

South Texas Veterans Health Care System

**NURSING SERVICE MEMO 16-03**

14 October 2016

TO: All Nursing Personnel

FROM: Associate Director for Patient Care Services (Nurse Executive)

SUBJECT: Procedure for Licensed Nurses Assisting in Clinical and Other Research

1. **PURPOSE:** To establish a policy and to provide nursing personnel with information regarding the rights and responsibilities of nurses who assist in a research study.
2. **POLICY:** The licensed nurse (RN/LVN), as an employee of ALMD, STVHCS, is expected to perform procedures and collect data for the Institutional Review Board (IRB) and the Research & Development Committee (R&D) approved clinical research. Only the Registered Nurse employee of ALMD, STVHCS is allowed to administer investigational drugs.
3. **RESPONSIBILITY:**
  - a. Associate Director for Patient Care Services (Nurse Executive)/Designee is responsible for administering this policy and assessing all protocols for impact on nursing staff.
  - b. Nurse Managers are responsible for monitoring compliance, ensuring competency, and arranging in-services for nursing staff.
  - c. Principal Investigators are responsible for providing in-services for nursing staff prior to implementation of an approved protocol.
  - d. Principal Investigators are responsible for notifying the Union prior to implementation of any clinical research that impacts working conditions of bargaining unit employees (Master Agreement, 1997, Article 50).  
<http://www.southtexas.va.gov/Research/Documents/UnionApprovalInstructionSheet.pdf>
  - e. Nursing staff are responsible for compliance with this policy.
  - f. Nursing Service R&D representative is responsible for notifying the Associate Director for Patient Care Services (Nurse Executive)/Designee regarding upcoming research and the impact on clinic nursing.
4. **PROCEDURES:**
  - a. The RN/LVN who assists with clinical research is responsible for:
    - (1) Verifying informed consent
    - (2) Knowing activities involved in research study procedures
    - (3) Knowing potential risks to participant and nurse
    - (4) Knowing what interventions might be necessary to treat potential adverse effects
    - (5) Verifying that investigational drug has been ordered by physician investigator and dispensed by pharmacy (RN only)

- b. Nursing staff participation, beyond routine duties, in clinical research must be negotiated in advance with Associate Director for Patient Care Services and scheduled through the Nurse Manager.
  
- c. Licensed nurses have a professional responsibility to refuse to participate in investigations, which raise serious ethical or clinical concerns. Such concerns must be discussed with Nurse Manager and/or Nurse Officer on Duty/ACNS, and can be brought to the attention of the Ethics Advisory Committee and/or Research and Development Service.

5. **RESCISSION:** Nursing Service Memo 11-03, ALMD, dated. June 13, 2011

6. **RECERTIFICATION:** 2021

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(Nurse Executive)