

Protocol IRB # _____

Protocol:

Principal Investigator:

Only register study personnel that will be using CCC-UPR resources.

[illegible]

***All study personnel must present evidence of Human Subject Protection, HIPAA and GCP training.**

**** All study personnel that will perform any task at the CCC-UPR Laboratory must present evidence of Hepatitis B vaccine and Bio-safety training**

PI or Co PI signature _____

Date: _____

List of General Functions:

- a- Initial telephone evaluations (pre-screening)
- b- Initial patient evaluations (screening)
- c- Informed consent process (discussion, obtain signatures)
- d- Vital signs (can only be performed by a licensed physician or nurse)
- e- Physical exam and/or medical history (can only be performed by a licensed physician)
- f- Determine eligibility of participants
- g- Complete case report forms (CRFs)
- h- Receive and/or dispense study drugs and/ or study device
- i- Complete scales (psychological scales, nutritional scales, quality of life scales, etc.)
- j- Perform specific study procedures (ECGs, nutritional evaluation, densitometry, etc.)
- k- Process laboratory samples* (These procedures will be done under the supervision of the CCC Laboratory Manager. Only medical technologists, nurses or physicians are allowed to perform these procedures)
- l- Receive and/or evaluate laboratory results
- m- Data entry
- n- Interview/evaluate participants by telephone
- o- Other functions (please specify) 1. 2. 3.

* All study personnel that will perform any task in the CCC-UPR laboratory must present evidence of Hepatitis B vaccine, and Bio-safety training.