#### Appendix 4: Overview of the PRMC Protocol Review

# **PRMC** Review

# **PRMC REVIEW**



# **FULL-BOARD COMMITTEE**

- Institutional/PI Initiated
  Interventional 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, noninterventional 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 NCIdesignated 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 biobanking 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)