UHL Defining Research – Managing uncertainty in categorisation of Research
Research & Innovation SOP RICORP-7002

University Hospitals of Leicester NHS Trust

Trust Reference: B44/2021

1. Introduction

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

> "For the purpose of this policy framework, research is defined 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/."

1.2 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.

1.3 The Research and Innovation (R&I) team is frequently approached with requests to arbitrate a conclusion. R&I are unable to make this decision and will always direct the query to the Health Research Authority (HRA) who will communicate the final opinion.

1.4 This Standard Operating Procedure outlines the process to be undertaken where the question - 'is my project research?' - is asked.

2. Scope

This SOP applies to all staff at UHL who are asking the question - 'is my project 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.

3.1.1 http://www.hra-decisiontools.org.uk/research/
The questions must be answered accurately to obtain an outcome. It is the responsibility of the project lead to input accurate answers to the questions.

3.1.2 The HRA Decision Tool will provide TWO answers:

- **3.1.2.1 Answer 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.

- **3.1.2.2 Answer NO** the activity is not considered as research:

Please liaise with the Audit team to register the activity appropriately.
INsite - Clinical Audit Team (xuhl-tr.nhs.uk)

3.1.3 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:

3.2.1 If there is uncertainty about the answer from the HRA Decision Tool you must ask the HRA for a decision.

3.2.2 Send an email to 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

3.2.3 Both Steps 1 and 2 are detailed in the Flow Chart appended to this SOP (Appendix 1).

3.2.4 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 – Fraud and Misconduct in Research will be followed.

3.3) Non Compliance

When it is found that a project has been conducted as an Audit, Service Evaluation or Quality Improvement Project that should have been registered as a research study, the SOP C- 2016 (UHL Fraud and Misconduct) and C-2013 (UHL Procedure in event of non-compliance) UHL will be implemented.

3.3.1 Research studies cannot be approved retrospectively. Data and / or samples collected without appropriate approvals must be destroyed.

4) Responsibilities

	Responsibility	Undertaken by	Activity
1.	R&I Corporate	R&I Office	Advise location of tool links
2.	R&I Corporate	R&I Office	Where necessary provide information on next steps on audit, SE or research processes.

5. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

6. Guideline Standards and Procedures

Supporting flowchart is provided in Appendix 1.

7. Education and Training

This SOP will be disseminated widely and communicated across the organisation. The SOP and Flowchart appended will be sent to individuals who ask the question 'is my project research?'

8. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Where identified as research relevant information is provided	Where identified as research, will be monitored under relevant SOP's	Head of Research Operations or delegate	Ongoing	Research compliance reported by EDGE

9. Supporting Documents and Key References

RICORP-7002 Appendix 1

SOP C-2016 UHL

Policy Framework for Health and Social Care Research

Health Research Authority (HRA)

10. Key Words

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

11. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

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12. 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		
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Is My Project Research Flow Chart - Appendix 1 SOP RICORP 2007 UHL