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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.

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| **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 CriteriaRecruiting PlanTarget Enrollment |
| **Study treatment (s)**(Justification for Dose (if applicable)) | Drug TypeFormulaStrengthQuantityNon 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