Is my project "research" or "non-research"?

The purpose of this document is to help you to correctly classify your project.

From August 6th 2024 the R&I Office will only register research projects.

From August 6th 2024 staff undertaking non-research projects i.e. clinical audits, service evaluations or usual practice projects should register these projects with Quality Safety & Improvement Directorate (QSID).

Non-research projects can be registered via portals under the "Useful Links" tab on the St James's Hospital Intranet, or alternatively, use the link below;

https://www.stjames.ie/intranet/qualitysafety/effectivecare/clinicalaudit/

It is important to correctly classify your project as either research or non-research (see Table 1), as projects classified as research require ethics approval, as per the Health Research Regulations 2018. **Failure to obtain ethics approval may impact on insurance and Clinical Indemnity.**

Table 1: Project classification

Research ₸	**Non-research**
Registration with: Research & Innovation	**Registration with: QSID**
• Clinical Trial • Medical Device Trial • Retrospective Chart Review • Observational Research Study • Translational Research Study • Device Trial (Not Subject to Medical Device Regulation) • Pilot Study • Feasibility Study • Case Studies^ • Pre-screening*	• Clinical audit • Service evaluation • Usual practice project
The following projects can be classified as research **and/or** non-research depending on the purpose of the project; • Hospital Staff – Survey/Questionnaire • Hospital Staff – Interview/Focus Group • Patient – Survey/Questionnaire • Patient – Interview/Focus Group *It is important to correctly classify your project as either research or non-research, as projects classified as research require ethics approval, as per the Health Research Regulations 2018. Failure to obtain ethics approval may impact on insurance and Clinical Indemnity.* If you are unsure whether your project is research, please contact the Research & Innovation Team at **research@stjames.ie**	

^*Case studies involving 5 or more patients require JREC approval.*

* *Pre-screening does not require R&I approval, providing staff conducting the pre-screening are employed by St James's Hospital (SJH) or the Wellcome HRB Clinical Research Facility (CRF). R&I approval is required where individuals conducting the pre-screening are NOT employed by SJH or the CRF.*

[ǂ] *For further information on each project type & the associated ethical, legal & data protection requirements see: Research & Innovation Application Form Guidance Document*

What is Research?

Research is defined in the Health Research Regulations 2018 as;

- research with the goal of understanding normal and abnormal functioning, at the molecular, cellular, organ system and whole body levels
- research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury
- research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals
- research with the goal of improving the efficiency and effectiveness of health professionals and the health care system
- research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status

Research includes;

Experimental, translational and clinical research; public health and social care research; population health research; basic and translational health research; research into treatment strategies; medical device or product development. It also includes any actions taken to establish whether an individual may be suitable for inclusion in the research.

In the case of quantitative research, statistical methods are used to achieve results that are 'generalisable' from a sample to the sampled population.

In the case of qualitative research, the context and findings are described and defined so that the conclusions can be applied or transferred to other settings.

If you are unsure whether your project should be classified as 'research' **or** 'non-research' (see Table 1) ask the following questions;

1. **What is the purpose of the project?**
   If the purpose of the project is to determine and/or assess current care or the standard of care a service achieves, this is not research.

   This is a Service Evaluation (SE). The Guidance Document contains information on SEs.

   However, if a proposed SE has the potential to **produce findings which can be extrapolated** and/or applied to, for example, different departments and/or hospitals.

This extrapolation is termed 'generalisable' and/or 'transferable' and this is an indication that you may be conducting research.

2. **What are the outcomes of the project?**

   If the outcome of the project is to determine the cause of a disease outbreak or an assessment of population health issues, this is not research. This is classified as a Usual Practice Project (UPP). The Guidance Document contains information on UPPs.

   UPPs can involve systematic, quantitative and/or qualitative methods. UPPs can also assess choices of intervention, treatment, care, or services based on best public health evidence or professional consensus. UPPs may involve analysis of existing routine data or administration of interview or questionnaire to those in the population of interest or a review of existing evidence.

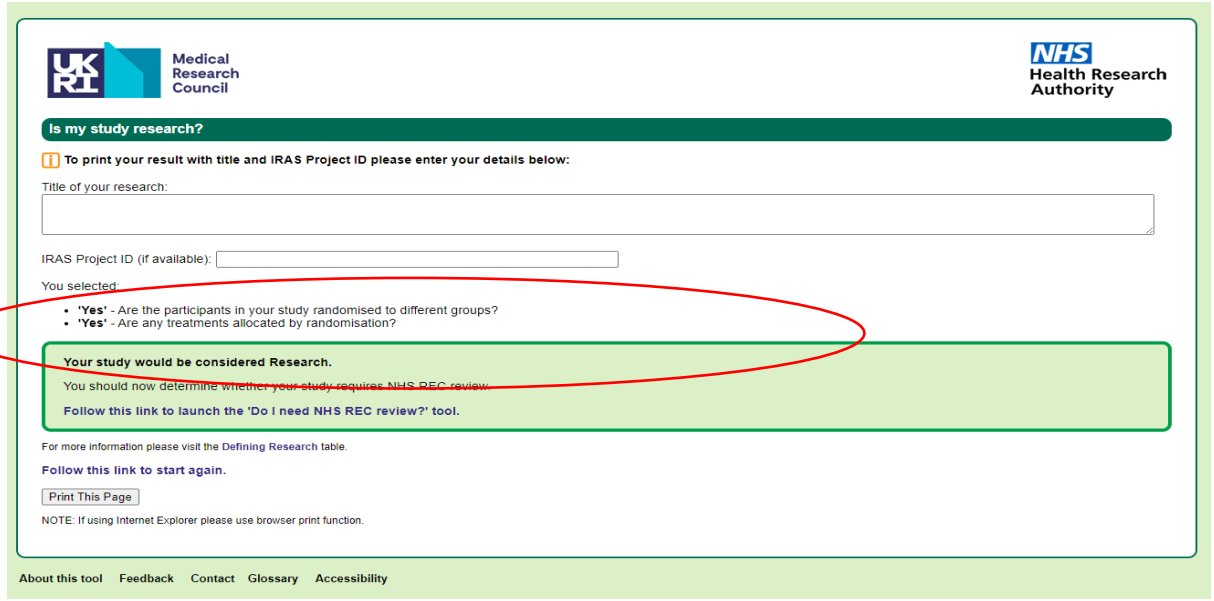
3. **How will the learning outcomes of the project be used/applied?**

   If the learning outcome from the project is to determine whether a service provided reached a predetermined standard, this is not research. This is classified as Clinical Audit (CA). CAs measure the delivery of an intervention against a standard. The Guidance Document contains information on CAs.

   An intention to publish may indicate that you are undertaking research. If the ultimate outcome of the CA is a publication, journals may require evidence that ethics approval is not required i.e. confirmation that the CA is not classified as research. If this is requested when you come to publish, JREC issues letters stating the type of study (i.e. Quality Improvement project).

Further information on **"What is not research?"** is available on the HRB website.

The NHS also provide a useful assessment tool to help you define whether your study is research.


Medical Research Council
NHS Health Research Authority
Is my study research?
To print your result with title and IRAS Project ID please enter your details below:
Title of your research:
IRAS Project ID (if available):
You selected:
'Yes' - Are the participants in your study randomised to different groups?
'Yes' - Are any treatments allocated by randomisation?
Your study would be considered Research.
You should now determine whether your study requires NHS REC review.
Follow this link to launch the 'Do I need NHS REC review?' tool.
For more information please visit the Defining Research table.
Follow this link to start again.
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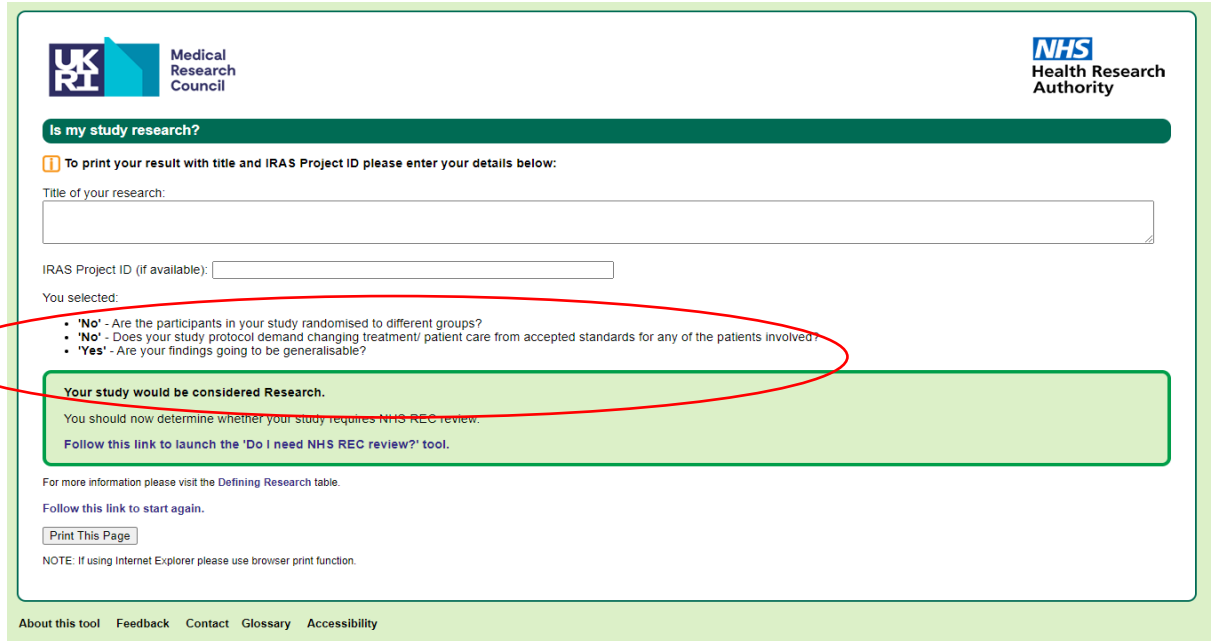
Medical Research Council
NHS Health Research Authority
Is my study research?
To print your result with title and IRAS Project ID please enter your details below:
Title of your research:
IRAS Project ID (if available):
You selected:
'No' - Are the participants in your study randomised to different groups?
'No' - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
'Yes' - Are your findings going to be generalisable?
Your study would be considered Research.
You should now determine whether your study requires NHS REC review.
Follow this link to launch the 'Do I need NHS REC review?' tool.
For more information please visit the Defining Research table.
Follow this link to start again.
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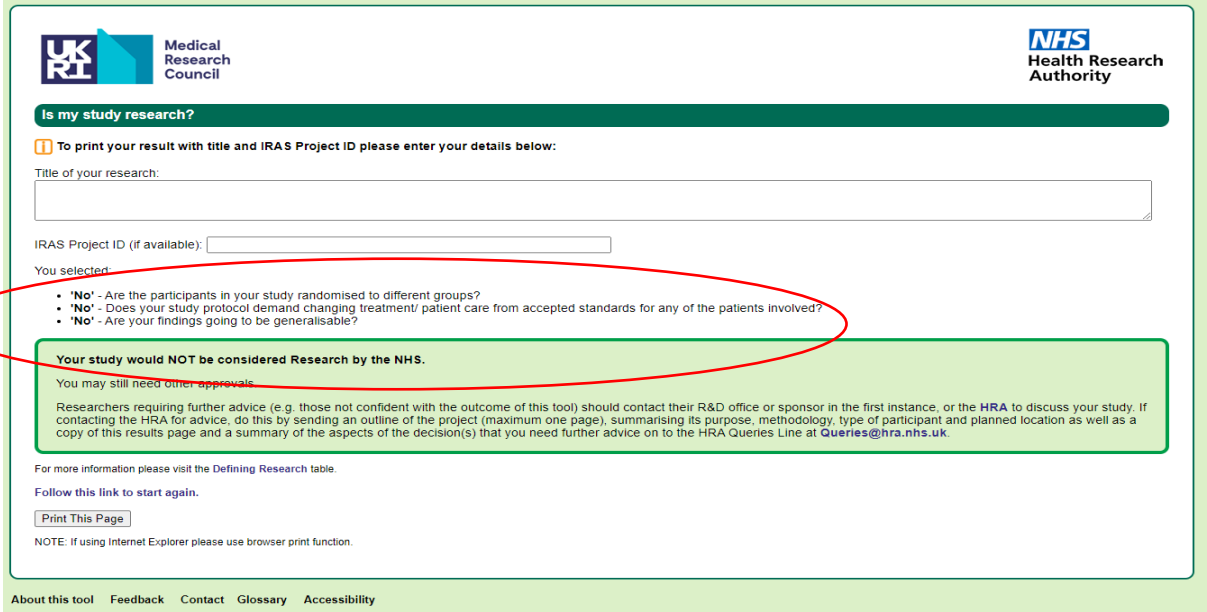

If you still unsure whether your project should be classified as “clinical research” or a “review of current practice/quality improvement” please contact research@stjames.ie.