CPRS DOCUMENTATION REQUIREMENTS

1. **OBJECTIVE:** To document research encounters/visits when conducting human research studies

2. **RESPONSIBILITIES:** Investigators and their research staff are responsible for documenting encounters with research participants (Veterans & Non-Veterans) in the Computerized Patient Electronic Record (CPRS) system when study subjects are admitted to VA facilities, treated as out-patients at VA facilities, or when research procedures or interventions are used in the medical care of research subjects at a VA facility. This would include the use of any clinical resources (i.e. – radiology, clinical laboratory or pharmacy, etc.). It must also be documented in CPRS if the research intervention may lead to physical or psychological harm.

3. **PROCEDURES:**
   a) Research staff required to document research subject's encounters/visits should receive CPRS access and training.

   b) Research staff must utilize CPRS to document encounters/visits with research participants when clinical interventions are involved. In some cases, documentation can be completed outside CPRS. Please consult the RCO or Research Office if you have any questions.

   c) Research encounters/visits must be entered in CPRS within 72 hours.

   d) Research participants who have a medical record in CPRS and are having lab work (blood, urine, etc.) analyzed by the Atlanta VAMC Pathology laboratory, must have an order and request entered into CPRS. If the coordinator/nurse performs the phlebotomy or collects the sample and the test is performed outside the facility, then no order/request is entered into CPRS.

   e) CPRS documentation should be supported with appropriate procedural (CPT CODES) and diagnostic (ICD9) codes

   f) The clinic location called "Research Study" should be used to document encounters for studies <u>not</u> impacting hospital services

4. **DOCUMENTATION REQUIREMENTS FOR NON-VETERAN RESEARCH PARTICIPANTS:**

   a) If the non-veteran **<u>is not</u>** using a hospital service as part of the research study such as laboratory, radiology, nuclear medicine, etc. a separate paper chart must be created to document the consenting process and any other research encounters/visits (if applicable) and kept with study files.

   b) If the non-veteran is using a hospital service as part of the research study, then the non-veteran research participant must be entered into VISTA/CPRS so that research encounters/visits may be documented.

   c) To enter a non-veteran in the system, contact Yolanda Robinson at ext. 5862 and provide the following information:

I. Full name
II. Date of birth
III. Social security number (required)
IV. Date enrolled in the study

d) To enhance the non-veteran research participant's privacy the researcher has the option of entering the PI's contact information instead of the study subject's information into CPRS. However, the study staff should obtain the subject's contact information in the event they need to contact the subject.

e) The following information can be entered in the system with the subject's authorization:
- Address (including county)
- Telephone number
- Next of kin
- Religion