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| **Section I: Instructions** | | | |
| **1.** **Use this worksheet to document the information needed for OSF to request CRBO services.** | | | |
| **Section II: General Information** | | | |
| **1. Principal Investigator (PI) Full Name:**  **If applicable, Non-OSF Co-PI Full Name:       Define division of responsibilities:**  **If applicable, Non-OSF Sub PI Full Name:       Define division of responsibilities:** | | | |
| **2. PI Employer:**    **If applicable, Co-PI Employer:**  **If applicable, Sub PI Employer:** | | | |
| **3. Protocol Title:**  **Study Acronym:**    *Please note, If there is not a sponsor provided Study Acronym, please enter in format of:* ***Sponsor Name-Protocol******Short Name*** | | | |
| **4. Protocol Number:** | | | |
| **5. NCT Number:** | | | |
| **6. Study location(s), including all facilities and study related activities:** | | | |
|  | **Location Name** | **Study Related Activity \*Planned In/Outpatient** |  |
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| **7. Study documents provided:** | | | |
| Final Protocol\* | | | |
| Draft Informed Consent Form (ICF)\* | | | |
| Draft Sponsor Budget\* (in Excel format) | | | |
| 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:  \* – Required  \*\* – All contracts are required, if there is a business need, there is flexibility regarding the timing of submittal | | | |
| **8. IND# / IDE#:** -OR- NA | | | |
| **9. Sponsor contact information:** | | | |
| Name & Title (Budget Negotiations): | | | |
| Phone #: | | | |
| Email:  Name & Title (Contract Negotiations):  Phone #:  Email:  Name & Title (Regulatory Contact):  Phone #:  Email: | | | |
| **10. 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:** | | | |
| **11. Should budget negotiations be delayed until site lead/leader gives approval?:** | | | |
| **12. Should contract negotiations be delayed until site lead/leader gives approval?:** | | | |
| **13. Notes for RA team and/or Budget/CA/Contracts team:** | | | |

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| ***To be completed by RA Team:***  **Any special instructions:**  **Payee:**  **CRO (if applicable):**  **Contracting parties, including legal entity names and addresses (or site location):** | |
| Legal Entity/Entities Name | Address or Site Location |
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