|  |
| --- |
| **INVESTIGATOR-SPONSORED *CLINICAL* RESEARCH APPLICATION**  For research proposals originating outside of the United States. |

|  |  |
| --- | --- |
| **Sponsor-Investigator Information** | |
| Principal Investigator: | |
| Title: | |
| Specialty: | |
| Phone: | |
| Email: | |
| Organization/Institution: | |
| Will there be additional investigators and/or working groups involved in this study? | * Yes * No |
| If yes, please describe: | |

Any personal data which relates to Investigator or Investigator’s staff (whether employees or independent contractors) and which is provided to Incyte or its affiliates may be held on one or more databases for the purposes of reviewing this proposal, determining Investigator’s involvement in future research or in order to comply with any regulatory requirements. For these purposes, personal data may be disclosed or transferred to Incyte Corporation or its affiliates, to representatives and contractors working on behalf of the Incyte or its affiliates and to applicable regulatory authorities. One or more of these recipients may be located in countries whose laws do not provide equivalent protection for personal data to those in Investigator’s country. By transmitting such data to Incyte or its affiliates, Investigator acknowledges these terms. Any enquiries or requests to modify or delete personal data held by Incyte should be directed to: [EU\_Data\_Privacy@incyte.com](mailto:EU_Data_Privacy@incyte.com)

|  |
| --- |
| **Basic Study Information** |
| Study Title: |
| Study Acronym: |
| Indication: |
| Site (Country): |
| Other Sites (Countries): |
| Total number of sites: |

|  |
| --- |
| Design (interventional, randomized, phase, etc.): |

|  |
| --- |
| Description (Background, Rationale/Hypothesis/Purpose): [2500 character limit] |

|  |
| --- |
| Primary Objectives: [1000 character limit] |

|  |
| --- |
| Secondary Objectives: [1000 character limit] |

|  |
| --- |
| Exploratory Objectives: [2500 character limit] |

|  |  |
| --- | --- |
| **Timelines** | |
| Estimated Duration from signing of contract (Months): |  |

|  |
| --- |
| **Type of support requested** |
| * Product Supply only * Financial Support only * Product Supply and Financial Support |

|  |  |
| --- | --- |
| **Product Supply Requested** | |
| Estimated quantity: |  |
| Total duration of treatment (Months): |  |
| Will non-Incyte product be utilized for this study? | * Yes * No |
| If yes, please describe and identify product and source(s): | |

|  |  |
| --- | --- |
| **Budget & Additional Sources of Support** | |
| Total Funding Requested (estimated total and currency)\* |  |
| Will you receive or plan to request any other sources of support for this study? | * Yes * No |
| Please identify [potential] source(s) of funding: |  |
| Please specify the amount of support anticipated from other source(s): |  |
| \* In order for Incyte to start the review of your proposal please complete also the enclosed Study Budget Template in as much detail as possible. | |

|  |
| --- |
| **References (Literature References)** |
|  |

Please submit the completed form by email to: [Global\_ISTs@incyte.com](mailto:Global_ISTs@incyte.com)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study Budget** | | | | |
| *Note: please report costs in your local currency.* | | | | |
|  | | | | |
| **Sponsor-Investigator Information** | | | | |
| Principal Investigator: |  | | | |
| Organization/Institution: |  | | | |
| Collaborators: | Specify Organization/Institution | | | |
|  | | | | |
| **Study Information** | | | | |
| Study Title/Acronym: |  | | | |
| Estimated duration (months): |  | | | |
| Estimated number of patients: |  | | | |
| Estimated number of sites (recruiting centers): | Specify Country if multiple countries will participate | | | |
|  | | | | |
| **Direct Costs** | | | | |
| **Description** | **Details** | **# Units** | **Unit Cost** | **Total Cost** |
| *Example: materials (Specify)* |  |  |  |  |
| *Example: patient exams (Specify)* |  |  |  |  |
| *Example: patient stipend* |  |  |  |  |
| … |  |  |  |  |
| **Total Direct Costs** | | | | **0.00** |
|  |  |  |  |  |
| **Personnel Costs** | | | | |
| **Description** | **Details** | **# Hours** | **Hourly Rate** | **Total Cost** |
| *Example: Computer Engineer* |  |  |  |  |
| *Example: CRA Manager* |  |  |  |  |
| *Example: Data Manager* |  |  |  |  |
| *Example: Pharmacist Pharmacovigilant* |  |  |  |  |
| *Example: Regulatory Assistant* |  |  |  |  |
| *Example: Research/Pathology Technician* |  |  |  |  |
| *Example: Sponsor Pharmacist* |  |  |  |  |
| *Example: Statistician* |  |  |  |  |
| … |  |  |  |  |
| **Total Personnel Costs** | | | | **0.00** |
|  |  |  |  |  |
| **Indirect Costs** | | | | |
| Total Costs that are subject to overhead (Personnel + Procedural) | | | |  |
| Institutional Overhead | | | |  |
| **Total Indirect Costs** | | | | **0.00** |
|  |  |  |  |  |
| **Other Costs (One-time costs without overhead)** | | | | |
| *Example: IRB Reviews* | | | |  |
| *Example: CRO costs* | | | |  |
| … | | | |  |
| **Total Other Costs** | | | | **0.00** |
|  | | | | |
| **Cost Summary** | | | | |
| **Total Direct Costs** | | | | **0.00** |
| **Total Personnel Costs** | | | | **0.00** |
| **Total Indirect Costs** | | | | **0.00** |
| **Total Other Costs** | | | | **0.00** |
| **Total Funding Requested** | | | | **0.00** |
|  |  |  |  |  |
| **Cost of Product (if applicable)** | | | | |
| **Description** | **Details** | **# mg/IU** | **Cost** | **Total Cost** |
| *Example: Product (drug, antibodies, etc.)* |  |  |  |  |
| *…* |  |  |  |  |
| **Total Product Costs** | | | | **0.00** |
|  |  |  |  |  |
| **Total Study Cost (Funding+Drug)** | | | | **0.00** |