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| **Associated Procedure / Instruction Ref:** | **080165-SOP** |

**Investigator SPONSORED STUDY SYNOPSIS Proposal**

The aim of this document is to provide Ipsen with a detailed plan for your proposed research project in order to assess the scientific rationale/medical benefit; overall feasibility; and patient safety. As such, please provide as much detailed information regarding the requested information as possible, and as you feel comfortable and necessary.

|  |  |
| --- | --- |
| **STUDY TITLE:** | |
| **SPONSOR INFORMATION** | Sponsor Institution (& State):  Principal Investigator:  Principal Investigator Title:  Medical License #:  PI Contact E-Mail: |
| **sUB-sITE iNFORMATION** (IF APPLICABLE) |  |
| **sTUDY tYPE**  (CHECK all that apply) | **Pre-Clinical**:  In Vitro  In Vivo  Ex-Vivo  **Clinical**:  Interventional  Non-Interventional/Observational  Epidemiological  Prospective  Retrospective  Cross-Sectional  Longitudinal  Product Related Non-Product Related  Single-Center Multi-Center  National International  **Product Under Investigation:**  Yes No |
| **Phase**  (CHECK all that apply) | N/A  Feasibility/Pilot  Phase I | Phase II | Phase III | Phase IV  Registry |
| **study PURPOSE** | |
| **BACKGROUND** |  |
| **RATIONALE** |  |
| **OBJECTIVE(S)** | Primary:  Secondary:  Exploratory:  Hypothesis: |
| **primary efficacy endpoint** |  |
| **secondary efficacy endpoint(s)** |  |
| **Exploratory Endpoint** |  |
| **safety endpoints and evaluations** |  |
| **Study Design** | |
| **Study Design** | Overall Design:  End of Study Definition  Treatment Schedule |
| **study population** | Inclusion Criteria  Exclusion Criteria  Recruiting Plan  Target Enrollment |
| **Study treatment (s)**  (Justification for Dose (if applicable)) | Drug Type  Formula  Strength  Quantity  Non Ipsen Drug Part of Study?  Yes  No |
| **Projected timelines**  (In months from contract execution) | First Patient In/Research Initiation:  Last Patient In:  Last Patient Out/Research Completion:  Database Lock (If Necessary):  Final Study Report to Ipsen:  Publication Submissions Plan |
| **STudy Procedures AND EVALUATIONS** | |
| **EVALUATIONS** | Specify material, data collection tool (paper vs EDC tool), methods, endpoints, and measurements to be used. |
| **StatisticAL METHODS** | Include sample size and analysis methods |
| **Safety Event Reporting**  (Include safety reporting requirements, reporting forms, reporting period, follow up information and regulatory reporting) |  |

By submitting this form, you confirm/Certify that

* You are qualified by training and experience to undertake the proposed research and have all necessary certifications and/or licenses;
* You are not barred by the FDA, the U.S. Public Health Services Office on Research Integrity, and/or any other National Governing Authority from performing research and/or assuming comparable roles on federally funded research/grant programs;
* This is your original idea and all research materials will be authored and/or their use for this purpose has been approved by the original author (as appropriate); and
* The requested support will not be otherwise funded/supported through additional means.

Completed form should be submitted with Principal Investigator’s current CV and study Budget to: InvestigatorSponsoredStudies@Ipsen.com