

### INTRODUCTION - WHAT ARE INVESTIGATIVE PROJECTS

Different types of projects are common in the NHS. Staff may initiate projects themselves or may become involved in ongoing projects. These include research, audit or service evaluation projects, patient satisfaction surveys or case studies.

There may be grey areas and distinguishing between research, audit and service evaluation can sometimes be difficult. Below we explain the differences, describe the advice and support which may be available to assist staff, and clarify the different governance arrangements for these projects in York Teaching Hospital.

It is important to be clear about the boundaries because if projects are misclassified this may lead to inappropriate claims being made, projects being undertaken without the correct approvals, professional codes of conduct being called into question or even the law being broken in areas such as data protection and/or the use of human tissue. Classifying a project correctly is therefore important to avoid risk to patients, the individuals involved in undertaking the research and the Trust.

### CONFUSED? YOU ARE NOT ALONE! WHAT EXACTLY IS THE DIFFERENCE

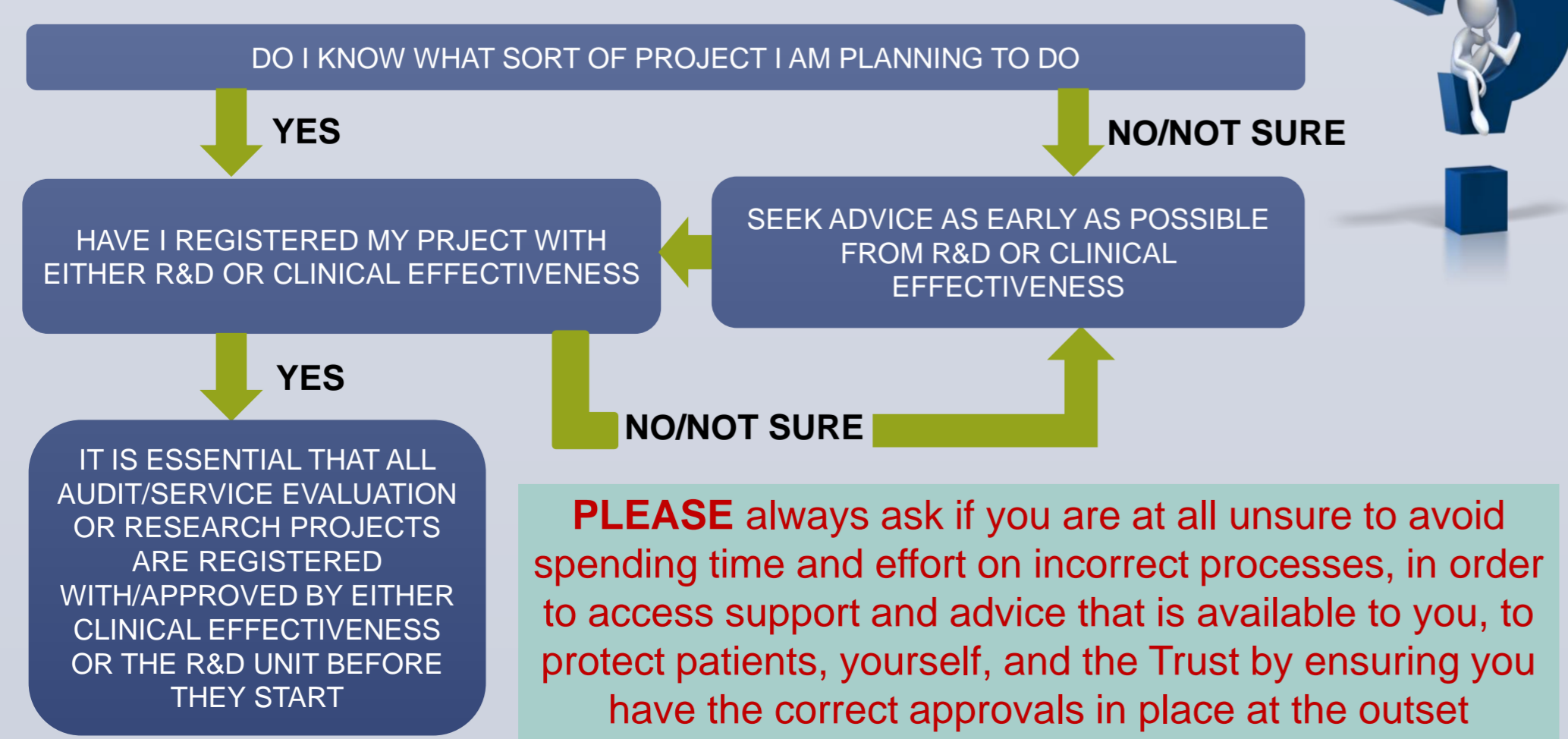
Clinical audit, service improvement/ evaluation and research projects are sometimes confused because they have many things in common. They all involve asking a question about clinical practice; they can focus on the structure, process or outcome of that practice; all require careful identification of the sample and may use similar methods for collecting information.



Audit / service evaluation and research are also linked and help to inform each other: without research we don't know what constitutes best practice and without audit / service evaluation we don't know whether we are offering best practice to patients.

However audit / service evaluation and research projects are distinct from each other particularly in relation to:

- the formal approvals they require
- their purpose
- the rigour with which they are carried out
- how the data are analysed
- the claims that can be made from the data



### KEY POINTS WHEN CONSIDERING THE ANALYSIS

When writing up audits and service evaluation projects, especially for external publication (including conference presentations), great care has to be taken especially with the way the data are analysed and the conclusions that are reached. An audit or service evaluation cannot tell us, for example, that a treatment is effective; only a research project in the shape of a randomised controlled trial can answer that question.

	Audit and Service Improvement / Evaluation		Research
Uses	Frequencies (number counts) Percentages Mean (average) Median (middle value) Mode (most frequently occurring value) Standard deviation or range	✔	Frequencies (number counts) Percentages Mean (average) Median (middle value) Mode (most frequently occurring value) Standard deviation or range
Examples	<b>Audit</b> of fractured neck of femur (# NoF) management. [College of Emergency Medicine Standard: 75% of patients with # NoF should have an X ray within 60 minutes of arriving at the ED] Result found in audit: 45% of patients with # NoF had an X ray within 60 minutes of arrival at the ED  <b>Service review</b> of patients having a paramedial forehead flap procedure. 25 procedures undertaken, 23 were for skin cancer (ages 46-88 years) and 2 for traumatic nasal avulsion (ages 33 and 35 years). Five patients required a more complicated 3 stage procedure. All patients surveyed were satisfied with the cosmetic result (average = 9.3/10) and the service provided (average = 9.5/10)		<b>Research</b> study where participants were randomised to be nursed on an alternating pressure mattress (n = 982) or an alternating pressure overlay (n = 990). Overall 207 (10.5%) people developed a total of 305 new pressure ulcers, most of which (n = 207) were grade 2 ulcers (97.4%). Eight people developed grade 3 pressure ulcers, three in the overlay group and five in the mattress group.
Inferential Statistics and Confidence Intervals	<b>Not</b> appropriate for this type of project. Inferential statistics only used when we want to 'infer' something about the data we have collected in terms of a wider population. In other words when trying to 'generalise' the findings from projects to a wider population of patients or to other hospitals or settings. This is a feature of <u>research only</u> .	✘	May use inferential stats e.g. <i>t</i> tests, ANOVA, Mann Whitney U test, Pearson correlation Coefficient, Wilcoxon test, Chi square test. The results of the above tests are used to assess the probability that study findings may just be due to 'chance'. Probability or 'p' value are quoted in results. Any p value less than 0.05 (5%) is regarded as 'statistically significant'. In other words there is only a small probability your findings are due to chance. 95% Confidence intervals are also frequently quoted.
Example	Inferential statistics are not used in audit or service evaluation projects	✘	"There was no difference in the proportion of participants who developed a new pressure ulcer of grade 2 or worse. The difference in proportion of patients developing an ulcer was 0.4% (10.7% of overlay patients; 10.3% of mattress patients); p = 0.75, 95% confidence interval = -2.3% to 3.1%"
Drawing Conclusions and Generalising Results	In drawing conclusions from a local project, you must <u>not generalise</u> the findings to a wider population -this is a feature of research. Your project has probably not been designed in a way that would allow you to generalise conclusions. If conclusions from a local project are generalised they may carry much more weight with readers than they deserve and have more influence on clinical practice than they should.	✘	If your research project has been designed properly, and has the appropriate approvals, you should be able to make 'generalisable' claims as this is the purpose of doing a research project. In other words the results from a study may be used to make claims that could be applied more widely. For example you are making a claim that an intervention is effective / not effective.
Examples	'When we offered additional physiotherapy to patients in our local intensive care unit, this appeared to improve the level of mobility they achieved on discharge from ICU.' <i>BUT NOT</i> 'Increased physiotherapy staffing in the form of specialist critical care rehabilitation teams is effective in improving the level of mobility within critical care.'	✔	'No difference was found between alternating mattresses and alternating pressure overlays in the proportion of people who develop a pressure ulcer.'

### ADVICE AND SUPPORT IS AVAILABLE PLEASE ASK



The R&D Unit and Clinical Effectiveness Teams are able to advise and support staff through the process of registering their project and/or applying to the necessary approvals internally and externally.

To register an **AUDIT** or **SERVICE EVALUATION** project please contact the clinical effectiveness team. Complete the project registration form found on Staffroom. [effectiveness@york.nhs.uk](mailto:effectiveness@york.nhs.uk)

For **RESEARCH** projects, the approvals required will depend entirely on the nature of the project so it is best to seek advice early on from the R&D Unit. It is advisable to send a written outline of the project planned. [research.governance@york.nhs.uk](mailto:research.governance@york.nhs.uk)

If unsure, please ask either team as we work together to categorise projects and, if unsure, we seek advice from the Clinical Lead for Research who makes the final decision.

**THE REQUIREMENT TO OBTAIN THE CORRECT APPROVALS FOR A PROJECT, AND TO THEN CARRY IT OUT AND REPORT IT IN ACCORDANCE WITH THAT APPROVAL IS ESSENTIAL TO:**

- ENSURE THAT CLAIMS RESULTING FROM THE STUDY ARE APPROPRIATE
- PROTECT OUR PATIENTS AND THE WIDER POPULATION
- PROTECT YOURSELF AS A PROFESSIONAL INDIVIDUAL
- ENSURE THAT PROJECTS ARE CARRIED OUT IN ACCORDANCE WITH THE CORRECT LEGISLATION
- PROTECT THE TRUST