CPRS DOCUMENTATION REQUIREMENTS

1. OBJECTIVE: To document research visits when conducting human research studies and to describe when documentation is not permitted.

2. RESPONSIBILITIES: Investigators and their research staff are responsible for promptly documenting visits with research participants in the Computerized Patient Record System (CPRS) for each research encounter/visit.

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

   b) Research visits must be entered in CPRS within 72 hours. This includes person-to-person visits and research telephone visits. This does not include telephone calls re: appointments.

   c) If the research project has obtained a Certificate of Confidentiality (CoC), do not document a CPRS note for studies that do not involve a medical intervention. For studies that do involve a medical intervention, a progress note entry should indicate that an individual has been enrolled in a research study, any details that would affect the subject’s clinical care, and the name and contact information for the investigator conducting the study.

   d) The clinic location called “ATL Research-Study” should be used to document visits for studies not impacting hospital services. If the project does impact hospital services, a research clinic will need to be created. See “Procedure for Setting up Research Clinics in CPRS” located on the AVAMC research website and contact the Clinical Studies Center for assistance.

   e) A research note “template” should be used for documenting research visits. Please refer to the “Research Note Titles & Templates” list posted on the AVAMC research website.

   f) The consent process should be documented by the research staff member who obtained the research consent. A research consent template should be used. Please contact the Research Compliance Officer for situations when this is not feasible.

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

   h) All research notes should include the Principal Investigators name and phone number, study staff name and phone number, and a statement that a copy of the consent and HIPAA is available to VA providers upon request.

4. DOCUMENTATION REQUIREMENTS FOR NON-VETERAN RESEARCH PARTICIPANTS:

   a) If the non-veteran is not 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 visits 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 CPRS so that research encounters/visits may be documented.

c) To enter a non-veteran in the system, contact:
   • Yolanda Robinson ext. 5862
   • Eddie Cooper ext. 6378
   • Janice Van Buren ext. 6643
   • Rosalind Harris 6458
   • Shan Dulaney ext. 6457

   and provide the following information:

   • Full name
   • Date of birth
   • Social security number (required)
   • Date enrolled in the study

d) All non-veterans must receive the “VHA Notice of Privacy Practices (NOPP). Refer to the “Notice of Privacy Practices for Non-Veterans” policy located on the AVAMC research website.