|  |  |
| --- | --- |
| **Section I: Study Information** | |
| **1. Study Name (Acronym):** | |
| **2.** **NCT #:** | |
| **3.** **Study Description** | |
| Protocol Title:      Investigational Product*:*        *IRB of Record:*       Principal Investigator:       Co-Investigator(s):       Primary Coordinator:       Secondary Coordinator: | *COPY exactly from PROTOCOL or Contract*  *If not in protocol name*  *\*Must Provide name, phone, and email for each person listed* |
| **4.** **IRB identification # (i.e. PIRB=IRB net #):** | |
| **5. Study Coordinators:** | |
| **6. Research Contacts:** | |
| **7. Links (optional):** | |

# **Section II: Recruitment Information (Optional)**

|  |  |
| --- | --- |
| **1. Patient Facing Name:** | |
| **2. Patient Facing Description:** | |
| **3. Do you want this to show in My Chart? Yes**  **No** | This will show available studies to the patient in MyChart based on their medical record. This displays the Patient Facing Name and Description above. |
| **4. When is the study going live?** |  |
| **5. What is the enrollment period?** |  |
| **6. Do you want to send recruitment requests? Yes**  **No** | If no, you can skip to question 8. |
| **7. Do you want to get a Recruitment Notification for Interested? (Coordinator and/or PI):**  **No**  **Yes**  **Coordinator;**  **PI; or**  **Coordinator & PI** | |
| **8. Do you want to get a Recruitment Notification for Declined? (Coordinator and/or PI):**  **No**  **Yes**  **Coordinator;**  **PI; or**  **Coordinator & PI** | |
| **9. Do you want to require provider approval before sending recruitment requests?** **Yes**  **No** | |
| **10. Do you want a tool to help identify patients for your studies? Yes**  **No**  \*\*This is very time consuming to build. Please only mark if you are planning to use.  \*\*We will not ask IT to build this if this box is not filled out | |
| **11. Inclusion/Exclusion Criteria:**  \*If you struggle with formatting you may put (See attachment) and include a separate document with the criteria. | |

# **Section III: CRBO ONLY**

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| **1. Study Code:** | | | |
| 2. **Study Type:  Billing Only  Device  Drug/Biologic  Expanded Use  HUD/HDE**  **Interactional/Descriptive Observational Procedure or Interventional** | | | |
| **3a. Billing Contact** | **Clinical Research Business Office** | | |
| **3b. Billing Address** | Address | 1420 W Pioneer Parkway | |
|  | City | Peoria | |
|  | State | IL | |
|  | Zip Code | 61615 | |
| **4. Principal Investigator:** | | | \*\*\*Look at study description above for PI name |
| **5. IDE Trial?:  IDE-Cat A  IDE-Cat B  IDE-None  N/A** | | | |
| **6.** **Certificate of Confidentiality?:** **Yes**  **No** | | | |
| **7.** **Billable Services?:** **Yes**  **No** | | | |
| **8.** **Federally Funded?:** **Yes**  **No** | | | |
| **9. Expanded Access Type?:  Device  Drug or Biological  Non-Significant Risk  Significant Risk**  **Unknown  N/A** | | | |
| **10. Medicare Registry (TAVRs etc.): Yes  No** | | | |
| **11. IDE#/PMA#** | | | |
| **12. IDE#/PMA#** | | | |
| **13.** **Is a billing protocol Necessary?:** **Yes**  **No** | | | |

# **Section IV: Notification Settings \*Optional**

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| --- | --- |
| **1. ADT (Admission, Discharge, Transfer) Event** | Default YES (Do nothing) |
| **2. Procedure Result\*** | RSH RESULTS ROUTING STUDY USERS – CC COORDINATORS |