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| --- | --- | --- | --- |
| **Section I: Instructions** | | | |
| **1.** Use this worksheet to document the information needed for OSF to request CRBO services. | | | |
| **2.** Press the F1 key while in a field to show help and/or example text. | | | |
| **Section II: General Information** | | | |
| **1. Principal Investigator (PI) Full Name:** | | | |
| **2. PI Employer:** | | | |
| **3. Protocol Title:** | | | |
| **4. Protocol Number:** | | | |
| **5. NCT Number:** | | | |
| **6. Study location(s), including all facilities and study related activities:** | | | |
|  | Location Name | Study Related Activity |  |
|  |  |  |  |
|  | | | |
| **7. Contracting parties, including legal entity names and addresses:**  *\*Please bring this to our attention if this is a multi-party agreement.* | | | |
|  | Legal Entity/Entities Name | Address |  |
|  |  |  |  |
|  | | | |
| **8. Study documents provided:** | | | |
| Final Protocol\* | | | |
| Draft Informed Consent Form (ICF)\* | | | |
| Draft Sponsor Budget\* | | | |
| Clinical Trial Agreement (CTA) Template or any Contractual/Grant Documents\* | | | |
| Investigator’s Brochure/Device Manual\* | | | |
| Drug Study Documents: | | | |
| IND Exempt Determination | | | |
| FDA Approval Letter for IND | | | |
| Device Study Documents\*\*: | | | |
| FDA Approval Letter for IDE | | | |
| CMS Approval Letter for IDEs (dated prior to 1/1/15) | | | |
| Other: | | | |
| **9. IND# / IDE#:** -OR- NA | | | |
| **10. Sponsor contact information:** | | | |
| Name & Title: | | | |
| Phone #: | | | |
| Email: | | | |
| **11. OSF requires the use of our local IRB. Does the sponsor require the use of a central IRB? No**  Yes  **If yes, please provide documentation and explain why:** | | | |
| **12. Any other important items PFS should know:** | | | |
| **13. Who will the payee be?:** | | | |
| **14. Should negotiations be delayed until site lead/MGR gives approval?:** | | | |

\* – Required

\*\* – Investigator Initiated Studies – CA only