

CAPE FEAR VALLEY HEALTH SYSTEM

Policy – Procedure

Title: Resident/Student Research	Current Effective Date:
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Purpose: To outline the process for review of research submitted by residents and students.

Audience: All Staff, Physicians, Allied Health Staff, Residents, Nurses, Students

Departments: All Hospital Departments, Medical/AHP Staff

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

Definitions:

1. Human Subject Research – A systematic investigation designed to contribute to generalizable knowledge that involves a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information.
2. Quality Improvement Project – An activity involving the inclusion of people that is intended to evaluate an existing practice and attempt to improve it based upon existing knowledge; the data from the evaluation is not intended to be applied to a larger population beyond the site of data collection or population studied.
3. Case Study/Limited Case Series - a detailed examination of an event (case study) or series of events (no more than three case studies).
4. Exempt Research – An activity meeting the definition of human subject research **AND** falling within one of the exemption categories as set forth by federal regulations.
5. Non-Exempt Research – An activity meeting the definition of human subject research that does **NOT** fall within one of the exemption categories as set forth by the federal regulations.

Policy: Residents and students desiring to participate in research activities at CFVH will submit proposed research to the IRB Subcommittee in accordance with the following guidelines.

Procedural Guidelines:

1. The Resident/Student, in conjunction with faculty sponsor, will evaluate the proposed study and make a preliminary determination as to the type of study being submitted. Options include:
 - a. Quality Improvement Project: See Appendix A for further information/submission detail.
 - b. Case Study/Limited Case Series: See Appendix B for further information/submission detail.
 - c. Exempt Research (indicate specific category below): See Appendix C for further information, list of exemption criteria and submission detail.
 - i. Retrospective Review
 - ii. Case Series (greater than three case studies)
 - iii. Educational Survey

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- d. Non-Exempt Research: See Appendix D for further information and submission detail.
2. The Resident/Student will complete a Project Approval Request Form (copy attached).
3. The Resident/Student will complete required documentation as identified in the relevant appendix based on preliminary determination of project type. Following review and approval of documentation by the associated faculty member, Project Approval Request Form and relevant documentation is to be submitted to the Medical Staff Office.
4. The Resident/Student may be asked to attend a meeting of the IRB Subcommittee and/or the full IRB to present/discuss their proposal.

Related Documents/Policies: N/A

References: N/A

Approved by IRB: 7/19/2018



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RESIDENT/STUDENT PROJECT APPROVAL REQUEST

NOTE TO PI: Any publication related to this study will require approval by Hospital Legal Services prior to publication. Please contact Legal Services at extension 5937 for additional information.

Completed form and a summary of the proposed research should be returned to the CFV Medical Staff Office: (fax) 910-615-5959; (e-mail) fgrimes@capefearvalley.com. For questions please contact the Medical Staff Office at the previously noted e-mail or by phone at (910-615-5813)

Proposal Title: _____

Your Name: _____ Date: _____

Contact Information: E-mail _____/Phone _____

University/Residency Program Affiliation: _____

Name/Contact Information for Faculty Advisor/Attending Responsible for Oversight of Project:

Name: _____ E-Mail _____/Phone _____

Preliminary Determination:

In compliance with policy titled “Resident/Student Research” I have made the following preliminary determination regarding the type of project being submitted:

- ___ Quality Improvement Project – Documentation as required in Appendix A is attached.
- ___ Case Study/Limited Case Series – Documentation as required in Appendix B is attached
- ___ Exempt Research (indicate specific category below) –Documentation as required in Appendix C is attached
 - ___ Retrospective Review (collection and analysis of existing medical record information; ordinarily seek to evaluate relationships between one or more biomedical, treatment, and/or demographic variables and one or more outcome measures in patients.)
 - ___ Case Series (greater than three case studies; a case study is a detailed examination of an event)
 - ___ Educational Survey – (includes evaluation of teaching sessions, curricula, courses, programs, simulations and surveys)
- ___ Non-Exempt Research – Documentation as required in Appendix D is attached

RESIDENT/STUDENT SIGNATURE

DATE

FACULTY STATEMENT: I confirm that I have reviewed this project proposal and approve for submission to the CFVHS IRB Subcommittee:

Faculty Member Signature

Date

Date Proposal Forwarded to IRB Subcommittee: _____