NICO
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Investigator Instructions for Completion and Submission of Request for Funding

NICO Technologies

Investigator Initiated Study (IIS) Program

Purpose and Objective of Program

NICO Corporation is committed to improved patient and economic outcomes through the continued expansion of valid clinical information supporting those outcomes with the use of minimally disruptive and automated technologies. With this commitment in mind, the Company has established an Investigator Initiated Study Program (IIS). The aim of the program is to evaluate existing retrospective data or conduct prospective high quality studies with the goal of manuscript submission for publication. Selected investigators may be provided financial support, accordingly. All projects supported by this program are conducted by the applicant(s) and their respective affiliate institutions. As such, NICO is neither involved in collecting information, in conducting research, or in the publication of any project findings.

Application Process

Requests for financial support may be submitted at any time. Requests are reviewed for scientific merit, feasibility, possible contribution to the respective body of clinical knowledge, and compatibility with NICO's long-term clinical and scientific focus. Those requests deemed to have substantial merit and scientific potential and are in line with NICO's clinical and scientific goals will be considered. Only sites in the United States or its territories are eligible to apply.

First, a potential investigator should submit a complete Proposal (Concept) Summary and Proposed Budget (see instructions, page 2). Upon submission of these proposals, a formal review by NICO Clinical Affairs will be conducted to determine if preliminary approval may be granted. The typical review turnaround time is 1-2 months from receipt of the request to investigator notification of preliminary approval. It is important that requests clearly describe the objective(s) and clinical or scientific importance of the proposal.

If preliminary approval is granted, a protocol is requested for submission. Final approval may be granted only upon review of a completed protocol and detailed budget.

Potential investigators must closely follow instructions in the submission of either the Proposal Summary or Complete Protocol (instructions for complete protocol to be provided upon preliminary approval).

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Instructions for Potential Investigators
Request for Funding
NICO Technologies
Investigator Initiated Study (IIS) Program

A "Request for Funding" may be submitted at any time. All submitted materials must be typed.

Submitting a Proposal (Concept) Summary

- Complete PARTS I and II of the application materials:
  - PART I: Proposal Summary
  - PART II: Proposed Budget

- Submit the following materials electronically*:
  - Completed PART I: Proposal Summary
  - Completed PART II: Proposed Budget
  - Principal Investigator (PI) – Curriculum Vitae
    - If a Resident/Fellow investigator, include CV of both investigator and mentor with detailed letter from mentor describing how research will meet career goals of submitting Resident/Fellow

**Materials must be submitted electronically via www.niconeuro.com/physicians/research.*

Only preliminary approval will be granted following review of PARTS I and II of the application materials. If preliminary approval of your request is granted, you will be required to submit a Complete Protocol. Protocol instructions will be provided via NICO Clinical Affairs upon preliminary approval of Proposal Summary.

IIS proposals may not be submitted through any NICO sales, clinical, or marketing representative(s).

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PART I: Request for Funding

Proposal Summary

To standardize the information to be reviewed for the IIS, all "Proposal Summaries" submitted must contain information on each of the following bolded sub-headings. Electronic submission forms are available at www.niconeuro.com/physicians/research.

Rationale: Study rationale and how it relates to clinical and/or economic outcomes.

Previous Work: Work/findings by the PI and/or other investigators in the area of proposed research.

Primary and Secondary Objective(s):

1) List one main objective on which the study will focus.
2) List any secondary objective(s), if applicable.

Study Design:

1) Details of study design: (i.e. retrospective, prospective, randomized, etc.).
2) Number of patients or subjects to be studied, including justification of sample size.
3) Population to be examined (i.e., inclusion/exclusion criteria).
4) Study duration (i.e. estimated beginning and end dates).

Primary and Secondary Measure(s):

1) List one primary measure that will be used to substantiate the primary study objective.
2) List any secondary measure(s), if applicable.

Anticipated Findings: Results anticipated from the proposed research.

Publication Plan:

1) Number of manuscripts planned.
2) Principal author of the primary publication.
3) Forecast date for submission of primary manuscript.
4) Choice journal for publication.

Type of Financial Support Requested:

1) Use Part II of application materials to provide a proposed budget for the study. You may add to the form to include detail as needed.

Additional Information: Any additional information you feel the committee should be aware of in the evaluation of your request should be included.

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PART II: Investigator Initiated Study Budget Worksheet

Budget Item/Category	Personnel	Supplies	Services	Equip	Other	Other	Total
(Briefly describe budget items)							$$$
							$$$
							$$$
							$$$
							$$$
Total	$$$	$$$	$$$	$$$	$$$	$$$	$$$

Study Cost:	
One-time Cost:	
One-time Cost Overhead at _____%:	
Total Study Cost:	

Payment Schedule:

- General Clinical Study payment schedule
  - 20% - Initial payment
  - 20% - At midpoint of project
  - 20% - At conclusion of the project
  - 40% - After receipt of final manuscript suitable for publication and documentation of submission to a journal

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Conditions of Award/Principal Investigator Responsibilities

Modifications to Approved Protocols
Prior written approval from NICO Clinical Affairs is required before any change in the approved protocol can be implemented.

IRB Documentation
Applicants should follow all applicable state and federal regulatory guidelines for IRB approval and legal review to ensure consistency with current state and federal regulations. Furthermore, for studies involving human subjects or live animals, the PI is required to provide NICO Clinical Affairs with a copy of the approval documentation of the Institutional Review Board (IRB) or similar.

Monthly and Follow-up Reports
For all studies, the PI is required to provide a monthly study progress update via written report to NICO Clinical Affairs. The report should briefly summarize the status of the study (i.e., subjects evaluated, enrollment, preliminary data, etc.).

Final Report
The standard timeframe for receipt of the final report is normally within 90 days of study completion. The investigator is required to submit a complete report of the study performed in a form suitable for publication. Failure to submit all parts of the final report will result in a delay of the final payment.

Study Disclosures
Prior to disclosing any study information, the PI must provide NICO Clinical Affairs with a copy of any proposed publication, manuscript, or presentation (including both abstract and poster presentation) for review. The standard time frame for receipt of this information by NICO Clinical Affairs is sixty (60) days prior to such presentation or submission for publication.

Archiving of Study Information
The study site is responsible for keeping study information.

Reportable:
NICO Corporation follows all reporting guidelines set forth by the United States Physician Payments Sunshine Act regarding tracking of payments and “transfers of value.” For full details on the Sunshine Act visit: http://www.policymed.com/2013/02/physician-payment-sunshine-act-final-rule-research.html