

1. Introduction

1.1 The UK Policy Framework for Health and Social Care define research as:

“as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for, or as a consequence of, the interventional part of the research, such as screening potential participants for eligibility, obtaining participants’ consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research. Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of this policy framework. Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework. A decision tool that provides a definitive answer about whether a project counts as research under this policy framework is available at <http://www.hra-decisiontools.org.uk/research/>.”

[Defining a project as research](#) rather than Audit, Service Evaluation / Development or Quality Improvement can sometimes be difficult. There are occasions where lines are blurred and there may be differences of opinion or ambiguity which are increasingly difficult to unpick.

The Research and Innovation (R&I) team is frequently approached with requests to arbitrate a conclusion. R&I can support this decision or direct the query to the Health Research Authority (HRA) where applicable.

This Standard Operating Procedure outlines the process for determining whether a project is research or not.

2. Scope

This SOP applies to all staff at UHL who are trying to establish whether or not a project is research.

3. Process

The individual leading the project is responsible for the process and for ensuring that all information provided is accurate. Where a question ‘is my project research?’ is asked the following process should be followed:

3.1 Step 1 – Is my project research?

Where individuals are unsure whether or not their proposed activity should be categorised as research, the first stage is to complete the HRA Decision Tool <http://www.hra-decisiontools.org.uk/research/>. The questions must be answered accurately to obtain an accurate outcome. It is the responsibility of the project lead to input accurate answers to the questions.

The HRA Decision Tool will provide two answers:

- **If the answer is YES** the activity is Research:

Please contact the R&I Office for further guidance on how to gain the research relevant approvals required **before** conducting your activity. It is important to note that **you do not have permission** to carry out the research until all approvals are in place, and you have received confirmation of capacity and capability and, where appropriate, a Sponsor Green Light.

- **If the answer is NO** the activity is not considered as research:

Please liaise with the UHL Clinical Audit team to register the activity appropriately.

[Insite - Clinical Audit Team \(xuhl-tr.nhs.uk\)](mailto:xuhl-tr.nhs.uk)

Please SAVE the outcome of the HRA Decision Tool with the documentation for your project. You may be asked to produce this evidence in the future. The staff member can choose the location to save this information.

3.2 Step 2 – Uncertainty remains:

Sometimes there may be a lack of confidence in the outcome of the tool. This may be down to uncertainty about the definitions or actual methods used, or there may be a need for an external decision. If this is the case please follow these steps:

If there is uncertainty about the answer from the HRA Decision Tool you can seek advice from the R&I team via UHLsponsor@uhl-tr.nhs.uk or you can ask the HRA for a decision via queries@hra.nhs.uk copied to RIAdmin@uhl-tr.nhs.uk.

Attach to the email the following:

- Printed outcome of the Decision Tool (.pdf)
- One page outline of the project which summarises purpose, methodology, type of participant and planned location
- Summary of the aspects of the decision tool on which you require further advice

IMPORTANT: Please note that retrospective approval cannot be given for activity categorised as research. Where research is found to have been carried out before all relevant approvals are in place the SOP C-2016 UHL Process for fraud in hosted research and SOP S-1019– Fraud and Misconduct in Research will be followed.

4. Supporting Documents and Key References

SOP C-2016 - UHL Process for fraud in hosted research

SOP S-1019 - Fraud and Misconduct in Research

[Policy Framework for Health and Social Care Research](#)

[Health Research Authority \(HRA\)](#)

Key Performance Indicator	Method of Assessment	Frequency	Lead
N/A	R&I Routine Audit	As required	R&I Quality Assurance Manager

5. Key Words

HRA, Audit, Research, Service Evaluation, Service Development, Quality Improvement (QI)

This line signifies the end of the document

6. This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
Author / Lead Officer:	Carolyn Maloney		Job Title: R&I Director of Operations
Reviewed by:	Nigel Brunskill		
Approved by:	R&I Governance Meeting		Date Approved: PGC 21.6.24 (v2)
REVIEW RECORD			
Date	Issue Number	Reviewed By	Description Of Changes (If Any)
October 2021	1	LW	New SOP
April 2024	2	JB	SOP expiry – full review and update.
DISTRIBUTION RECORD:			
Date	Name		Received