**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**