**Purpose:** This application is designed to facilitate the Institutional Review Board (IRB) review of proposed human subjects research. Some categories of minimal risk research qualify for **exemption** from the federal regulations and do not require additional oversight by the IRB or may only require limited IRB oversight; however, these projects do require review by the IRB to determine their eligibility and the degree of IRB oversight.

An **Exempt Determination** from the IRB is required to conduct exempt human subject research at CFVHS. Use this form to request an exempt determination from the IRB,

**No human subject research activities may occur until and Exempt Determination is issued.**

**Instructions:**

* **Initial Requests:** Complete this form only after you have determined that your research may qualify for exemption under one of the exempt categories. Please see the IRB website for detailed information regarding Exempt Research.
* **Amendment Requests:** To amend research previously determined to be exempt, complete this form only after you have assessed that your protocol may still qualify for exemption. Provide responses according to the amended research plans. If your project is no longer eligible for exemption, stop and prepare a New Protocol (Non-Exempt) Application Form.

**Complete this form and email to the IRB Office at** **irb@capefearvalley.com** **or** **sleming@capefearvalley.com** **if emailing from an external site. Attach all applicable protocol support documents as prompted throughout this application.**

Please note:

* Remember this form and supporting documents should be written in lay terms and define specific terms prior to using initials. Double check your submission for completeness and accuracy prior to submitting. Use the ***IRB Research Plan Guidance*** document and template when completing your **Research Plan**.
* Incomplete applications will be placed **ON HOLD**. It will not be processed until all required documents have been. Double check and ensure that **all** document fields have been completed prior to submitting to the IRB
* This application should be accompanied by a **Research Plan**. The CFVHS IRB will not defer Exempt review to another IRB.
* This form guides you to submit many other documents/forms which can be found on the IRB website. **Use the Checklist at the end of this document to ensure your application is complete.**
* **All** project personnel must have completed human subjects research protection training and received certification, **prior** to IRB review.
* Save this form before proceeding so your work will not be lost.
* This form must be submitted in its original format, MS Word format. The IRB will not accept this form in pdf or google docs format.

Direct any questions regarding this form or human subjects research to the IRB Office by email or phone (910) 615-5839.

The IRB will review and verify the exempt determination. If the IRB determines the project does not qualify for exemption, you will need to prepare and submit a protocol using the New Protocol (Non-Exempt) Application Form.

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| **Submission Date:** Click or tap to enter a date. |

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| **Section 1: Project and investigator Information*** The IRB allows one investigator to be named the Principal Investigator. Other investigator may be considered Co-Investigators.
* The Principal Investigator must be the CFVHS Faculty Advisor or Attending responsible for the Resident/Student.
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| Project Title: *Title* |
| Principal Investigator (PI)(Faculty Advisor or Attending Responsible, if applicable): | Enter Name |
| Rank/Title: | Rank/Title. | Institution/Department: | Institution/Department |
| Role/responsibilities in this project: | Click or tap here to enter text. |
| Preferred Phone Number: | XX-XXX-XXXX | Institutional Email | Click or tap here to enter text. |
| Medical Student/Resident: (if applicable) | Enter Name | Program Year | enter text. |
| University/Residency Program Affiliation: | Click or tap here to enter text. |
| Phone Number: | XX-XXX-XXXX | Email: | Click or tap here to enter text. |
| Clinical Site, if applicable: | Click or tap here to enter text. | Letter of Support attached: | [ ]  Yes [ ]  No [ ]  NA |
| Anticipated Start Date: | Click or tap to enter a date. | Estimated End Date: | Click or tap to enter a date. |

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| **Section 2: Research Requests** |
| 1. **Exemption Verification Request (select one of the following):**
 |
| [ ]  **INITIAL REVIEW REQUEST** |
| [ ]  **AMENDMENT REVIEW REQUEST** |
| * **Is the project end date changing?**
 |
| [ ]  Yes [ ]  No | Revised End Date (month & year): | Click or tap to enter a date. |
| * *For amendment requests, provide responses in the remainder of this form according to the amended research plans.*
 |

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| **Section 3: Screenings** |
| * Complete this section to identify project characteristics that do not qualify for exemption.
 |
| 1. **Below are specific characteristics that disqualify a project for exemption. Answer the following:**
 |
| [ ]  Yes [ ]  No | 1. Does this research involve the use of any drug, substances, or biologics?
 |
| [ ]  Yes [ ]  No | 1. Does this research involve the use of an investigational medical device?
 |
| [ ]  Yes [ ]  No | 1. Does this research involve the use of any ionizing radiation (X-ray, DEXA scan, etc.)?
 |
| [ ]  Yes [ ]  No | 1. Does this reserach involve the use of genetic information and/or tests?
 |
| [ ]  Yes [ ]  No | 1. Does this research proposed to study prisoners as a targeted population?

Note: If a participant becomes a prisoner, the project will no longer qualify for exemption. |
| 1. **In some circumstances, projects otherwise qualified for exemption must undergo expedited or full board review by the IRB. These are typically due to additional, project specific circumstances. Answer the following to determine if your project is otherwise ineligible for exemption:**
 |
| [ ]  Yes [ ]  No | 1. Is there a state, federal or other applicable law (e.g., tribal, or other international law) that prohibits an exemption determination?
 |
| [ ]  Yes [ ]  No | 1. Does the agency funding your research or an agency with whom you are working prohibit an exemption determination and require that you have IRB approval?
 |
| [ ]  Yes [ ]  No | 1. Any other project specific requirements that prohibit exemptions (e.g., sponsor’s requirements)?
 |
| * *If you answered “yes” to any of the questions above, stop completing this form and proceed with preparing a New Protocol (Non-Exempt) Application Form.*
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| **Section 4: Exempt Category (ies) (§ \_104)*** Select one or more of the categories below that appear to be applicable to your research.
 |
| [ ]  **EXEMPT CATEGORY 1:**Research, conducted in established or 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:• This research is about education and educational interventions such as educational outcomes (such as scores and grades) and classroom observations.• Research certified as exempt under this category may still be subject to FERPA regulations. |
| Provide the following information below, as applicable: * Submit documentation of the school/organization permission
* If recruitment/enrollment of PI’s own students, provide the plan for ensuring that the PI will not know which students are participating (e.g., having a co-investigator obtain consent, etc.)

If the project will take place during regular class/school time, describe the plan for the students who do not want to participate and for ensuring that the research activities are not a significant deviation in time or effort from regular school/organization activities[ ]  Not applicable[ ]  Applicable: Click or tap here to enter text. |
| [ ]  **EXEMPT CATEGORY 2:**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;**Note: Research activities involving children under this criterion are those involving education tests, or observation of public behavior where the investigators do not participate in the activity being observed.**[ ]  (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**Note: Research activities involving children under this criterion are those involving education tests, or observation of public behavior where the investigators do not participate in the activity being observed.**[ ] (iii) If the identifiable data is sensitive in nature and 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 45 CFR 46.111(a)(7).**Note: Research activities under this criterion does not apply to research with children.**  |
| [ ]  **EXEMPT CATEGORY 3:**1. 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) If the identifiable data is sensitive in nature and 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 45 CFR 46.111(a)(7).1. Benign behavioral interventions are brief in duration, harmless, painless, and not physically invasive, not likely to have a significant adverse lasting impact on subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples include playing an online game, solving puzzles under various conditions.
2. The research involves deception. If yes, and 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 (this is not the same as requiring an informed consent process and documentation of consent) 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 purpose of the research.
 |
| [ ]  **EXEMPT CATEGORY 4:*** *If your project only includes Category 4 activities, you may use the* ***IRB Exempt Category 4 – Secondary Research of Identifiable Information/Biospecimens Application Form****.*

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;**Note: If access to medical records (identifiable PHI) is required, complete and submit Appendix A: HIPAA and Use of PHI.**[ ]  (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 (HIPAA regulations), 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** **Note: If access to medical records (identifiable PHI) is required, complete and submit Appendix A: HIPAA and Use of PHI.**[ ]  (iv)The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research 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.**Note:** See ***De-Identified Materials Agreement Template*** to determine if this is required with your submission. |
| [ ]  **EXEMPT CATEGORY 5:**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.• Each federal department or agency conducting or supporting the research and demonstration project must establish, on a publicly accessible federal website 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. |
| [ ]  **EXEMPT CATEGORY 6:**Taste and food quality evaluation and consumer acceptance studies, provided that at least one of the conditions below is met:[ ]  Are wholesome foods without additives consumed?[ ]  Does the food to be consumed contain 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? |
| * *If you were unable to identify an applicable exemption category, your project does not qualify for exemption, stop completing this form and proceed with preparing a New Protocol (Non-Exempt) Application Form.*
 |
| **Section 5: Location of Research*** List each location where the research will take place.
* If “other external site” such as non-CFVHS facilities or entities such as schools, factories, offices, etc. are used the researcher has an obligation to ensure that the outside entity is aware of the proposed research project and has no objections (e.g., agrees to participate). To respect the rights of entities, research to conducted at these locations **may** require a letter from an authorized representative to be submitted to the IRB. Please include all **letters of support** with your submission.
 |
| [ ]  Cape Fear Valley Medical Center | [ ]  Harnett Health Systems |
| [ ]  Bladen County Hospital | [ ]  Betsy Johnson |
| [ ]  Hoke Hospital | [ ]  Harnett Health Clinic/Center: specify: Click or tap here to enter text. |
| [ ]  Highsmith Rainy – Specialty Hospital |  |
| [ ]  Cape Fear Valley Rehabilitation Center | [ ]  International: specify country: Click or tap here to enter text. |
| [ ]  Behavioral Healthcare |  |
| [ ]  Other external site: Click or tap here to enter text. |

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| **Section 6: Informed Consent*** Obtaining the informed consent of potential participants is ethically important in the responsible conduct of research. While the informed consent process for exempt research does not need to include all elements of informed consent in the Common Rule regulations, researchers should employ a consent process when interacting with participants.
* Researchers are strongly encouraged to use one of the **IRB informed consent form templates**.
* At minimum, the informed consent process needs to include disclosure of the following to participants:
* That the activity involves research.
* A description of the procedures.
* That participation is voluntary.
* Name and contact information for the Researcher.
 |
| 1. **Does the research involve interaction or benign behavioral intervention with participants?**
 |
| [ ]  Yes [ ]  No | If “yes,” the **Research Plan** must include an informed consent process or provide justification for not obtaining informed consent from participants. |
| 1. **If conducting an informed consent process, provide a copy of the informed consent form and/or script?**
 |
| [ ]  Informed consent form/script attached.[ ]  n/a – not conducting informed consent |

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| **Section 7: Developing Materials for Submission** |
| 1. Identify additional application forms to include with your submission.
* Check all that apply and attach completed form(s) in the submission email.
 |
| **Check all that apply to your protocol** | **Applicable Form** |
| [ ]  Funded or Sponsored | **Funding and Sponsorship Form** |
| [ ]  Research Personnel & Certification of human subject research protection training (required) | **Research Personnel Form**, attach training certification for **all** project team members |
| 1. Develop a **Research Plan** and Identify Protocol Materials for Submission
* The list below to identify key consideration for your protocol. Use this list to (1) develop your Research Plan document and (2) identify other materials to your submission email to complete your submission. The list below are key considerations for which the IRB will need specific information to evaluate your proposed research.
1. Develop your Research Plan:
* It is expected that a research will have developed and will follow a detailed Research Plan. It is recommended that researchers use the IRB’s Research Plan Guidance document to assist with developing a plan. Having a well-developed Research Plan will assist the investigator when working through this form and answering the targeted questions and will assist the IRB’s verification of exempt determination. Additionally, if the proposed research does not qualify for exemption, IRB review is mandatory, and a Research Plan will be required for submission.
* Identify any supplemental content to include within your Research Plan document.
1. Develop any supplemental forms and/or materials noted for submission (see below).
* It is strongly encouraged that a researcher has developed data/information collection materials and assessments (if possible) when developing a research plan and when working through this form. Researchers must submit data/information collection materials and assessments to assist the IRB’s verification of the exempt determination. Additionally, if the proposed research does not qualify for exemption, IRB review is mandatory, all data/information collection materials and assessments will be required for submission. Guidance documents regarding key considerations listed below are available on the IRB website.
1. Attach all protocol materials to your submission email to the IRB Office.
* Grant, thesis, dissertation, or course work proposals may NOT be submitted in lieu of the Research Plan.
 |
| **Key Considerations** **(Check all that apply to your protocol)** | **Supporting Materials to Develop & Submit** |
| [ ]  **Research Plan (required)** | **Research Plan Template**IRB Research Plan Guidance Document |
| [ ]  HIPAA (Protected Health Information) | **Attachment A: HIPAA & Use of PHI** |
| [ ]  Consenting Participants | Informed Consent forms, assent forms, scripts, etc. |
| [ ]  Recruiting Participants | Emails, letters, scripts, flyers, posters, brochures, etc. used to recruit participants. |
| [ ]  Research with Minors | Parent/Guardian Permission, if applicableChild Assent Forms/Scripts, if applicable |
| [ ]  Using Translations/Translated Materials | **Translations Declaration Form and Back Translation Declaration Forms** |
| [ ]  Letters of Support  | Permission/approval required by department, schools, owners of listservs, etc. |
| [ ]  Data Collection Materials/Assessments | Surveys, questionnaires, data collection spreadsheets or forms |

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| **Section 8: Data Sources** |
| 1. **Will this research include obtaining, accessing, or using data from outside sources, e.g., universities, data repositories, government agencies, etc.?**
 |
| [ ]  Yes [ ]  No | If “yes,” name the source(s) below and answer questions “a” and “b” below. If “no,” move to Section 10. |
| Name of outside sources: | Click or tap here to enter text. |
|  | [ ]  Yes [ ]  No | 1. Are there terms, restrictions, or conditions regarding the data?
 |
|  | If “yes,” describe: | Click or tap here to enter text. |
|  | [ ]  Yes [ ]  No | 1. If “yes,” include a copy of the agreement (data use agreement/materials transfer agreement) and contact the IRB Office to ensure the appropriate institutional approval/signature is obtained to enter into the agreement.
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| **Section 9: Human Subjects Conflict of Interest*** It is the responsibility of the Principal Investigator (PI) to ensure that any research personnel, including the PI, responsible for the design, conduct, and reporting of research complete the IRB Conflict of Interest Disclosure Form in Human Subjects Research.
* The PI must keep completed copies of all Human Subject COI Disclosure forms for their records.
* The PI must submit with this application Human Subject COI Disclosure forms only for those individuals who have identified a real, perceived, or potential conflict of interest on their form.
 |
| [ ]  Yes, conflicts are identified, and Human Subject COI Disclosure form(s) are attached for the following individuals:Click or tap here to enter text.[ ]  No conflicts are identified. Keep a copy of COI Disclosure form(s) for your records, but do not submit with this application. |

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| **Section 11: PRINCIPAL INVESTIGATOR and, if applicable, RESIDENT/STUDENT AGREEMENT** |
| * I confirm that I have reviewed this project submission and approved for submission to the CFVHS IRB.
* By signing the IRB Investigator Agreement Form, I certify that I will conduct this research as determined by the CFVHS IRB.

[ ]  ***IRB Investigator Agreement*** has been signed and is attached to the application email. |

**Checklist for Exempt Research:**

|  |  |  |
| --- | --- | --- |
| Attached | N/A | Document |
|[ ]  -- | Exempt Research Application Form |
|[ ]  -- | Investigator Agreement, signed by the Principal Investigator and, if applicable, the resident/student. |
|[ ]  -- | Research Personnel Form and required applicable training documentation. |
|[ ] [ ]  Human Subject Conflict of Interest Disclosure Form(s) |
|[ ] [ ]  Funding and Sponsorship |
|[ ]  -- | A Research Plan and applicable appendices (grant applications or excerpts from a grant will NOT be accepted as a Research Plan |
|  |  | Attached | N/A |
|  |  |[ ]  [ ]  Appendix A –HIPAA and Use of PHI |
|[ ] [ ]  Recruitment Materials: Emails, letters, scripts, flyers, posters, brochures, etc. |
|[ ] [ ]  Informed Consent/Assent Materials |
|[ ] [ ]  Debriefing Materials |
|[ ] [ ]  Declarations of Translation and Back-Translations for non-English speaking documents |
|[ ] [ ]  Data Collection Materials (questionnaires, surveys, data collection forms, focus group/interview scripts, case report forms, etc.) |
|[ ] [ ]  Data Use Agreement(s)/Transfer of Materials Agreement |
|[ ] [ ]  Permissions, letters of support, and IRB approval documentation as identified in Part 7 of this form |
|[ ] [ ]  Clearance or approval documentation from applicable CFVHS oversite authority/committee |
|[ ] [ ]  For funded and/or sponsored research: The human subjects portion of the grant proposal |