PROCEDURE FOR SETTING UP RESEARCH CLINICS

1. **OBJECTIVES:**
   a) Describe procedures to initiate a "Research Clinic" in the Computerized Patient Record System (CPRS) for a specific research project that is impacting a hospital service

   b) To comply with documentation requirements and distinguish research documentation versus standard of care and avoid billing to research participants for protocol specific test and procedures

2. **DEFINITION:**
   a) A "Research Clinic" is a "non-billable" computer location in VISTA/CPRS for:
      - Capturing workload for research encounters
      - Placing order for tests and procedures performed for research purposes

3. **RESPONSIBILITIES:**
   a) The Principal Investigator (PI) and/or designee is responsible for complying with documentation requirements

   b) The Clinical Studies Center (CSC) handles and oversees the initial process

   c) The PI or designee is responsible for inactivating a research clinic created to the protocols when the study ends

4. **PROCEDURES:**
   a) An individual "Research Clinic" location is needed for studies utilizing hospital ancillary services for tests/procedures above and beyond standard of care. For example: laboratory, radiology, Pulmonary Function Laboratory, Nuclear Medicine, etc.

   b) Individual research clinic locations are identified by the study name or acronym

   c) Emory IRB and R&D Committee approval is required prior to requesting a research location

   d) Staff will need access to VISTA/CPRS to use research clinics

   e) To initiate the process complete:
      - A Research Clinic Profile and Encounter Data Form online at http://www.atlaref.org/forms/vamc.cfm

   f) The name of any research clinic should always start with the word "ATL Research", and should be identified by the study name or acronym

   g) Once both request forms are completed send them to the CSC Director via email for review and approval

   h) Provide copies of IRB and R&D approval letters by email or fax to (404) 417-2902

   i) Staff will be notified when the research clinic has been set up

   j) Notify the CSC Director when all subjects' follow-up has been completed to inactivate the clinic