Yale CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

Protocol Review Committee
Review Requirements by Protocol Type

Protocol Type	Sponsor Type	Review Required	Review Type	Scientific Review	Biostatistical Review
Interventional	National	Yes	Expedited[1]	1 Reviewer	N/A
	Externally Peer-Reviewed	Yes	Expedited[1]	1 Reviewer	N/A
	Institutional	Yes	Full Board	2 Reviewers	1 Reviewer
	Industry	Yes	Full Board	1 Reviewer	1 Reviewer
Non-Interventional, i.e., Quality of Life Studies, etc.	National	Yes	Administrative[2]	N/A	N/A
	Externally Peer-Reviewed	Yes	Administrative[2]	N/A	N/A
	Institutional	Yes	Administrative[2]	N/A	N/A
	Industry	Yes	Administrative[2]	N/A	N/A
Ancillary or Correlative, i.e., specimen/ data collection[3]	National	Yes	Expedited[1]	1 Reviewer	N/A
	Externally Peer-Reviewed	Yes	Expedited[1]	1 Reviewer	N/A
	Institutional	Yes	Full Board	1 Reviewer	1 Reviewer[4]
	Industry	Yes	Full Board	1 Reviewer	1 Reviewer[4]
Observational including cancer patients and healthy populations	National	Yes	Administrative[2]	N/A	N/A
	Externally Peer-Reviewed	Yes	Administrative[2]	N/A	N/A
	Institutional	Yes	Administrative[2]	N/A	N/A
	Industry	Yes	Administrative[2]	N/A	N/A
Exempt from Review: Any Non-hypothesis driven research[3]			Retrospective chart review, biorepository, tissue bank, Single Patient IND, Expanded Access protocols		

[1] Submissions are reviewed by sub-set of committee members who perform expedited reviews and/ or a biostatistician. The quality assurance risk assessment is conducted by the Office of Quality Assurance and Training and the data and safety monitoring plan is reviewed and approved by the reviewer at time of review. Approved submissions are listed on the Protocol Review Committee (PRC) meeting agenda for notification to PRC membership.
[2] Submissions are reviewed administratively by the PRC Regulatory Analyst. The quality assurance risk assessment is conducted by the Office of Quality Assurance and Training and the study is assigned a data and safety monitoring plan. Acknowledged submissions are listed on the PRC meeting agenda for notification to PRC membership.
[3] Only studies that can be linked to individual participant data will be reported to the NCI.
[4] If protocol includes statistical plan. Not applicable if no statistical plan is required based upon the study design.