CAPE FEAR VALLEY HEALTH SYSTEM
Policy – Procedure

Resident/Student Research
APPENDIX C
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 "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 research 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).**

CAPE FEAR VALLEY HEALTH SYSTEM
Policy – Procedure

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 _____

****

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: _____

Resident/Student Research
APPENDIX C
Exempt Research Template

GUIDELINES:

Projects that are thought to meet the definition of human subject research but 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.

A completed Research Review Summary should be submitted with the Project Approval Request Form. The Research Review Summary should clearly identify the applicable Exemption Category (see attached) and should include a detailed summary of the proposed research including the following elements:

Project Title

Project Type (Retrospective Review; Case Series; Educational Survey)

Exemption Category (See attached list of exemption categories)

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

EXEMPTION CRITERIA
(Updated to Reflect 2018 Changes to the Common Rule)

CATEGORY I

Research, conducted in established o commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

CATEGORY II

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by *.111(a)(7).

CATEGORY III

i. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

   a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

   b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

   c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by *.111(1)(7).

ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria re met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

CATEGORY IV

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

CATEGORY V

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act as amended.

i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects
ii. Reserved.

CATEGORY VI

Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

CATEGORY VII

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determination required by **111(a)(8)

CATEGORY VII

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with .116(a)(1) through (4), (1)(6), and (d);
ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with .117;
iii. An IRB conducts a limited IRB review and makes the determination required by .111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

*.111(a)(7). - When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Revised 4/4/2018

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? <u>The word "research" must be in the consent form heading on each page.</u>
____	___	_____	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.