**INSTRUCTIONS:**

**Please include the following documents in your submission to** **iisrequests@amrytpharma.com****.**

**Your proposal will not be reviewed until a full complement of documents is received:**

[ ]  **Completed and signed INVESTIGATOR RESEARCH PROPOSAL CONCEPT STATEMENT**

[ ]  **Budget – provide details, as projected, at this time**

[ ]  **CV of each investigator**

[ ]  **Other documents that provide additional information for reviewers.**

**You will receive acknowledgement from** **iisrequest@amrytpharma.com** **confirming the receipt of your proposal.**

|  |  |
| --- | --- |
| **NAME OF APPLICANT**  |  |
| **TITLE/POSITION OF APPLICANT** |  |
| **APPLICANT EMAIL ADDRESS** |  |
| **NAME AND LEGAL MAILING ADDRESS OF INSTITUTION** |  |
| **Names and Institutions of any Co-Investigators (if known at this time)** |  |
| **TITLE OF STUDY PROPOSAL** |  |
| **STUDY RATIONALE** |  |
| **OBJECTIVES (PRIMARY AND SECONDARY)** |  |
|

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| **STUDY DESIGN**(Including duration of study participation, study population, etc.) |

 |  |
| **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. |  |
| **TOTAL AMOUNT OF STUDY DRUG REQUIRED FOR DURATION OF STUDY** |  |
| **PROPOSED SHIPMENT SCHEDULE OF DRUG** (e.g., monthly, based on lab values, based on weight/other criteria, etc.) |  |
| **PROPOSED PUBLICATIONS, INCLUDING TIMELINE** |  |
| **NAME AND EMAIL ADDRESS OF REPRESENTATIVE WHO WILL SIGN AGREEMENT ON BEHALF OF THE INSTUTION** |  |
| **APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE:** I certify that the statements herein are true, complete, and accurate to the best of my knowledge.**SIGNED BY INVESTIGATOR DATE:**--------------------------------------------------- ----------------------------------------- |
| **AMRYT CONTACT NAME** |  |

**Outline of Study Budget**

**Instructions:**

Please provide the details as projected at this time. You may provide the information in another format, 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.

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| **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.)**Please note publication costs and support with medical writing must be requested at this stage. They cannot be requested when it comes to publication preparation. |       |
| **PATIENT TRAVEL AND LODGING COSTS** |       |
| **TIME REIMBURSEMENT COSTS FOR STUDY SUBJECTS** |       |
| **EQUIPMENT** |       |
| **LAB COSTS (E.G., SAMPLE ANALYSIS, GENETIC TESTING)** |       |
| **DRUG SUPPLIES** |       |
| **OTHER (please specify)** |       |
| **OTHER (please specify)** |       |
| **OTHER (please specify)** |       |
| **TOTAL**  |       |