**Guidance:**

Non-Human Subjects Research (NHSR) are projects that do not fit the definition of research (Not Research (NR)) or projects that fit the definition of research but do not actively involve human subjects, do not access private identifiable human information or biospecimens, or are not purposed to support the marketing of an FDA-regulated drug, biologic, or device product. For more information, please see, ***IRB Guidance: Non-Human Subject Research (NHSR) Categories***.

Since the focus of these projects do not fit the definition of research under 45 CFR 46.102(e), they will be evaluated as not involving research with humans. For such projects, privacy, and confidentiality regulations (HIPAA) must still be followed. The IRB will review and provide consultative assistance, but at this time is not responsible for approving how privacy, data storage and confidentiality measures are implemented in the case study/series project.

Please ensure you have discussed your potential case study with your Faculty/Staff Advisor, Program Director, and the GME Research Director ***prior*** to submitting this form.

**Instructions:**

* Prior to the initiation of any actual or potential human research activity, investigators are required to submit actual or potential human subjects research projects to the IRB and the IRB is required to review and make a determination of these activities for which CFVHS is engaged.
* Use the ***Human Subjects Research Determination Worksheet*** found on the IRB website to determine if your project meets the federal definition of “research” and/or “human subject” before submitting this form to the IRB for an official IRB determination.
* **Please complete this form and email to the IRB office at** **irb@capefearvalley.com****. Remember to include all supporting documents.**
* If you are using multiple public data sets the chances of identifying an individual, increases and therefore the project may require IRB review and approval under the appropriate category of research.
* Projects may be conducted by residents or students in conjunction with a faculty advisor
* **Letters of support (LOS)** from the clinical site or area, acknowledging awareness of and support for the project activities must be attached. The support letter should include the signature of the clinical administrator or clinical leader of the respective site or area.
* **Do not use this form if you are submitting GME Case Report/Series or QI/QI/PE project. Use the appropriate GME form on the IRB website for these specific types of projects.**

**Examples of activities that are generally considered not to be Human Research:**

The following are examples of activities that are generally considered not to be Human Research. If your activity is limited to one of the examples below, then it is likely not Human Research which would need to be reviewed by the IRB. Note that **publication is not a determining factor** for whether an activity is Human Research

**Categories of activities that are generally considered not to be Research and/or Human Subject Research:**

**1. Journalistic or Documentary Activity (including Oral History):** The activity is limited to investigations or interviews (structured or open-ended) that focus on specific events (current or historical), views, etc. These types of projects do not meet the federal definition of research. Such investigations or interviews may be reported or published in any medium, e.g., print newspaper, documentary video, online magazine. For detailed information please see [OHRP Guidance: Scholarly and Journalistic Activities Deemed Not to be Research](https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html).

**2. Quality Improvement/Quality Assurance Review/Project Program Evaluation**:

See ***IRB Guidance: Quality Improvement Projects*** found on the IRB website for a detailed explanation and GME/IRB submission instructions.

Only projects requiring an authoritative determination for publication or presentation are required to be submitted to the IRB.

**3. Case Report/Series:**

See ***IRB Guidance: Case Report/Series*** found on the IRB website for a detailed explanation and GME/IRB submission instructions.

Only projects requiring an authoritative determination for publication or presentation are required to be submitted to the IRB.

**4.** **Research Using Public or Non-Identifiable Private Information or Biospecimens about Living Individuals:** The activity is limited to analyzing data or biospecimens about living individuals (1) where the data have been retrieved by the investigator from public, non-restricted data biospecimen sets or (2) where the private data or biospecimens have been provided to the investigator without any accompanying information by which the investigator could identify the individuals. If the data/specimens provider has access to the identity of the subjects, the investigator must enter into an agreement with the data/specimen provider stating under no circumstances will the identity of the subjects be released to the investigator.

Note: that “de-identified data” according to HIPAA may be identifiable according to the DHHS definition of “Human Subjects” above. Please consult ***Human Research Determination Worksheet*** for clarification and contact the IRB Office with any questions regarding research with data.

**5.** **Research Using Health Information from Deceased Individuals:** This activity is limited to analyzing data (identifiable or not) about deceased individuals.

Deceased individuals cannot be Human Subjects according to DHHS, but they may be Human Subjects according to FDA. HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance.

**6. Course-Related Activity:** The project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments and otherwise do not meet either of the definitions of Human Research. This type of research stays within the classroom.

Some course-related activities, even those conducted by students, may yield information suggesting additional investigation or analysis. If an additional activity entails Human Research, then it must be submitted to the IRB Office for review.

**7. Instrument/Questionnaire Development:** This activity is limited to interacting with individuals to obtain feedback on the types of questions which could or should be used to develop an instrument or questionnaire. The focus is on the development and construction of a data collection tool and not on the individuals who are providing the feedback on the questions being developed. This will be true even when the feedback may be specifically sought from an identified group of people most likely to be affected by the topic of the instrument, survey, or questionnaire. The instrument/questionnaire development process will apply to many aspects of reliability and validity testing of the instrument or questionnaire. Note that once the process gets to the level of testing discriminant, concurrent or predictive validity, the activity may need to be reclassified as human subject research.

If the participant is asked to provide additional information unrelated to instrument/questionnaire construction, such as demographic information, that will be analyzed as part of a research study, the project may need to be submitted to the IRB for review.

**NHSR Application Form Starts on Next Page**

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| **Submission Date:** Click or tap to enter a date. |
| Section 1: Project and investigator Information |

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| --- |
| Project Title: *Title* |
| Principal Investigator (PI)(Faculty Advisor or Staff 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. |
| Primary Contact: | Enter Name | Title: | enter text. |
| Program/Department: | 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 |

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| Section 2: Project Type |
| [ ] Journalistic or Documentary Activity (including Oral History)[ ]  Quality Improvement/Quality Assurance/Program Evaluation (non-GME)[ ]  Case Report/Series (non-GME)[ ]  Research Using Public or Non-Identifiable Private Information about Living Individuals[ ]  Research Using Health Information from Deceased Individuals[ ]  Course-Related Activity[ ]  Instrument/Questionnaire Development |

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| Section 3: Project Details |
| 1. **Background and Purpose:**

*Include brief background including literature review results with citations, discuss the purpose of the project, what you expect to do with your findings. Include specific aims which clearly support the project purpose.* |
| Click or tap here to enter text. |
| **2. Subject Population or the Subject of the research:** *Provide a brief description.* |
| Click or tap here to enter text. |
| 1. **Research Methods and Data Collection Methods Used**

*Provide a concise description of how data will be collected. If applicable:** *Aims to support your purpose?*
* *Include how subject information will be identified (identifiable, coded with/without key, de-identified, anonymous)*
* *Who is involved with information collection?*
* *What information will be collected? What measurements will be collected to achieve your aims?*
 |
| Click or tap here to enter text. |
| **4. Does access to the data set require special conditions to be met, such as HIPAA regulations:** [ ]  **Yes** [ ]  **No** |
|  **4.a. If “yes”, please provide an explanation of the required special conditions and how they will be met, such as but not limited to storage on CFVHS secured server in password protected, encrypted (if applicable) files or in locked file cabinets in locked offices, etc.:** |
| Click or tap here to enter text. |

|  |
| --- |
| **5. Data to be collected:***Describe the data that you will gather about individuals or attach your data collection tool. List all data points.* |
| Click or tap here to enter text. |
| Section 4: PRINCIPAL INVESTIGATOR and RESIDENT/STUDENT SIGNATURE |
| * 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. |

DO NOT RETURN IN .PDF FORMAT.