***The purpose of this checklist is to ensure that the following items are provided to the Protocol Review & Monitoring System (PRMS) team for study oversight. Protocol Review and Monitoring Committee (PRMC) approval is required for all cancer-related studies that require IRB review.***

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| ***Pre-PRMC Approval***  |
| [ ]  Initial IRB shell and IRB #. The IRB# will be used as protocol # in OnCore and is required for PRMC submission.[ ]  Submission to PRMC via electronic PRMC application to <https://intranet.winship.emory.edu/prmcsubmission/Account/Login/?ReturnUrl=%2Fprmcsubmission%2FParticipant%2FIndex%2F4874>Include the following:-Protocol scoring form-Feasibility documentation (required once your team has been trained on feasibility process)-Protocol document-IB (if applicable)-Consent(s)-Questionnaires (if applicable)-Study accrual goals (overall and annual) and accrual duration |
| ***Post-PRMC Approval***  |
| [ ]  Cancer relevant studies with billables, meeting the NIH definition of a clinical trial, and/or Invoiced by the Office for Clinical Research (OCR) are activated and opened to accrual by OCR. Cancer relevant observational studies without billables are activated by PRMS Team or the Winship Regulatory Start-Up Team. Questions regarding billables can be sent to OCR@emory.edu [ ]  Once activated, real time patient registration and accrual data entry in Emory’s CTMS, OnCore/EPIC as required.  -In order to register patients in OnCore, teams must upload a consent in CRA console[ ]  Accrual data is required for local and participating site enrollees. To obtain Oncore training and access, please contact the Office for Clinical Research (OCR) at OCR@emory.edu.[ ]  Real time updates to PRMS Team via winshipprmc@emory.edu on study status changes, i.e. IRB initial approval, open to accrual, closure to accrual, suspensions, on hold, IRB closeout[ ] Real time updates to PRMS Team via winshipprmc@emory.edu on accrual goal changes[ ]  Submission of significant protocol amendments that impact study design/safety to PRMS Team via winshipprmc@emory.edu [ ] Accrual data reconciliation for Data Table 4 (DT4). Subjects reported via OPEN on national trials should match what is provided in monthly pediatric accrual reports[ ] For Multi-site IITs, quarterly reporting of participating site accruals via NCI’s Clinical Trials Reporting Program (CTRP). This requires an active CTRP account.[ ] For Multi-site observational and ancillary/correlative studies where Emory is the lead site, a list of participating sites, approval and activation dates for each site, and a contact at each participating site. Study teams are responsible for capturing participating site accruals in OnCore.[ ] Monthly meeting documentation detailing protocol reviews  |