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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