**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