Please Complete the below form and submit to NSRSC@RCSI.ie

|  |
| --- |
| **1. Trial Title** |
| **2. Sponsor** |
| **3. Trial Registration Number** |
| **4. Consultant Chief Investigator & Lead Institution**  *Name/Institution/Address/Contact details* |
| **5. Principal Investigators-other institutions** *Name/Institution/Address/Contact details* |
| **6. Trainee Sub-Investigators**  *Name/Institution* |
| **7. Trial Summary** |
| **8. Background & Rationale**  *What is the basis for the study, cite relevant literature, Describe current standard practice and the potential clinical impact of this trial* |
| **9. Trial Objectives and Endpoints**  *List the primary and secondary objectives and endpoints* |
| **10. Trial Design**  *Include trial type/design e.g. single or multi-centre, assessor blinded, cluster randomised?* |
| **11. Patient Population**  *Define the patient population, number of patients to be enrolled including sample size calculation, anticipated enrolment period, duration of patient participation, trial completion, withdrawal criteria and procedures* |
| **12. Patient Eligibility Criteria**  *List Inclusion/ Exclusion criteria* |
| **13. Patient Enrolment Procedure**  *Describe where and how recruitment will occur, how consent will be obtained, who will obtain consent. Describe the method of randomisation/blinding* |
| **14. Trial Intervention**  *Describe the intervention and control group* |
| **15. Infrastructure supports in place and/or requirements**  *Outline the infrastructural supports in place for this trial e.g. if the trial requires patient interviews, are interview facilities available? For trials of operative techniques, is operating space available? Please contact the NSRSC in advance if requesting infrastructural supports* |
| **16. Data Analysis Plan**  *Describe how patient data will be collected, stored and analysed*  *Describe the outcomes that will support progression to a future definitive trial and how these data will be captured. Describe how the feasibility of the intervention will be assessed.* |
| **17. Patient and public involvement** |
| **19. References** |
| **19. Budget and funding**  *Please list costs under the following headings and provide appropriate budget justification:*   |  |  | | --- | --- | | Infrastructure |  | | Running Costs |  | | Third-party randomisation service |  | | Open Access Publication Charges |  | | Other |  |     **Budget Justification:** |

**20. Signatures**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Applicant signature Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Chief Investigator signature Date

Completed applications should be submitted by email to NSRSC@rcsi.ie

**NSRSC Support Contacts**

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