RCSI SURGICAL AFFAIRS

The Royal College of Surgeons in Ireland
National Surgical Research Support Centre (NSRSC)
Feasibility Trial Scheme

Aims & Scope of the Call

A key objective of the National Surgical Research Support Centre is to develop a portfolio of multicentre surgical trials in Ireland. Surgical trials fall within the Medical Research Council's definition of complex interventions [1]. Determining the value of an intervention for surgical patients can be divided into four broad phases: identification / development of a complex intervention; feasibility; evaluation; implementation. Feasibility testing is now recognised as a critical component and should precede progression to full evaluation. The NSRSC wishes to support surgeons undertaking feasibility trials with the potential to progress to evaluation through a definitive trial.

The purpose of a feasibility trial is to ask if something can be done, if it is necessary and should proceed and if so, how. Feasibility trials generally perform the future trial/part of the future trial on a smaller scale [2]. Examples of questions that feasibility trials are designed to answer include:

- Is the proposed intervention acceptable to patients, surgeons and other stakeholders?
- For surgical trials in particular, can the proposed intervention be delivered by a range of potential providers e.g. for a trial of inguinal hernia repair techniques, can all surgeons perform the repairs using the required approaches?
- Is the proposed intervention likely to be cost-effective?
- What levels of participant recruitment and retention are achieved? Based on these figures, how long would a full trial take to complete?
- Does the proposed data collection method work in practice?
- Are the proposed full trial outcome measures realistic or should they be revised based on feasibility data?
- Can sufficient data be obtained in a feasibility phase to allow a sample size calculation for a full trial within the same patient population?
- Can a surrogate outcome be used to generate a signal that the proposed intervention is likely to have the expected benefit e.g. can a reduction in post-operative troponin levels be demonstrated in order to support the hypothesis that a certain intervention will reduce myocardial infarctions in a full trial?

Funding agencies such as the US National Institutes of Health, UK National Institute of Health Research and Ireland's Health Research Board require systematic evidence to support trial applications. Applicants to the NSRSC Feasibility Trial Scheme should provide systematic evidence to support the case for trials of their specific intervention i.e. a systematic review comprising systematic identification of previous work, critical appraisal, evidence synthesis, interpretation of findings. Simple narrative reviews are not sufficient.

A feasibility trial should not seek to establish definitive evidence regarding the role of an intervention in clinical practice.

Eligibility

Applications are encouraged from all surgical disciplines. The minimum eligibility criteria are:

1. Randomised study design
2. Consultant principal investigator with named trainee sub investigators
3. Minimum of one named surgical trainee per site committed to participant recruitment, consent and data collection
4. Non-regulated interventions only
5. Trial can be completed in a 12-month timeframe
6. Planned recruitment opening in Q1 2023

At this stage, applications for feasibility studies of regulated medicinal products or devices will NOT be considered. The NSRSC seeks to demonstrate the presence of an all-island active multicentre network. Therefore, applicants are encouraged to consider including at least two recruitment sites in at least two provinces. This may not be possible or desirable for trials being conducted in specialties that are only present in a small number of sites on the island.

Support Available

NSRSC can provide support with trial design, sponsorship for non-regulated trials, ethical applications, data management and analysis. Support is also available to assist with costs such as third-party randomisation, open access publication charges and small equipment charges. Please note salary costs are not available.

Application Process

Potential applicants are strongly encouraged to contact the NSRSC to discuss their proposal and budget in advance of submitting an application. Applicants should submit the application form to NSRSC@rcsi.ie by the closing date (Friday 24th June, 5pm).

Evaluation Process

Applications will be reviewed by the NSRSC Scientific Advisory board
The criteria the board will consider when making recommendations will include:

- Scientific merit
- Potential for progression to a full randomised controlled trial,
- Capacity for the support requested
- Potential impact on clinical practice and patient care.

Closing date for applications is Friday 24th June 2022 at 5pm

NSRSC Support Contacts

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References

1. Skivington K et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021;374:n2061.
2. Eldridge S et al. Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework" PLOS One 2016 http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0150205