NS Clinical Research Proposal

Investigator Initiated Studies

Please complete all sections of this form (in English). This will help us to process your Research Proposal efficiently. Additional sheets can be attached as required (Please list these in Section 4 below). Following a review, you will receive a response and comments from Stryker within **28 Business Days**.

Please contact the NS Clinical Research Department if any further information or details are required.

**Stryker Instruments**

**Clinical Research \_Stryker Neurosurgical**

[**clinicalresearchns@stryker.com**](mailto:clinicalresearchns@stryker.com)

In order to process your application in a timely manner, **please provide the following information as clearly and accurately as possible:**

* Research proposal/protocol
* Description and quantity of Stryker product requested (if applicable)
* Itemized study budget
* CV and/or resume for each Investigator/Co-Investigator

**Content:**

Section 1: Contact Details

Section 2: Research Proposal Information

Section 3: Budget Breakdown

Section 4: Declaration

Section 1

|  |  |
| --- | --- |
| Contact and Site Details | |
| Principal investigator’s name: |  |
| Telephone: |  |
| Email address: |  |
| Site / Hospital (Research to be conducted at): |  |
| Site / Hospital Address: |  |

Section 2

|  |  |
| --- | --- |
| Study Title: |  |
| Study Objective: |  |
| Study Hypothesis: |  |
| Study Design: |  |
| Proposed Length of study, First Patient Visit (FPI), Last Patient First Visit (LPFV),Last Patient Visit(LPV) | Study Length:  FPV:  LPFV  LPV: |
| Length of Follow-Up: |  |
| Indication or treatment evaluated: |  |
| Inclusion criteria for study participants: |  |
| Product(s) evaluated: |  |
| Alternative treatments: |  |
| Comparison considered in the study (e.g. against literature, standard of care): |  |
| Primary endpoint: |  |
| Expected change in primary criteria: |  |
| Study subject sample size and buffer for drop out: |  |
| Secondary criteria: |  |
| Expected change in secondary criteria: |  |
| Functional Outcomes Scores, endpoints and expect change: |  |
| Randomization method, if applicable: |  |
| Methodology of analysis of the results: |  |
| Expected adverse events: |  |
| Study limitations: |  |
| Regions with subject recruitment. Regions that will likely benefit from the results: |  |
| Background literature and reason why taken for reference: |  |

Section 3

Please choose appropriate option regarding your grant application:

Budget planning completed in the table

Budget planning completed in an individual budget breakdown attached to this application

Budget planning completed in Stryker’s budget breakdown template attached to this application

|  |  |
| --- | --- |
| Amount of requested funding ($/£/€): |  |
| Breakdown of funding ($/£/€):  Staffing support, supplies (e.g. per patient fee), costs for EC submission, materials, other costs, etc. |  |

Section 4

|  |
| --- |
| I have attached a signed copy of my CV (short form)  I have attached a signed copy of the CV (short form) of any co-investigators or other personnel to be involved in the proposed study |
| Please List any additional documents attached to this proposal (Including any Budget templates):   |  |  |  | | --- | --- | --- | | Document Type | Document Name | Number of Pages | |  |  |  | |  |  |  | |  |  |  |   The Clinical Investigation will be conducted in accordance with the ethical principles originating from the Declaration of Helsinki and in compliance with the Clinical Research Proposal, Good Clinical Practice and the applicable regulatory requirement(s).  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date and signature of the principal investigator |
| Please return your application to the Stryker Clinical Research Experts or to the local contact to be forwarded to our Clinical Research Team:  **Stryker Instruments**  **Clinical Research \_Stryker Neurosurgical**  [**clinicalresearchns@stryker.com**](mailto:clinicalresearchns@stryker.com) |