CAPE FEAR VALLEY HEALTH SYSTEM
Policy – Procedure

Title: Resident/Allied Health Research Review Subcommittee – Scope and Operational Guidelines	**Current Effective Date:**

Purpose: To outline the scope and operational guidelines of the Cape Fear Valley Health (CFVH) Resident/Allied Health Research Review (RAHRR) Subcommittee.

Audience: All Staff, Physicians, Allied Health Staff, Residents, Nursing, Clinical Students

Departments: All Hospital Departments, Medical Staff/AHP Staff

Keywords: Research, Case Study, QI Project, IRB, Institutional Review Board, Resident, Student

Definitions: N/A

Policy: The CFVH RAHRR Subcommittee (Subcommittee) will function as a subcommittee of the CFVH Institutional Review Board (IRB). The Subcommittee is authorized by the CFVH IRB to make a final determination regarding whether a proposal submitted by residents, medical students, allied health students, nursing students submitted with an initial assessment of exempt research meets exemption criteria (Category I – Non-research or Category II - exempt research).

Procedural Guidelines:

1. **Scope**
    a. The Subcommittee is authorized by the CFV IRB to review proposals submitted by residents, allied health students, nursing students and medical students in conjunction with federal guidelines for the purpose of determining that the submission falls into one of the following categories:
        i. Category I: Non-Research - does not meet the definition of human subject research – IRB oversight is not required (e.g., QI project, single case review); or
        ii. Category II: Exempt research (exemption category to be identified) – IRB oversight is not required; or
        iii. Category III: Non-exempt research - full IRB review required.
    b. Category I/Category II Determination - If the Subcommittee makes a unanimous decision regarding Category I/Category II assignment, notice of the decision (authorized determination that IRB oversight is not required) will be issued to the individual submitting the proposal. (NOTE: Notice of Category II determination should identify the relevant exemption category). A summary of the proposal(s) and determination will be provided to the IRB for informational purposes in a timely manner.
    c. Category III Determination – If the Subcommittee makes a Category III determination, additional documentation as necessary to support an application to the full IRB will be requested from the individual submitting the proposal and all relevant documentation will be submitted to the full IRB for review in accordance with usual processes.

d. Lack of Unanimous Decision - If the members of the Subcommittee present (or in the event of electronic communication, those responding) at a meeting at which a quorum has been established are unable to reach a unanimous decision regarding Category assignment, the proposal and relevant documentation will be forwarded to the full IRB for review and recommendation.

2. **Additional Functions:**
   a. Develop policies and templates to assist residents/students in developing quality submissions/proposals;
   b. Help establish a culture of learning regarding clinical research by providing education to residents/students/faculty regarding the overall research process, the role/function of the full IRB and the role/function of the Subcommittee.
   c. When appropriate, provide constructive feedback to residents/students regarding project submissions.

3. **Membership**:
   a. The Subcommittee will be composed of at least four members representing various disciplines to include: CFV IRB; GME Program; Nursing Research; Allied Health staff.
   b. Members are subject to the approval of the CFV IRB;
   c. The Chairman will be elected by the members of the Subcommittee;
   d. Members are expected to participate in relevant research education on an initial and ongoing basis;

4. **Meetings**
   a. The Subcommittee shall meet as necessary to fulfill its responsibilities.
   b. A quorum of the Subcommittee shall be 50% of its members.

5. Process for Review:
   a. Generally, submissions for review should be received in the Medical Staff Office at least two weeks prior to the next scheduled meeting of the Subcommittee.
   b. Upon receipt, the proposal will be forwarded to one member of the Subcommittee for preliminary review. The preliminary reviewer will be selected on a rotational basis.
   c. The preliminary reviewer will utilize the Reviewer Checklist to evaluate the content of the proposal.
      1. If the submission content is NOT acceptable, preliminary reviewer will return the proposal to the PI for revision/resubmission with appropriate comments/guidance to help facilitate revision. The PI will resubmit updated draft to preliminary reviewer for further evaluation; the preliminary reviewer will continue to work with PI in preparing an acceptable submission.
      2. If the submission IS acceptable, the preliminary reviewer will forward the Reviewer Checklist and a copy of the proposal to the Medical Staff Office for distribution to the IRB Subcommittee members.
   d. The final submission will be reviewed by the IRB Subcommittee at its next meeting.
   e. The PI will be informed of the scheduled meeting date and invited to attend to present their proposal/respond to questions as determined appropriate by the Subcommittee Chair.
   f. If the members present at the Subcommittee meeting reach a unanimous decision, the decision of the Subcommittee will be final and will be communicated to the PI and a summary of the proposal forwarded to the next meeting of the full IRB.

g. If the members present at the Subcommittee meeting are unable to reach a unanimous decision, the PI will be informed and the proposal will be forwarded to the full IRB for consideration at its next meeting. The PI may be invited to attend to present their proposal/respond to questions as determined appropriate by the IRB Chair.

Related Documents/Policies: N/A

References: N/A

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Approved by IRB: 7/19/18