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Investigator Initiated Study Program Details

To help to prepare a successful concept, we are providing the following guidance. Please be aware that this is a highly competitive process with numerous studies approved. It is best to check http://www.clinicaltrials.gov to ensure similar studies are not ongoing.

The program encourages Residents/Fellows to be involved in conducting IIS under the guidance of a mentor. In such cases, please specifically mention, in concept form, the intent of a mentored IIS, include CVs of both the investigator and mentor, and provide a detailed letter from the mentor describing the mentoring plan and how this IIS will help the investigator meet his or her career objectives.

An accurate budget is essential for evaluating IIS proposals. Approved "Summary Protocols" that have increases in budgets may be withdrawn or subject to supplementation by third parties (i.e. grants procured by other mechanisms).

The IIS program does not include any investigational pipeline devices at this time for independent clinical investigations and will not be considered. Should you choose to apply, please follow the **Investigator Instructions for Completion and Submission** document.

The IIS program is under Medical/Clinical Affairs. Sales representatives/marketing personnel may not participate in the process or receive/accept/forward research proposals or respond to research/IIS questions. Specific questions should be directed to Clinical_Affairs@niconeuro.com.

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Areas of Interest (AOI)

Below is a high level overview of various Areas of Interest for the Investigator Initiated Study (IIS) program. Please ensure that your concept proposal falls within one or more of these areas. Concepts that are not designed to encompass the AOIs may be rejected without further review. However, concepts outside of the AOIs that represent 'out of the box' thinking and are ultimately of great interest, may be considered.

Enhanced Recovery After Neurological Surgery (ERANS)

In various surgical specialties, the concept of Enhanced Recovery After Surgery (ERAS) has been well defined and applied for improved patient recovery and outcomes. However, in the neurological surgery community, this concept lacks scientific support. As the complexity of the neurological surgery space poses heightened risks for patient recovery, many hospitals and administrators are seeking exploration into the concept of ERANS involving minimally invasive techniques. ERANS protocols that involve the inclusion of minimally invasive surgical devices with BrainPath and Myriad are of interest. Such proposals must include a provision for measuring patient outcomes (eg: length of stay, post-operative complications, costs, etc). Other economic outcome projects will be considered.

Scientific Justification of "Why Access Matters"

Understanding the effect of neurosurgery on access and fascicular anatomy is paramount. While imaging technology improvements have led to greater knowledge of the connectivity and critical function of white matter tracts, the effect of minimally disruptive surgery on the structure and function of the brain is lacking. Imaging coupled with minimal disruption surgical technologies may preserve these critical white matter tracts and reduce post-operative deficits. Study proposals that address and document pre- and post-surgical changes in fascicular anatomy and white matter tracts following minimally invasive surgery using BrainPath as well as documentation of post-surgical deficits/improvements are of interest. Basic science, animal studies and clinical proposals will be considered. Patient populations of interest are adults and pediatrics.

Disease State Applications

A greater understanding of the pathophysiology, genetics, molecular biology and/or metastatic spread and recurrence of primary and secondary brain tumors is critical to fostering improved patient outcomes and tailoring treatment strategies. In an effort to advance knowledge surrounding subcortical and invasive neurological disease, proposals designed to investigate lesion removal and tissue preservation using BrainPath, Myriad and/or the Tissue Preservation System (TPS) are of interest. Laboratory science, animal models and clinical proposals will be considered.

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Proposal Decision Timeline

Activity	Review Cycle
Deadline for Proposal Summary	None – Open
NICO Clinical Affairs review of Proposal Summary & communication with prospective investigator	1-2 months from receipt
PI sends Full Protocol Submission with Detailed Budget	Within 6 weeks of notification of proposal (concept) summary approval
NICO Clinical Affairs sends Full Protocol comments to investigator	Within 4-6 weeks of full protocol submission
PI sends Final Full Protocol Submission to NICO Clinical Affairs	Within 2 weeks of receipt of comments
Final Full Protocol approval by NICO Clinical Affairs	Within 2 weeks of receipt of final protocol