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| Institutional Review Board | | **NEW PROTOCOL SUBMISSION CHECKLIST**  **- Reliance Agreement Submission** |
|  | 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  Reliance Agreement 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) containing Local Context Information | |
|  | Documents as applicable to the research study-  Recruitment Materials  Data Collection Tools  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 | |