**El Centro Regional Medical Center:**

**Clinical Trial Project Proposal Requirements**

**Title Page:**

* **Project Title**
* **Principal Investigators (Name, credentials, position/department)**
	+ The CV must be attached to the proposal
* **Team Members and Sub-PI if applicable**
	+ Names, credentials, position/department, study role
	+ All CV/ resumes must be attached to the proposal
* **Date Of Submission**

**Proposal**

* **Project Title**
* **Statement of Purpose and Background**
	+ A concise description of the problem warranting the study and the significance of the problem
	+ Benefit for ECRMC participation in Clinical trial
	+ Research question(s) &/or hypothesis if applicable
	+ Indicate if ECRMC will be the Primary Site or Sub-site to another organization
* **Protocol Description**
	+ Study Design and Study Phase
	+ IRB specify if the study will utilize Central or another organization IRB
	+ Sample
		- Target sample, including inclusion & exclusion criteria
		- Sampling method
	+ Recruitment and consent process and procedures
	+ Resources require i.e. Pharmacy, imaging, physical space
	+ Data Collection
		- Method
		- Instruments, with evidence of reliability and validity for each
		- Attach all study instruments
		- Timeline, include endpoints
* **Analysis Plan**
* **Budget**
	+ Attach proposed budget
	+ If no budget available, include disclosure of direct and indirect costs/ disbursements