

Responsibility by Study Type

Investigator-Initiated

Industry-Sponsored

NCI/Cooperative Group

Research Proposal: Study Request Survey

PI

(incl. Protocol & Budget Allocation Outline)

PI

PI (Sponsor)

RadOnc Clinical Trials Committee Meeting

PI

Approval Required

Multidisciplinary Disease Base Team Meeting

PI

Approval Required

Management Decision Made:
RadOnc or CPDM

CPDM

Fiscal Support

If multidisciplinary
RadOnc / CPDM

CPDM

PRMC Feasibility

RadOnc / CPDM

CPDM

Cost Estimate Forms

RadOnc / CPDM

CPDM

Contract

Sponsor

Budget

PI (CPDM)

Sponsor

Protocol

PI (BERD)

Sponsor

Informed Consent Form

RadOnc / CPDM

CPDM

CTO

RadOnc / CPDM

DSMC

RadOnc / CPDM

CUIMC IRB

RadOnc / CPDM

CPDM

Central IRB

CPDM

ClinicalTrials.gov

RadOnc / CPDM

Site Initiation Visit

PI + RadOnc / CPDM

PI + CPDM

Systems Set Up

(ARC, data collection, payment invoicing, core services)

RadOnc / CPDM

CPDM

Recruitment

(website postings, informed consents, enrollment)

RadOnc / CPDM

CPDM

Study Management

(data collection, data entry, invoicing)

RadOnc / CPDM

CPDM

Monitoring

RadOnc (monitor to be hired) / CPDM

Sponsor

Process Step