SENTARA

Policy:	Nursing Research		
Division:	Sentara Healthcare	**Original Date:**	May 2014
Manual:	Nursing	**Review/Revision Date:**	November 16, 2020
Section:	General Nursing	**Approved By:**	Sentara Policy and Procedure Committee
Location(s):	SCH, SLH, SMJH, SRMH, SNGH, SOH, SVBGH, SPAH, SWRMC, SNVMC, SMG, SLC, SCOHS, SAMC, SHRH	**Owner:**	Sentara Research Collaborative

Revision Description (Most Recent): Reviewed & updated template

Policy Statement/ Purpose:

Define the structures and processes for obtaining approval to conduct nursing research at Sentara Healthcare.

Philosophy:

To create an environment in which the advancement of the profession of nursing through scholarly inquiry is developed and supported. This is accomplished through a structured process where members of our nursing staff can participate in nursing research. Such an approach is essential in developing new knowledge that allows nurses to evaluate current practices and future developments to the achievement of optimal patient outcomes.

Vision:

Nurses at all levels of practice at Sentara will participate in the integration of evidence-based practice and will provide support to those nurses who are conducting research; both of which moves the organization towards achieving excellence in patient care outcomes and professional nursing practice.

Guidelines for Sentara Nurses:

Research conducted by Sentara nurses must go through a scientific review and approval process by the divisional Nursing Research entity or Sentara Quality Research Institute (if there is no formalized divisional research entity), and a Human Subjects Review by the Institutional Review Board (IRB).

Scientific Review:

A. Nurse Investigator(s) will meet with their divisional Nursing Research entity. In the absence of a formalized divisional nursing research entity, the Nurse Investigator(s) will meet with a representative from the Sentara Quality Research Institute.
    a. Under the direction of the divisional Nursing Research Forum, the investigator(s) will draft a research plan, which may include the following:
        i. Identify area of interest (problem).
        ii. Validate the significance to Sentara Nursing strategic plan, goals, priorities, or focuses.
        iii. Develop the research question.
        iv. Complete a literature review to establish the significance of study problem and the state of the science (what is known/what is not known).
        v. Develop the research plan including: methodology; population, sample selection and size; instrument(s) for data collection; key individual(s) that are required to complete research plan (e.g. contact person for data abstraction); and the research procedure needed to answer the research question.
        vi. Establish research budget to submit for funding.
        vii. Projected plan for analysis and interpretation of data.

viii. Develop consent forms (if appropriate), data collection instruments, questionnaires, and cover letters where appropriate.
ix. Identify key individual(s) that are required to complete research plan (e.g. contact person for data abstraction).
x. Establish necessary equipment required for study.
xi. Establish a time frame for study.
xii. Write the proposal for the IRB.
xiii. Develop a plan for disseminating results

B. The research plan will be evaluated by the Chief Nurse Executive based on the following criteria:
   a. Relevance to Sentara Strategic Plan.
   b. Adequacy of research plan.
   c. Plan for dissemination of results within and outside of Sentara.

C. The review of the research plan by the Chief Nurse Executive will result in one of the following:
   a. Full approval; research application ready to be sent to the IRB.
   b. Approval pending revisions; after which, the research application may be sent to the IRB.

D. Following approval by the Chief Nurse Executive, the research application will be submitted to the IRB.
   a. Sentara nursing research projects will only be sent to the IRB approval boards with an RN member who sits on the board.
   b. All Sentara nursing research projects require a nurse IRB board member to vote on the approval of their research projects.
   c. Upon approval by the IRB, the Nurse Investigator must inform the Nurse Executive.
   d. Data collection can begin once IRB approval has been obtained.

Exceptions: None.

Monitoring:

Document Management – The Nurse Executive Council shall be responsible for developing, communicating, and maintaining this policy and related procedures and job aids necessary for the implementation and continuance of the policy. This policy shall be reviewed at least every three years for repeal or amendment as appropriate.

SENTARA NURSING RESEARCH

This guidance document applies only to submissions where a nurse employed by Sentara Healthcare wishes to have a nursing research project involving human subjects approved by the EVMS IRB.

Membership of the IRB

The membership of the EVMS IRBs historically has included and will continue to include nurses of varying backgrounds. These nurses may be from several local institutions. Nurse members have full voting privileges, the same as all other appointed members of the Boards. The membership will include an alternate member for each nurse to ensure availability for meetings.

Review by the IRB

Protocols submitted to the EVMS IRB where a nurse employed by Sentara Healthcare is the principal investigator will be reviewed by an EVMS IRB that has a nurse included as part of the membership. Review level is determined by the level of risk and types of procedures involved in the study. Studies may be reviewed by a sub-committee of the Board or by a convened Board.

If the protocol requires convened Board review the nurse, who is a voting member, will be present for the discussion and vote.

If the protocol qualifies for exempt or expedited review based on the regulations the study will be reviewed by the sub-committee of one of the EVMS IRBs. The nurse will be present for the discussion and may comment on the outcome of the review.

In either case, the nurse member may not have a conflict as defined by the EVMS IRB SOPS. If so, the alternate nurse member will be present and have the same privileges as the primary member.

Documentation

The minutes of convened IRB meetings are confidential as the EVMS IRBs serve multiple institutions. However, copies of redacted minutes will be made available as needed to demonstrate that the IRB reviews are consistent with this document.

Related Documents:

Procedures/Job Aids	Sentara Hospitals, Clinical Investigational Protocol Submission Hospital Administration Review Responsibilities Checklist; EVMS Institutional Review Board – Sentara Nursing Research (attached); Guidelines for Preparing and Disseminating Scholarly Work – Procedure
Regulatory References	