Appendix 4: Overview of the PRMC Protocol Review

PRMC Review

FULL-BOARD COMMITTEE
- Institutional/PI Initiated Intervventional New Studies
- Industry Sponsored Interventional New Studies
- Any Administrative-Review Study at Reviewer’s Discretion
- Justification to Unsatisfactory Accrual Notice

ADMINISTRATIVE
- Expedited Review by Chair, Vice Chair, or their designee
  - Cooperative Group and NIH Grant Peer-Reviewed Studies
  - Prospective, hypothesis-driven, non-interventional studies (e.g., observational, ancillary, and correlative studies).
  - Prospective Institutional or Industry molecular and genetic epidemiology studies
  - Protocols that evaluate aspects of cancer care
  - Multi-site institutional trials previously approved by a PRMS from another NCI-designated Cancer Center
  - Amendments
  - PI Response to PRMC Comments
  - Continuing Review (active interventional trials, active non-interventional institutional trials)
  - 7/10-Year Resubmission (active interventional trials)
  - Expanded Access (recruiting new patients)
  - Justification to Unsatisfactory 6-month Accrual Notice

NO PRMC REVIEW
- Cooperative Group and NIH Peer Reviewed bio-banking studies or registries
- Reports, Chart Review, single-subject compassionate use protocols
- Non-hypothesis-driven research such as registries, databases (pure data collection), and serum and tissue bio-banking protocols
- Standard of care studies if not asking a scientific question
- IND Single Use Trial
- Amendments of Cooperative Group and NIH Grant Peer-Reviewed Studies
- Continuing Review (closed to accrual or non-interventional, except for institutional)
- Expanded Access (not recruiting patients)
- 7/10-Year Resubmission (closed to accrual or non-interventional)