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|   Institutional Review Board | **NEW PROTOCOL SUBMISSION CHECKLIST****- Full Board Standard Submission** |
| **REQUIREMENT**NOTE: Submission must be completed in its entirety at least 21 days prior to meeting. Full Board meetings are held on the 2nd Tues. of each month. Materials submitted without the required signatures may delay review. |
|[ ]  Obtain TCH protocol # from IRB Office at IRB\_Office@thechristhospital.com |
|[ ]  Documents required with all submissions[ ]  Study Application[ ]  PI Assurance and Responsibilities (signed by PI)[ ]  Departmental Assurance and Responsibilities (signed by Department Head)[ ]  Disclosure of Financial Interest forms for all key research personnel[ ]  CITI Course Transcripts (HSR Core for Non-Biomedical Studies, HSR Core and Good Clinical Practice (GCP) for Biomedical Studies), if not already on file with the IRB[ ]  Protocol[ ]  ICF(s) utilizing TCH IRB template OR Waiver |
|[ ]  Documents as applicable to the research study-[ ]  Investigator Brochure (drug studies)[ ]  Instructions for Use (device studies)[ ]  Recruitment Materials[ ]  Study-related Materials[ ]  Any relevant grant applications[ ]  FDA IDE Approval Letter (IDE studies)[ ]  FDA IND Approval Letter (IND studies)[ ]  Investigator Medical License (as applicable, if not already on file with the IRB)[ ]  Investigator CV (if not already on file with the IRB)[ ]  Any other relevant documentation |