**Concept Proposal: Request of Napo Pharmaceuticals’ Product Support for Investigator-Initiated Trial**

This form is to aid in the submission of unsolicited clinical concepts and protocols by independent Investigators and to request Napo Pharmaceuticals Sponsorship of Investigator-Initiated Trials. Incomplete proposals may delay approval for consideration.

**1.0 Clinical Site Information**

|  |  |
| --- | --- |
| Organization/Institution: |  |
| ***Investigator*** |  |
| Name & title: |  |
| Department: |  |
| Address: |  |
|  |  |
| Telephone: |  |
| Fax: |  |
| Email Address: |  |
| Major Therapeutic Area of Interest/Specialty: |  |
| Clinical Trial Experience: |  |
| Experience with IITs: |  |
| Current Clinical Trials: |  |
|  |  |

|  |  |
| --- | --- |
| ***Contact Person*** | ***(if different from above)*** |
| Name & title: |  |
| Address: |  |
|  |  |
| Telephone: |  |
| Fax: |  |
| Email Address: |  |
| Preferred method of contact: |  |
|  |  |

|  |  |
| --- | --- |
| ***Research Coordinator*** | ***(if different from Contact Person above)*** |
| Name & title: | See above |
| Address: |  |
|  |  |
| Telephone: |  |
| Fax: |  |
| Email Address: |  |
| Preferred method of contact: |  |
| Clinical Trial Experience: |  |
|  |  |

**2.0 Project Description**

|  |  |
| --- | --- |
| Rationale:  References: |  |
| Hypothesis & Objectives: |  |
| Study Title: |  |
| Phase of Research: |  |
| Study Design: |  |
| Product: |  |
| Target Population: |  |
| Sample Size: |  |
| Treatment Regimen: |  |
| Treatment Duration: |  |
| Primary Endpoints: |  |
| Major Eligibility Criteria: | **Subject Characteristics (Inclusion Criteria):**  **Subject Characteristics (Exclusion Criteria):** |
| Duration for Enrollment: |  |
| # of Sites Participating: |  |
| Location of Sites: |  |
| Estimated Dates |  |
| First Patient In: |  |
| Last Patient Out: |  |

**3.0 Product Required**

|  |  |
| --- | --- |
| Name of Product: |  |
| Is a Placebo Needed:  Other: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Dosing Regimen/Duration: |  |
| Quantity per Subject: |  |
| Number of Subjects: |  |
| **Total Product Required:** |  |
|  |  |

**4.0 Other Information**

|  |
| --- |
| Do you know any other research groups working on the same or related studies? |
| Have you worked with Napo Pharmaceuticals previously? If so, please explain. |
| Please list any complete and pending FDA or state inspections and history of FDA 483s. |
| Have you been disqualified or debarred by any governmental agency or are currently the subject of an investigation or inquiry by the government or your employer?  If so, please explain. |
| Does your facility have adequate locked storage area for drug? If so, please explain. |
| Please describe your publication plan. |

**6.0 Other documentation**

Please provide the following documents:

* CV with a list of your publications

**7.0 Signatures**

|  |  |
| --- | --- |
|  |  |
| Signature (Investigator) | Date |
| *\*If the Investigator is an employee of an Institution, and does not have the authority to sign for the Institution, please have document co-signed by authority of the Institution* | |

Please email completed proposal and/or all inquiries to iit@napopharma.com

***Any approvals, consents or oral agreements by Napo Pharmaceuticals have no legal or other binding effect unless and until a separate written legal agreement is executed by the parties covering the study. Notwithstanding any such agreement, Napo Pharmaceuticals reserves the right to terminate any support or involvement in the study at any time whatsoever, subject to its sole discretion.***