

## AMRYT INVESTIGATOR RESEARCH PROPOSAL CONCEPT STATEMENT

Instructions: Please submit the following to [iisrequest@amrytpharma.com](mailto:iisrequest@amrytpharma.com)

- Completed and signed INVESTIGATOR RESEARCH PROPOSAL CONCEPT STATEMENT
- Budget- provide the details, as projected at this time
- CV
- Any other documents that provide additional information for reviewers

You will receive notification from [iisrequest@amrytpharma.com](mailto:iisrequest@amrytpharma.com) confirming the receipt of your proposal.

<b>NAME OF APPLICANT</b>
<b>TITLE/POSITION OF APPLICANT</b>
<b>APPLICANT EMAIL ADDRESS</b>
<b>NAME AND LEGAL MAILING ADDRESS OF INSTITUTION</b>
<b>NAMES AND INSTITUTIONS OF ANY CO-INVESTIGATORS (if known at this time)</b>
<b>TITLE OF STUDY PROPOSAL</b>
<b>STUDY RATIONALE</b>
<b>OBJECTIVES (PRIMARY AND SECONDARY)</b>

**STUDY DESIGN INCLUDING DURATION OF STUDY PARTICIPATION, STUDY POPULATION**

**INCLUSION AND EXCLUSION CRITERIA**

**EFFICACY ENDPOINTS**

**SAFETY ENDPOINTS**

**OTHER ENDPOINTS**

**STUDY TIMELINES AND MILESTONES**

**OUTLINE OF STUDY BUDGET-** (Please refer to the budget template at the end of this document; you may submit in an alternate form (e.g., spreadsheet, Word) provided it delivers the same information, as projected at this time.

<b>TOTAL AMOUNT OF STUDY DRUG REQUIRED FOR DURATION OF STUDY</b>					
<b>PROPOSED SHIPMENT SCHEDULE OF DRUG (e.g., monthly, based on lab values, based on weight/other criteria, etc.)</b>					
<b>PROPOSED PUBLICATIONS, INCLUDING TIMELINE</b>					
<b>NAME OF REPRESENTATIVE WHO WILL SIGN AGREEMENT ON BEHALF OF THE INSTUTION</b>	<b>EMAIL ADDRESS OF REPRESENTATIVE SIGNING ON BEHALF OF INSTITUTION</b>				
<p><b>APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE:</b> I certify that the statements herein are true, complete and accurate to the best of my knowledge.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><b>SIGNED BY INVESTIGATOR</b></td> <td style="width: 50%; border: none;"><b>DATE</b></td> </tr> <tr> <td style="border: none;">-----</td> <td style="border: none;">-----</td> </tr> </table>		<b>SIGNED BY INVESTIGATOR</b>	<b>DATE</b>	-----	-----
<b>SIGNED BY INVESTIGATOR</b>	<b>DATE</b>				
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<b>AMRYT CONTACT NAME</b>					



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### Outline of Study Budget

Instructions: Please provide the details as projected at this time. You may provide the information in other formats, e.g., Excel, Word, provided it includes the same information as listed below.

VAT: Investigator Initiated Studies (IIS) are provided by Amryt to support independent scientific research. The support of Amryt through a research grant does not infer any material benefits and Amryt is not engaging the requestor as a service provider. As a result, Amryt does not pay VAT in addition to the research grant requested.

Facilities and Administrative Costs (Overhead)	
Personnel Salary Costs Investigator	
Co-Investigator(s)	
Study Coordinator	
Administrative	
Other	

Related Personnel Costs (e.g., health insurance)	
Fees, e.g., IRB	
Publication Costs (e.g., copyright on images, etc.)	
Patient Travel and Lodging Costs	
Time Reimbursement Costs for Study Subjects	
Equipment	
Lab Costs (e.g., sample analysis, genetic testing)	
Drug Supplies	
Other	
Other	
Other	

Other	
Other	
Other	
Total	