**CHIRB/CIRI Study Supplement**

**Instructions:** Studies conducted at Baylor St. Luke’s Medical Center (BSLMC) which utilize Catholic Health Initiatives Institutional Review Board (CHIRB) as the IRB of Record or which utilize Catholic Health Initiatives Institute for Research and Innovation (CIRI) study support services should complete this form and submit it with the BSLMC Administrative Application.

The study team should attach this completed form to CHIRB submissions. The BSLMC Research Office will also forward the form to CHIRB and CIRI as applicable.

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| Principal Investigator (PI) last/first name: |  | IRB of record number: |  |
| Study Title: |  |
| Will this study utilize CHIRB as the IRB of record? | ☐ Yes ☐ No |
| Will this study utilize CIRI for study start-up or billing? | ☐ Yes ☐ No |
| Is an Investigator Service Agreement (ISA) in place with the Principal Investigator?  | ☐ Yes ☐ No |
| **Submission Type** |
| Industry Sponsored?  | ☐ Yes ☐ No  | Investigator-Initiated?  | ☐ Yes ☐ No  |
| Funded/awarded Grant\*? | ☐ Yes ☐ No  | Prime or subrecipient? | ☐ Yes ☐ No  |
| Cooperative Agreement?  | ☐ Yes ☐ No  | Other (describe)? |  |
| Will access to a CHI facility and/or protected health information be required by Sponsor (or designee)? | ☐ Yes ☐ No  |
| ***If this project is grant-funded, please attach documentation of the grant submission and the notice of award/subaward.*** | ☐ Attached ☐ N/A |
| ***If this project requires review and execution of a new contract, please attach the draft agreement.*** | ☐ Attached ☐ N/A |
| **Third Party/Ancillary Services** |
| Will any non-CHI third party services (i.e. radiology, pathology, anesthesiology, laboratory, etc) be required to conduct the project? If so, provide the name of the group and list services provided. Insert rows as needed. |
| Name of Group: | Services Provided: |
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| **Principal Investigator’s Certification** |
| My signature certifies that: 1) I accept responsibility for completing applicable CIRI and institutional research training, the proper technical content and quality of the proposed project, and securing all required institutional, department and/or facility approvals prior to starting the project; 2) no individuals on the project will have commitments in excess of 100% effort; 3) the information contained in this form and attached application or proposal is true, accurate and complete to the best of my knowledge; 4) I accept responsibility for compliance with the Protocol (if applicable), the project/award terms and conditions (including but not limited to submission of all data and reports, and regulatory compliance), and all applicable CHI, institutional, and CIRI policies and procedures; 5) if a joint appointment with another organization exists, full disclosure has been made to the NIH or other sponsors as required, and my time and effort will not be double billed for the same effort; 6) I understand that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil or administrative penalties; 7) I have appropriate credentials and privileges at the facility(ies) /institutions where the project will take place and that such credentials and privileges encompass the conduct of the project; 8) If required, I have a valid license in the state where the project is performed; 9) if my employment status, licensure, or privileged or credentialed status with the facility(ies) changes, I will notify CIRI with two (2) days of any such change. |
| Principal Investigator’s Signature: |
| Date:  | PI’s phone:  |
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| ***Below section for CIRI/CHIRB use*** |
| Acknowledged by Local/Site Research Manager or Designee:  |
| Date:  |
| CPM, MGC, or Designee: |
| Date: |