

**Radiation Oncology Research Proposal:
Protocol & Budget Allocation Outline**

Study Summary Paragraph:

Study Objectives:

Aim 1:

Aim 2:

Study Calendar:

		Treatment						Follow-up			
	Pre- Study	TIME 1	TIME 2	TIME 3	TIME 4	TIME 5	TIME 6	TIME NN	TIME NN	TIME NN	Off Study
Pathological confirmation ^a											
CBC w/differential, platelets											
Serum chemistry, hepatic panel											
B-HCG											
LABS											
MORE LABS											
EKG (as indicated)											
Adverse event evaluation											
Pharmacokinetics											
Tissue collection											
Tumor measurements								Every 3-6 months post chemoradiotherapy, per institutional standard of care			
Radiologic evaluation ^{b, c}								At 3-6 months post chemoradiation, per institutional standard of care. Imaging annually if in clinical complete response.			

a. within XX days of enrollment

b. Per institutional standard of care--FDG-PET/CT or FDG-PET/MRI obtained at XX Time and CT chest, abdomen, pelvis at 6 months after completion of YYY recommended

c. Follow-up imaging including CT chest and CT or MRI scans of the BODY PART, preferably with IV contrast, performed annually for years 1-2 years after completion of TREATMENT

Protocol Schema:



Subject Selection and Withdrawal:

Inclusion Criteria:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

Exclusion Criteria:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

Budget Allocations:

Common Budget Considerations:

- **IRB initial review and renewals**
- **Spanish translations (50 pages to include amendments)**
- **Assessments that are not standard of care**
- **Other departmental collaborations**
- **Staff Support (ex: CPDM Research Nurses, CRCs)**
- **Biostatistics (flat rate or percent salary)**
- **Physics support**
- **Blood and/or Tissue and/or other specimen collection**
- **Imaging Correlative studies**
- **If drug is involved, Research Pharmacy costs, courier service**
- **Data Capture System (RedCap, Velos, etc)**
- **Quality of Life Questionnaires (licenses if not openly available)**