**El Centro Regional Medical Center:**

**Multidisciplinary Research Council**

**Clinical Trial Project Proposal Requirements**

**Title Page:**

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

**Proposal**

* **Project Title**
* **Statement of Purpose and Background**
	+ **Concise description of the problem warranting the study and significance of the problem**
	+ **Benefit for ECRMC participation in Clinical trial**
	+ **Research question(s) &/or hypothesis if applicable**
	+ **Indicate if ECRMC will be Primary Site or Sub-site to another organization**
* **Protocol Description**
	+ **Study Design and Study Phase**
	+ **IRB specify if study will utilize Central or another organizations 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**
		- **Time line, include end points**
* **Analysis Plan**
* **Budget**
	+ **Attach proposed budget**
	+ **If no budget available, include disclosure of direct and indirect costs/ disbursements**