



# Study Proposal

Please complete the following form overviewing your proposed study and upload for review at: Investigator Initiated Study - Submission

**Study Title** 

Point of Contact/Email

Investigator(s)

# Institution IRB

Is this study captured under an existing general research IRB at your institution?	Yes	No
Will this study require additional IRB approval at your institution? Yes No		

*If yes, please provide an overview of the anticipated time frame and current status or drafting/submission/other:* 

Study Concept/Summary

**Study Hypothesis** 



# Study Type

Investigator Initiated Study Program



Primary Aim(s)

The following questions refer to specific study types. Please fill out any of those which apply to your specific submission.

## Study Size

Please indicate planned study size, as well as number of samples per patient (if applicable).

Patient/Sample Type (Totals)	n	Sample/Patient
Human Patient(s)		
Animal Patient(s)		
(please specify type of animal)		

## If multiple cohorts:

Please describe the breakdown of patients.

## If multiple samples collected per patient/animal:

Please list each sample planned (i.e. tumor core, contrast-enhancing edge, parenchyma, etc).

## Patient Selection Criteria

Please share your planned inclusion/exclusion criteria by which you'll identify your study cohort.

Inclusion:



Exclusion:



#### **Tissue Specific Scenarios**

## For studies involving human, intraoperative collected tissue:

*Please provide additional information on your intended method of tissue collection and transport in/from the OR. If multiple methods are planned, please describe each separately.* 

#### For studies involving animal, lab collected tissue:

Please provide additional information on your intended method of tissue collection. If multiple methods are planned, please describe each separately.

#### For studies implanting tissue cells for growth:

*Please provide additional information on where from/how the tissue for implantation is/was obtained (i.e. tumor bank, OR collected tissue, other animal, etc).* 

#### For studies analyzing tissue information:

Please note any lab analyses you intend to perform as part of your study.





# Technology

*Please specify the technologies to be used in this investigation, and which equipment already is stocked at your institution.* 

## NICO Specific Technologies

*Please indicate which NICO technology you intend to include in your study and if you currently have the technology onsite.* 

NICO Technology	Planned Use in Study	Equipment at Institution
Myriad NOVUS		
Myriad Original (Blue)		
BrainPath 11mm		
BrainPath 13.5mm		
Myriad Tissue Trap		
Automated Preservation System (APS)		
Ancillary – EM Navigation Adapter, Other		

## Grant Request:

*Please provide the requested Research Grant Amount you are requesting for this study. Grants awarded are scheduled across milestone achievement.* 

## **Publication Plan**

Please indicate your goal(s) for publishing. This may include specific journals of interest, number(s) of publication(s) planned, and any abstract submissions for professional meetings throughout the duration and at conclusion of your project.





## Milestone Timeline Anticipated

*Please provide an estimated outline of milestones from project start to conclusion. At least four milestones should be described initially and can be as specific or broad as you choose.* 

Milestone Planned	Description	Anticipated Duration
Milestone 1		
Milestone 2		
Milestone 3		
Milestone 4		
Milestone 5 (optional)		
Milestone 6 (optional)		

If you'd like to describe additional milestones, please do so in the text box below: