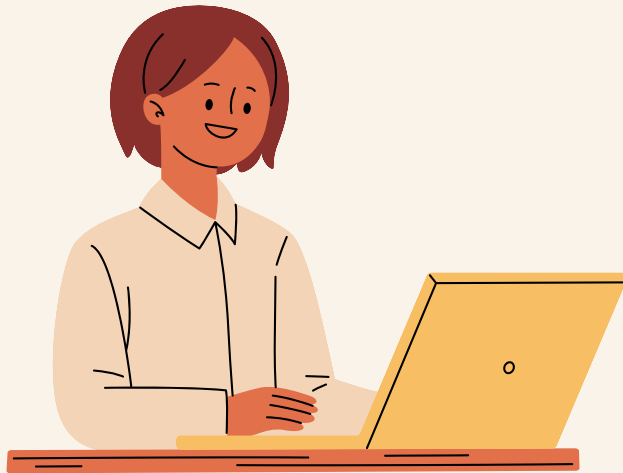
# CLCH RESEARCH & DEVELOPMENT (R&D) TOOLKIT

**SO, YOU HAVE A CLINICAL RESEARCH  
IDEA?**

**WELCOME TO THE CLCH R&D TOOLKIT!**

**WE ARE HAPPY YOU ARE HERE!**





**THE TOOLKIT HAS 8 QUESTIONS  
AND WAS DESIGNED TO HELP YOU  
WITH THE FIRST STEPS OF RUNNING  
CLINICAL RESEARCH AT CLCH**



**IT IS VERY SIMPLE TO USE: JUST  
GO THROUGH THE QUESTIONS  
AND ANSWER THEM WITH YOUR  
PROJECT OR RESEARCH IDEA IN  
MIND**



DON'T BE AFRAID OF  
JARGONS AND TERMS,  
THERE'S A GLOSSARY HERE  
TO HELP YOU

THERE ARE LOTS OF  
RESOURCES TO HELP  
CLARIFY QUESTIONS!



DON'T PANIC IF YOU GET STUCK,  
R&D TEAM IS HERE TO HELP  
JUST REMEMBER, RESEARCH IS FOR  
EVERYONE!



# CLCH RESEARCH & DEVELOPMENT (R&D) TOOLKIT



1

## IS THIS PROJECT CONSIDERED CLINICAL RESEARCH?

*Clinical research is an investigation based on rigorous scientific methods to understand, detect, diagnose, treat, and prevent health conditions*

*It can be randomised clinical trials (RCT), interventional, observational or qualitative studies*

*It addresses a specific question or hypothesis to generate new knowledge that is generalisable and transferable*

Yes

GO TO QUESTION 2

No

### THE PROJECT CAN BE:

**Audit:** contact Clinical Effectiveness

**Service Evaluation:** contact Clinical Effectiveness

**Quality Improvement:** contact QI Team

**Transformation:** contact PMO Team

See  
additional  
resource  
page

Not sure

### RESOURCES

- Is my study clinical research? The HRA decision tool
- What is patient-centered clinical research?
- Contact R&D if unsure



2

**HAS THIS PROJECT BEEN  
APPROVED BY AN NHS RESEARCH  
ETHICS COMMITTEE (REC)  
REVIEW?**

*Normally, research studies that recruit  
NHS service users require a NHS REC  
review*

**Yes**

**GO TO QUESTION 3**

**No**

**GO TO QUESTION 7**

**Not sure**

## **RESOURCES**

- Do I need NHS REC review? [The HRA decision tool](#)
- Check if the study was approved at the [HRA Research Summaries](#) search platform



3

**COULD YOU, THE CHIEF INVESTIGATOR, OR THE SPONSOR SECURE ENOUGH FUNDING FOR THE PROJECT, AND IT IS IN THE NIHR PORTFOLIO?**

*Usually, the Government, the NIHR, charities, or private companies are the main research funders*

**Yes**

**GO TO QUESTION 4**

**No**

**SEE THE FUNDING RESOURCE PAGE ABOUT OPPORTUNITIES**

**Not sure**

## **RESOURCES**

- Check if the study is receiving NIHR funding at the [NIHR Open Data Funded Portfolio](#) platform
- Contact the study Sponsor, Chief Investigator or Principal Investigator



4

**IS THE RESEARCH STUDY OPEN TO PARTICIPANT RECRUITMENT OR RECRUITING NEW NHS RESEARCH SITES ?**

*Usually, NHS research sites are clinical services that look after service users who meet the inclusion criteria of the study*

**Yes**

**GO TO QUESTION 5**

**No**

## **DECISION**

Contact the study Sponsor, Chief Investigator or Principal Investigator to check when it will open to recruit.  
If the study recruitment is ended, it cannot usually be implemented at CLCH

**Not sure**

## **DECISION**

Contact the CLCH R&D Administrator requesting EDGE consultation on project status



5

## IS THE PROJECT SUITABLE FOR DEVELOPMENT IN CLCH HEALTHCARE SETTINGS?

*In-hospital admission, extended  
research visits, out-of-hours visits, and  
pharmacological interventions are  
aspects to be considered.*

*Does CLCH have the infrastructure  
needed for the research study, or can  
CLCH collaborate externally to meet  
requirements?*

**Yes**

**GO TO QUESTION 6**

**No**

### DECISION

The study must be suitable for development in CLCH settings or able to collaborate with site partners. Contact the study Sponsor, Chief Investigator or Principal Investigator to check other opportunities

**Not sure**

### DECISION

Contact the study Sponsor, Chief Investigator or Principal Investigator to double-check this information





6

**DOES CLCH HAVE THE NECESSARY QUALIFIED AND EXPERT PERSONNEL TO DELIVER THE STUDY AND ELIGIBLE PARTICIPANTS FOR ITS INCLUSION?**

*Qualified and expert personnel are professionals with the relevant clinic qualifications and protected time to deliver all aspects of the research study described in the study protocol. Suitable potential participants are the CLCH patients, service users, and relatives who match the inclusion and exclusion criteria and may be keen to take part in this study*

**Yes**

**DECISION**

CLCH can run research after the Confirmation and Capacity and Capability (CCC) is confirmed. Contact the CLCH R&D Administrator for further procedures.

**No**

**DECISION**

If CLCH cannot run the study, it might not be suitable to be implemented

**Not sure**

**DECISION**

- Check the skills and qualifications needed with the study Sponsor, Chief Investigator or Principal Investigator
- **Research skills can be developed.** See the [additional resource page](#)



7

**HAS THIS PROJECT BEEN  
SUBMITTED TO AN NHS RESEARCH  
ETHICS COMMITTEE (REC) REVIEW?**

*NHS service user recruitment can't  
start until the research project has all  
needed approvals*

**Yes**

**GO BACK TO QUESTION 3**

**No**

**GO TO QUESTION 8**

**Not sure**

## **RESOURCES**

- Check the submission status with the study Sponsor, Chief Investigator or Principal Investigator
- [How to prepare and submit your research proposal](#)
- See the additional resource page



8

## HAS THIS PROJECT ALREADY BEEN FULLY DESIGNED AND DESCRIBED IN A STUDY PROTOCOL?

*A fully designed research study has background information, theoretical framework, study rationale, research question, objective, methods and study design, variables, assessment and questionnaire, statistical analysis plan, schedule of events, and costing.*

**Yes**



### RESOURCES

- Check the submission status with the study Sponsor, Chief Investigator or Principal Investigator
- [How to prepare and submit your research proposal](#)
- See the [additional resource page](#)
- See [funding resource page](#)

**No**



### RESOURCES

- [NHS Research Toolkit](#) to prepare a research proposal
- Study Protocol [templates](#)
- [NIHR Trial planning and design toolkit](#)
- See the [additional resource page](#)

**Not sure**



### DECISION

- Check with the study Sponsor, Chief Investigator or Principal Investigator
- See the [additional resource page](#)



# FUNDING RESOURCE PAGE

## TYPES OF FUNDING

Know about types of research funding

## ALL SPECIALITIES

- NIHR Funding opportunities
- UK RI Funding Finder
- Royal College of Nursing
- The British Academy
- Marie Skłodowska-Curie Actions (MSCA)
- Medical Research Council (MRC)
- UK Clinical Research Collaboration (UKCRC)
- UK Research Office (UKRO)
- Sigma Global Nursing Excellence
- Association of Medical Research Charities (AMRC)
- The Health Foundation

## RESPIRATORY/COPD

- British Thoracic Society
- Asthma + Lung UK

## CHILDREN

- Royal College of Paediatrics and Child Health
- Froebel Trust
- Great Ormond Street Hospital Children's Charity
- Children's Cancer and Leukaemia Group

## STROKE/CARDIOVASCULAR

- UK Stroke Association
- British Heart Foundation
- Heart Research UK
- European Society of Cardiology

## DEMENTIA/NEURODEGENERATIVE DISORDERS

- Alzheimer's Society
- Alzheimer's Research UK
- Age UK
- Motor Neurone Disease Association

## CANCER

- Cancer Research UK
- Children with Cancer UK
- Blood Cancer UK

## DIABETES

- Diabetes UK
- British Heart Foundation joint with Diabetes UK
- Diabetes Research & Wellness Foundation

## MENTAL HEALTH

- Medical Research Foundation
- Mental Health Research Incubator

## SEXUAL HEALTH

- British Association for Sexual Health and HIV
- Wellbeing of Women



Central London  
Community Healthcare  
NHS Trust

# ADDITIONAL RESOURCE PAGE 1/3



## CLCH – RESEARCH & DEVELOPMENT (R&D)

- [R&D Team](#)
- [R&D Hub](#)
- [R&D Strategy](#)
- [Research Governance Policy](#)
- [R&D resources Hub page](#)

## TRAINING & CAREER DEVELOPMENT

- [Good Clinical Practice \(GCP\)](#)
- [NIHR Career Development](#)
- [National Institute for Health and Care Research Learn & Support](#)
- [Your Path in Research](#)

## LIBRARY & EVIDENCE SERVICES

- [CLCH Library Information Page](#)
- [OpenAthens](#)
- [NHS Knowledge & Library Hub](#)
- [KnowledgeShare](#)

## NATIONAL RESOURCES

- [Be Part of Research](#)
- [National Institute of Health and Care Research \(NIHR\)](#)
- [Health Research Authority \(HRA\)](#)
- [Research Ethics Committee](#)
- [Integrated Research Application System \(IRAS\)](#)
- [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#)
- [Clinical Trials Toolkit](#)

## PATIENT & PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE)

- [UK Standards for Public Involvement](#)
- [Public involvement in NHS, health and social care research](#)
- [Involve Patients](#)
- [NIHR Evidence](#)
- [INVOLVE](#) - Starting out
- [Equality, diversity and inclusion \(EDI\)](#)

## CLINICAL ACADEMIC CAREER PATHWAYS

- [Health Education England \(HEE\)](#)
- [Clinical Academic Careers Framework](#)
- [Integrated Academic Training \(IAT\) Programme](#)
- [HEE-NIHR Integrated Clinical and Practitioner Academic Programme](#)
- [A guide to starting out in clinical academic research](#)





## NATIONAL/ INTERNATIONAL REGULATIONS & GUIDANCE

- UK Policy Framework for Health & Social Care Research
- Medicines For Human Use (Clinical Trials) Regulations 2004 (as amended)
- EU Clinical Trials Directive 2001/20/EC
- EU Good Clinical Practice (GCP) Directive 2005/28/EC
- Human Tissue Act 2004
- Data Protection Act 2018
- Mental Capacity Act 2005
- Freedom of Information Act 2000
- General Data Protection Regulation 2018
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
- Regulating medical devices in the UK



# ADDITIONAL RESOURCE PAGE 3/3



## AUDIT, SERVICE EVALUATION, QUALITY IMPROVEMENT AND TRANSFORMATION PROJECTS

