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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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