Frequently Asked Questions for Conducting Research Studies within the STVHCS System

How do you capture workload and VERA reimbursement when involved in clinical research without triggering Veteran co-pay requirements?

Clinical stop codes (primary and secondary) can be utilized for clinical research visits. A Research Clinic should be established within CPRS and the title of the clinic should denote "Research". The clinic could be nonspecific for all studies i.e." **Department Name** Research Clinic" or it could be protocol specific i.e. "**Study Name** Research Clinic". This is something the Department and Investigators should decide.

The STVHCS Patient Account Department under Mr. Kristopher Vlosich (617-5300 ext. 1-5141) ensures that any clinic with the name "Research" in them is removed from patient billing. This department does appreciate a heads up to the clinic names so that they can watch for them. Ms. Norma Ferguson (694-6382) is also available to help with these types of questions.

Research VERA is captured based on research expenditures and is not tracked through documentation in CPRS. The above addresses capture the clinical VERA reimbursement for research visits.

Are there restrictions on where the Investigators can see research patients?

Veterans who are recruited from the STVHCS for research studies must be seen at the STVHCS unless a request for off-site procedures is approved by the Research and Development Committee. A request for off-site procedures memo to the R&D Committee would be included in the protocol submission to the R&D Office. Requests for off-site procedures are reviewed for overall liability and risk to the institution by the R&D Committee. All off-site procedures must be adequately justified (i.e. specialized equipment not available at the VA) and cannot be a matter of convenience.

If the clinical services are unable to accommodate research study visits within the clinic (i.e. visits are not associated with standard care and clinic volume does not allow for scheduling) the research visits can be scheduled and subjects seen in the Bartter Research Unit (BRU) on the 7th floor of the ALM hospital. Mary Moore, RN (617-5300 ext. 1-6218) is the BRU Nurse Manager and contact to discuss scheduling research visits on the BRU.

What documentation is required in the medical record and how is patient confidentiality protected during a research encounter?

From a Research stand point the following is required to be documented in the medical record for all research related visits:

- When a VA patient signs an informed consent document and is enrolled in a VA study, a research note must be entered using the "Research Enrollment/Consent Note" template located in CPRS. The "Research Enrollment/Consent Note" template must be used to flag the participant's medical record in CPRS. The note will be in the postings (CWAD- Crisis notes, Warning notes, Advanced Directives) indicating the patient is enrolled in a research study. When the IRB determines that flagging the medical record and scanning the informed

consent document would increase the subject's risk or compromise the study results, flagging the record and documentation in the subject's health record will be waived. The IRB approval letter must state the flagging requirement has been waived to protect the subject or study integrity.

- Any changes to the research protocol resulting in an addendum or updated informed consent document must be entered into the subject's health record. After a patient signs the addendum or update, a research study note must be entered using the "Research Consent/Update Note" template located in CPRS.

- Any research information, which has the potential to impact the medical care of the participant, must be entered into the medical record (CPRS). A "Research Progress Note" must be entered to provide the following relevant information to providers participating in the care of that patient:

    - Any research procedures or interventions that may impact a patient's clinical care, including the indications and potential risks of physical or psychological adverse events.
    - Any results, including laboratory studies, physical exam findings, or medical interventions, from the research that is relevant to the medical care of the participant.
    - Any information regarding possible drug interactions and/or toxicity of the pharmaceutical agents administered as part of the research protocol.
    - <u>All progress note titles are standardized to start with "Research".</u>
    - A research progress note is not required for the following:
        (1) Case report forms
        (2) Surveys
        (3) Questionnaires
        (4) One time visits AND no additional PHI is collected after the one time visit AND no information collected would benefit another provider
    - When a participant is dis-enrolled or terminated from a research protocol, a research study note must be entered using the "Research Disenrollment/Termination Note" template located in CPRS.

The note format utilized for the research progress notes and the protection of confidentiality of any diagnoses should follow standard clinical practice and professional judgment of the provider.

Additional information on research documentation can be found in the following SOP:
http://www.southtexas.va.gov/Research/Documents/42DocumentationPatientsHealthRecord.pdf