# General Requirements

1. Delete this page and the approval page before use, ensuring that the correct headers and footers for the template are retained.
2. Change the spellings to United Kingdom English if wished.

1. The following text colours are used within the template:
2. Black text = text which must not change (with the exception of spelling changes).

b) Orange text = instructions for final user of template.

c) Blue text = example text.

1. Delete or replace all orange text in the template, changing the font colour as required prior to use. Black text must not be changed other than for localization of spellings.

1. For version date enter the date of document completion and for version number enter the version of the document completed. Be sure to increase version numbers in whole number increments (e.g. 1.0 for first version and 2.0 for the second version).

# Revision History, Ownership, and Approvals

## Revision History

| Revision | Released Date | Effective Date | Description of Change |
| --- | --- | --- | --- |
| A | 07 Aug 2018 | 18 Sep 2018 | Initial creation. |
| B |  |  | Reissued with rebranding as part of SOP-CD-28\_RevC update. No content change. |

Release and effective dates for current revision applied after final approval by

| Name and Title | Signature and Date / DocuSign Stamp |
| --- | --- |
|  |  |

## Approver(s), Author(s), and Owner(s)

| Name and Title | | Signature and Date / DocuSign Stamp |
| --- | --- | --- |
| Tom Pynsent  Clinical EUMDR Manager  **(Author)** |  | |
| Jing Xie  Clinical Senior Vice President  **(Owner/Approver)**  (signing as GCO and GCS approver) |  | |
| Kate Drysdale  Senior Clinical Compliance and Training Manager  **(Approver)** |  | |

The purpose of this form is to facilitate a process to review, approve, and support clinical study proposals initiated by an external clinical investigator. [studyrequest@smith-nephew.com](mailto:studyrequest@smith-nephew.com)

(Please complete this form in English)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date Completed: | | | | Completed by: | |
| Investigator Name: | | | | Practice Name: | |
| Investigator Specialty(ies)/Area of Practice: | | | |  | |
| Mailing Address: | | | |  | |
| Email Address: | Office Phone: | | | Mobile/Cell Phone: | |
| Other contact (if any): | | | | Title: | |
| Mailing Address (if different from above): | | | | | |
| **STUDY INFORMATION** | | | | | |
| Study Title: | | | | | |
| What is the publication/presentation plan of the study results?  ☐ Journal Publication ☐ Abstract Publication ☐ Podium ☐ Other:  Target journal(s) for publication:  Target conference for presentation(s): | | | | | |
| Market product(s) or procedure to be investigated (please use full market name[s] and manufacturer if non-S&N): | | | | | |
| What is the main objective of the study? | | | | | |
| What is the primary endpoint for this study? How is it going to be measured? | | | | | |
| What are the secondary endpoints? How are they going to be measured? | | | | | |
| What Health Care Economic Assessments will be included? | | | | | |
| Potential proposed countries: | | | | | |
| Study design (e.g. prospective, randomized, matched, single-blind): | | | | | |
| Comparison group(s) if any: | | | | | |
| Study design (e.g. prospective, randomized, matched, single-blind): | | | | | |
| Comparison group(s) if any: | | | | | |
| Population description and inclusion/exclusion selection criteria: | | | | | |
| Brief description of study procedures to be used (e.g. measurement methods, questionnaires, standard scales): | | | | | |
| Define all visit time points (e.g. pre-op, op, discharge, 1, 3, and 6 months): | | | | | |
| **STATISTICS** | | | | | |
| How is the study powered? | | | | | |
| Sample size: | | Sample size per arm/cohort (if applicable): | | | ☐ N/A |
| Statistical Methodology ☐ Superiority ☐ Non-inferiority ☐ Other: | | | | | |
| **BUDGET AND MILESTONES** | | | | | |
| Please confirm the total study cost. (Please attach the budget form to your IIS submission.): | | | | | |
| Total study budget: | | | Please confirm currency: | | |
| **Please note that no work can be reimbursed prior to contract execution:** | | | | | |
| Please complete the anticipated dates for following milestones for the study: | | | | | |
| **Milestones** | | | **Anticipated dates** | | |
| 1. IRB/IEC Target date | | |  | | |
| 2. First subject first visit | | |  | | |
| 3. Last subject last visit | | |  | | |
| 4. Final data analysis | | |  | | |
| 5. Publication submitted | | |  | | |