CAPE FEAR VALLEY HEALTH SYSTEM
Policy – Procedure

Resident/Student Research
APPENDIX D
Non-Exempt Research

SUBMISSION CHECKLIST:

Prior to submitting request please ensure the following are included:

____ **Completed Resident/Student Project Approval Request form (attached)**

____ **Project Description including all elements identified in the "Non-Exempt Research Template" (attached)**

____ **Completed Research Review Summary Form (attached)**

____ **Patient consent (if applicable) including all elements identified in the "Informed Consent Template Checklist" (attached).**

_____ **Documentation of current education for each investigator and protocol coordinator (One option for meeting this requirement is completion of Good Clinical Practice web-based training course (all modules) https://gcp.nidatraining.org).**

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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 via e-mail to Lenelle Davis at ldavis@capefearvalley.com. For questions please contact Lenelle Davis at the noted e-mail address.

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 _____

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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:

_____ _____
Faculty Member Signature Date

****

Date Proposal Forwarded to IRB: _____

CAPE FEAR VALLEY HEALTH SYSTEM
Policy – Procedure

Resident/Student Research
APPENDIX D
Non-Exempt Research Template

GUIDELINES:

Projects that are thought to meet the definition of human subject research that do NOT qualify for exemption based on established exemption categories as identified by 45 CFR 46. 104(d) are to be submitted to the CFV IRB for an authoritative determination of their status by using the "Project Approval Request Form". As a result of this review, the submission will be declared to be exempt from further IRB review, or determined to be a research study involving humans that is subject to further IRB review. **(NOTE: If project is determined to require full IRB review, you will be notified and additional paperwork/documentation may be required for full IRB review).**

A completed Research Review Summary should be submitted with the Project Approval Request Form. The Research Review Summary should include a detailed summary of the proposed research including the following elements:

Project Title

Project Aims

Project Methods

Data Collection Plan

Timeline

Evaluation Plan

Protected Health Information

Privacy, Data Storage & Confidentiality

Patient Consent (Is patient consent required? If no, indicate N/A. If yes, attach proposed patient consent prepared utilizing attached Consent Form Checklist to ensure all required elements are addressed).

Signature and Date of Submission:

CAPE FEAR VALLEY HEALTH SYSTEM
RESEARCH REVIEW SUMMARY

TITLE OF PROPOSAL/ACTIVITY: _____

PRINCIPAL INVESTIGATOR: _____ **CO-INVESTIGATOR(S):** _____

WHICH OF THE FOLLOWING ARE INVOLVED IN THIS STUDY:	**YES**	**NO**
Experimental devices, instruments, machines	___	___
Experimental procedures	___	___
Drugs under investigation	___	___
If yes, list name, manufacturer and drug study phase (I, II, III) _____		
Placebo(s)	___	___
Approved drugs for Non-FDA approved indications	___	___
Protocol approved at collaborating institution	___	___
If yes, name of institution: _____		
Patients as investigational subjects	___	___
Patients as control subjects	___	___
Pregnant subjects	___	___
Minors (less than 18 years)	___	___
Mentally incompetent subjects	___	___

DOES THIS RESEARCH PROPOSAL FALL INTO AN EXEMPT/NON-EXEMPT CATEGORY?

___ Exempt (see attached list of exemption categories) Exemption category _____
___ Non-exempt

IN THE JUDGMENT OF THE PRINCIPAL INVESTIGATOR, RESEARCH SUBJECTS WILL BE PLACED:

___ At no risk
___ At no more than minimal risk (NOTE: Minimal risk is defined as the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
___ At more than minimal risk

Specify and quantitate each risk; describe steps taken to minimize recognizable risks: _____
_____

The potential or anticipated benefits of this activity to the subjects or to mankind in general outweigh any recognized risks.
This opinion is justified by the following reason(s): _____
_____

POTENTIAL CONFLICT OF INTEREST

The following questions apply to any investigators or study staff involved with research, and/or their immediate family members (spouse, dependent children, others) and is inclusive of any business interest with which the investigator/study staff may be affiliated . Within the past 12 months or the next 12 months, have your or will you:

Receive any form of compensation from the Sponsor, including salary, consulting fees, honoraria, royalties, equipment, etc?	___ Yes	___ No
If so, does or will that compensation exceed $10,000	___ Yes	___ No
Have an ownership interest of any nature in the Sponsor or product under study, including equity, stock options, etc.?	___ Yes	___ No
If so, does or will that interest exceed $10,000 in value?	___ Yes	___ No
If so, does that interest represent more than 5% ownership in the Sponsor?	___ Yes	___ No
Hold any position with the Sponsor, including officer, director, trustee consultant, member of advisory board, etc.?	___ Yes	___ No
Have an intellectual property interest on any technology or invention Used in this study, including patient rights, copyright, etc.?	___ Yes	___ No

If the answer is "yes" to any of the questions above, please include an explanation with this summary. As with any changes to the research itself, relationships or interests that develop later should be brought to the IRB's attention for further consideration.

WILL ANY SUBJECT INCUR ADDITIONAL PERSONAL EXPENSE (HOSPITAL CHARGES, ETC.)? AS THE RESULT OF PARTICIPATING IN THIS PROTOCOL? ___ Yes ___ No

If yes, please define: _____

WILL STUDIES BE DONE ON PATIENTS OF ATTNEDING PHYSICIANS OTHER THAN INVESTIGATORS LISTED ON THE PROPOSAL? ___ Yes ___ No

If yes, please attach a statement signed by those attending physicians confirming they have consented to the involvement Of their patients (if the patient consents).

HOW WILL CONFIDENTIALITY BE MAINTAINED? _____

HOW WILL INFORMED CONSENT BE OBTAINED (written/oral)? **DESCRIBE PROCESS** (by whom, one or more meetings, third party consent, etc.): _____
_____

ATTACH A BRIEF SUMMARY OF PROPOSAL: This summary will be read by all committee members, including those who are "non-medical". It must be written using language they can understand. The summary should be succinct (100-400 words). Include: purpose of study; number, age and sex of subjects; duration; compensation; research methods; benefits; and risk. **DO NOT WRITE "SEE PROTOCOL".** You must attach a well-written summary.

DOES THIS STUDY REQUIRE A CONTRACT WITH CFVHS? ___ Yes ___ No

If yes, has the contract been finalized ___ Yes ___ No

NOTE: If contract is required, IRB approval is contingent upon fully executed contract.

_____ _____

SIGNATURE, PRINCIPAL INVESTIGATOR DATE

CAPE FEAR VALLEY HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD
INFORMED CONSENT TEMPLATE CHECKLIST

Does the first page of the consent contain the required "concise summary" ___ Yes ___ No

YES	NO	N/A		
____	___	_____	1.	Can the entire consent form be understood by a lay person? (Try it out on your spouse, parents, or lay neighbors!)
____	___	_____	2.	Does the consent form heading include the word research? The word "research" must be in the consent form heading on each page.
____	___	_____	3.	Is there a statement indicating why the subject is being asked to take part in the study?
____	___	_____	4.	Is there a statement to indicate the purpose and why the study is being done?
____	___	_____	5.	Does the consent form indicate the study Phase and if so is there an explanation given to indicate what each phase entails? Ex. Phase 2, find out what effects (good and bad) ____ has on you and your type of cancer.
____	___	_____	6.	Is there and indication or statement as to how many people will take part in the study? If approximate, then the consent form should state, about _____ people will take part in this study.
____	___	_____	7.	Does the consent form clearly state what is involved in the study and for randomized studies is there an explanation of "randomization?"
____	___	_____	8.	Is the length of the study participation clearly stated?
____	___	_____	9.	Does the consent form identify the risks and benefits of study participation?
____	___	_____	10.	Are other options/alternatives to study participation identified?
____	___	_____	11.	Does the consent form indicate how confidentiality of participants is to be maintained?
____	___	_____	12.	Are study costs clearly identified and compared to what would be the usual costs if the participant was not a part of the study
____	___	_____	13.	Is there a statement to indicate that the participants insurance may or may not pay for some costs associated with the study and who is responsible for costs of travel, hospitalization, procedures, and tests?
____	___	_____	14.	Does the consent form address participant rights regarding new information that may affect the participants health, wealth, or willingness to remain in the study?
____	___	_____	15.	Is there a statement that study participation is voluntary and the participant may withdraw without jeopardizing continued care?
____	___	_____	16.	Is there a statement indicating that the participants study records may be reviewed and or monitored by internal and external sources, i.e., National Cancer Institute, Food and Drug Administration?.
____	___	_____	17.	Does the consent form indicate whom the participant is to call for problems or questions?
____	___	_____	18.	Does the consent form identify where the participant can receive more information about their diagnosis and rights as a research participant?
____	___	_____	19.	Is there a statement to indicate if the participant will or will not receive compensation for participation, if compensation is to be received are the amounts clearly stated and from whom the participant will receive the compensation and when ?

YES	NO	N/A	
____	___	_____	20. Are issues of reproduction and the use of contraceptive devices addressed for both men and women?
____	___	_____	21. If the study involves a period of time (days—weeks), the consent form must indicate the need for contraceptive measures in sexually active women and men "If sexually active, I will take contraceptive measures for the duration of the research." (or other similar language as determined appropriate by the IRB)
____	___	_____	22. Is there a statement to indicate continued availability of therapy after completion of the study?
____	___	_____	23. Does the consent form address under what circumstances the study participant's participation may be terminated?
			24. Does the consent form address the issue of hospital/research compensation?
			25. If applicable, does the consent form contain the following statement "A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by US law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

PLEASE NOTE THE FOLLOWING

All consent forms must list the principal investigator and any associates
Each page must have an appropriate title, consent form number, pagination (1 of 3 etc.), space for the participant's medical record number, and initials. The word research must be in the title of each consent form (all pages).

At the end of the consent form space must be provided for the date and signature of the participant/subject (parent and minors) or legal guardian, signature of individual who obtains consent, (should be investigator or co-investigator) and the person witnessing the signing of the consent form.

When a consent form has been modified all previous forms must be discarded.

NOTE: AFTER A CONSENT FORM HAS BEEN MODIFIED, ALL PREVIOUS FORMS MUST BE DISCARDED.