Request Comments

Organization

Organization/Institution Legal Name	:		
Tax ID #	:		
Tax Status	:		If Other:
Contact	:		
Address	:		
Primary Phone	:	Ext:	
Secondary Phone	:	Ext:	
Fax	:		
Email	:		
Organization/Institution Type	:		
Website URL	:		

Sponsor-Investigator Information :

Organization/Institution Name	
Organization/Institution Tax ID	:
Sponsor-Investigator First Name	:
Sponsor-Investigator Last Name	:
Sponsor-Investigator Email	:
Sponsor-Investigator Phone	:
Primary Degree	:
Medical Specialty	:
If other, then specify	:
Medical License Number	:

Basic Study Information

Is this Full Proposal related to a Concept previously submitted to Ironwood IIS?	
If Yes, Please select the grant ID of the previously submitted Concept.	

Study Title

Hypothesis/Study Objective/Purpose

Background/Rationale

Therapeutic Area

Study Type

Please indicate the type of support you are requesting from Ironwood

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Study Design

Study Design

If Other, please describe

Study Type

Experimental Design

General Description of Experimental

Total Number of Sites

Total Number of Subjects

Study Details

Inclusion Criteria	:
Exclusion Criteria	:
Safety Evaluations	:
Primary End Point	:
Secondary End Point(s)	:
Exploratory End Point(s)	:

Expected Outcome :

Primary Country :
Other Proposed Countries :

Additional Study Details Study Timeline

Estimated total study duration(months) :
Will you be enrolling subjects? :

Provide the approximate time in months from contract execution in the Time Estimated column

Study Event	**Time Estimated (in months)**	**Comments**
IRB if applicable		
Study Report		
Publication Submission		

Duration of study Treatment (Per Subject) :
Number and Description of Each Treatment Arm/Group :
Doses per Subject per Treatment :
Number and Timing of Visits/Evaluations :
All Assessments to be Performed :

Statistical Analysis Plan :

Justification for sample size :

Economic Measurements :
Additional Information :
References (i.e. Literature References) :
Provide information confirming which Ethics Committee will be used to approve the research :

Will your IRB require Sponsor Investigator IND? Ironwood requirements for INDs may differ from your IRB. for more information, visit the FDA website for Investigational New Drug (IND) applications :

Please certify that you have read, understood, and agreed to follow the FDA Adverse Event Reporting Requirements and Ironwood Adverse Event Reporting Requirement. ☐

Ironwood and FDA policies on Adverse Event Reporting:

Do you intend to publish and/or present the result of this study when it is complete? :

Do you have previous research experience similar to this proposed study? :

If no, please provide a brief description of any resources that you will use to assist with this research :

How many additional research projects are you currently involved with? :

How much time do you anticipate these additional projects take? Please provide a percentage :

How much time do you anticipate this project will take? Please provide a percentage :

Additional Investigator Information

* Will there be sub-investigators involved in this study?

* Will any of the sub-investigators be paid directly by a portion of this research trial?

If there are sub-investigators involved in this study, enter the requested information below:

Payee Information

Payable To	:
Attention	:
Payment Address: Line 1	:
Payment Address: Line 2	:
Payment Address: Line 3	:
Payment Address: City	:
Payment Address: State/Province/Region	:
Payment Address: Country	:
Specify if other Country	:
Payment Address: Postal Code	:

Budget Overview

Total Budget

Protocol Execution Costs : This section should be used by the requestor to record costs associated with the execution of the study protocol. Please identify all subject costs, such as consultations, procedure charges, and lab tests.

	Unit Cost/Hourly Rates	Unit Volume or Number of Hours	Total Cost	Description of Activity
	Cost per Subject	**# Subjects**		
Pharmacy Dispensing Fee				
Non-Ironwood Product Costs				
Other Protocol Execution Costs (Please explain in detail)				
TOTAL Protocol Execution Costs				

CRO Costs : This section should be used by the requestor to record all payments and fees directly paid to a CRO.

This section should only be completed if you are using a CRO for your study.

	Unit Cost/Hourly Rates	Unit Volume or Number of Hours	Total Cost	Description of Activity
Protocol Development				
Ethics Committee Submission				

Data Management				
Study Management				
Other CRO Costs (Please explain in detail)				
TOTAL CRO Costs				

Study Administration Costs : This section should be used by the requestor to record expenses related to the initial setup and administration of the trial. The staff related costs should be recorded as time spent performing trial setup activities, such as writing a protocol or creating patient diaries. The administrative costs should be attributed to trial setup fees, or technology costs associated with setting up or integrating systems.

	Unit Cost/Hourly Rates	**Unit Volume or Number of Hours**	**Total Cost**	**Description of Activity**
Staff Related Costs				
Subject Recruitment Costs				
Equipment Costs (must be limited to costs for equipment and consumables that will be used only for the purpose of conducting the study)				
IT Related Costs (other than staff expense)				
IACUC (or equivalent) Submission Fee (Cost Per site x Sites)				
IACUC (or equivalent) Follow-up Annual Fees (Cost Per site x Sites)				
Other Study Administration Costs (Please explain in detail)				

TOTAL Study Administration Costs				
Data Analysis/ Publication Costs : This section should be used by the requestor to record costs associated with analyzing and publishing data from the study. The staff related costs should be recorded as time spent performing data analysis activities, such as reviewing subject data or creating tables. If a vendor is used for data analysis, please identify all vendor charges and fees separate from staff related costs.				
	Unit Cost/Hourly Rates	**Unit Volume or Number of Hours**	**Total Cost**	**Description of Activity**
Staff Related Costs				
Other Publication Costs (Please explain in detail)				
Other Data Analysis Costs (Please explain in detail)				
TOTAL Data Analysis/ Publication Costs				
TOTAL Direct Costs				
Indirect Costs				
	Percent Overhead	**Amount of Study Budget Subject to Overhead**	**Total Overhead**	

Overhead Costs				
TOTAL Indirect Costs				
TOTAL Clinical Trial Budget				

Additional Sources of Support

* Will you receive any other source of support for this study?
* Please specify the amount of support anticipated from other sources
* Amount of support requested from Ironwood

Please attach the following documents, and any additional documents in the email with your application to grants@ironwoodpharma.com:
Protocol
Questionnaire
Consent
Primary Investigator CV

Budget Allocations

Account Code	Cost Center	TA Element	Percent	Amount

Acknowledgement

I understand that when Ironwood evaluates my request, no preferences will be given based on prescribing or purchasing Ironwood products or to influence the prescription or purchase of Ironwood products. I understand that if my request is approved that I am not expected or obliged to prescribe, purchase, or recommend any Ironwood products.

I certify that no one at Ironwood has made any promises or representation to me about whether or not my request will be approved. I understand that my request will be reviewed and evaluated by Ironwood's Review Committee and that my request may not be approved.

If my request is approved, I agree to execute a Research Agreement with Ironwood. In that Agreement, I will agree to:
- Use the funds for actual and reasonable expenses of the project;
- Use the funds only for the purposes set out in my request and the Research Agreement;
- Furnish Ironwood with a reconciliation report concerning my expenditure of the funds, supported by appropriate substantiation; and
- Promptly refund any unused funds to Ironwood.

If my request is approved, I agree to abide by and conduct the research according to all applicable laws, rules and regulations as well as applicable guidelines, standards and codes of practice.

I certify that neither I or my organization is on the United States Department of the Treasury Office of Foreign

Assets (OFAC) Control List, the United States Department of Health and Human Service's Office of Inspector General (OIG), or the Food and Drug Administration (FDA) probation, debarment or exclusion lists or any other exclusion lists that would prohibit me, my organization, nor any partner organization(s) from receiving funding from Ironwood.

I certify that the statements made in this request are true, complete and accurate to the best of my knowledge.

☐ **By clicking here you have read, understood and agree to all of the above terms and conditions.**