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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](mailto:IRB_Office@thechristhospital.com?subject=IRB%20Protocol%20Number%20Request) | |
|  | 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 | |