**Deciding whether this is the right form for you to use:**

If your **ONLY** research procedure is the collection and **analysis of identifiable information (data) or identifiable biospecimens** and you are *not planning to prospectively collect biospecimens solely for research purposes*, this is the appropriate protocol template to use. (For example, medical record review use, recording and analysis of information both retrospectively and prospectively, use and analysis of biospecimens collected for non-research purposes, or used and analysis of information/biospecimens that were collected in prior research studies, student educational records, government datasets, etc.)

If your project involves procedures **other than information/biospecimen specimen analysis (e.g., surveys, interviews, collection of biospecimens), do NOT use this protocol template** -- use the appropriate protocol template found on the IRB website.

**Are the information/biospecimens identifiable? If the information/biospecimens are de-identified, do not use this protocol template.** If your project **solely** involves the use and analysis of **de-identified** information and/or biospecimens and is not part of a larger-scope project that is human subjects research, you should use the ***Non-Human Subject Research (NHSR) Application Form***. See ***De-Identified Materials Agreement Template*** to determine if this is required with your submission.

In general, information/biospecimens are considered to be identifiable when the information/biospecimens can be linked to specific individuals by the researcher either **directly, or indirectly through coding systems**, or when characteristics of the information obtained are such that a reasonably knowledgeable person could ascertain the identities of individuals. Keep in mind that, even though a dataset has been stripped of direct identifiers (e.g., names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g., age, gender, ethnicity, place of employment). For further detail on when information and specimens are considered to be de-identified, see [HHS Office of Human Research Protections Guidance on Research using Coded Data and Specimens](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html). If you are unsure whether the data/specimens you plan to analyze would be considered de-identified for IRB purposes, please contact the IRB.

**Note** under HIPAA regulations, **accessing** medical information/biospecimens requires either a HIPAA authorization signed by the patient or a a Waiver of HIPAA authorization to be granted by the IRB. If requesting a wavier, you must complete and *attach* ***Attachment A: HIPAA and Use of PHI***.

**What if the data provider insists on an IRB exemption or approval?**

Some information (data) providers will not release a dataset for analysis unless you provide an IRB letter showing that you have an exemption or IRB approval. In those situations, the IRB will review your project even if the data do seem to be de-identified.

**Instructions:**

* This form must be submitted to the IRB office by email at [irb@capefearvalley.com](mailto:irb@capefearvalley.com).
* Submissions should be submitted by the **PI**. Trainees should provide their Advisor all of the submission materials for their review prior to submission to the IRB.
* *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.*
* Remember this form should be written in lay terms and define specific terms prior to using initials. Please double check your submission for completeness and accuracy prior to submission.
* Incomplete submissions will be placed **ON HOLD**, if a submission is incomplete, it will not be processed until **all** required documents and criteria have been submitted or met. **Double check and ensure that all document fields have been completed prior to submitting to the IRB.**
* All project personnel must have completed human subjects research protection training and received certification, prior to the submission of any research protocol for IRB review. See ***IRB: Guidance: Human Subjects Protection Training***.
* Save this form before proceeding so your work will not be lost.

**Note:**

* If the IRB determines that a project meets all the criteria for exempt, category 4 research, the regulatory requirements for informed consent does not apply.
* Exemption certification/determination is not IRB approval, it is a determination. All project materials should state that the project has been certified as exempt by the IRB.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*PLEASE DELETE THESE INSTRUCTIONS PRIOR TO YOUR SUBMISSION TO THE IRB\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

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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 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. | | |
| Primary Contact | | | | Enter Name | | | | | | | | | | |
| 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 |
| Anticipated Start Date: | | | Click or tap to enter a date. | | | | | | | Estimated End Date: | | | | Click or tap to enter a date. |
| **Section 2: Project Key Personnel**   * Identify all key personnel who will be involved with the conduct of the research and describe their role in the project. Role may include design, recruitment, consent process, data collection, data analysis, and reporting.*Exempt determinations are made by individual institutions; reliance on other institutions for exempt determination is not feasible. Non-CFVHS personnel conducting exempt research activities must obtain approval from the IRB at their home institution.* * Key personnel are required to maintain human subjects training through CITI Programs. The IRB will accept CITI certification from another institution, if it is current. * **Attach all human research protection training certificates to your submission email.** * Your submission will not be processed until all project personnel have completed required human subjects protection training. | | | | | | | | | | | | | | |

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| **Name:** | **Email:** | **Affiliation** | **HSR Protection Training Complete:** | **Role**  **(PI, Co-PI, Research assistant, Coordinator):** | **Delegated by PI to obtain informed consent:** |
| Name | E-mail address | Affiliation | Yes  No | PI | Yes  No |
| Name | E-mail address | Affiliation | Yes  No | Role | Yes  No |
| Name | E-mail address | Affiliation | Yes  No | Role | Yes  No |
| Name | E-mail address | Affiliation | Yes  No | Role | Yes  No |
| Name | E-mail address | Affiliation | Yes  No | Role | Yes  No |

|  |  |
| --- | --- |
| **Section 3: Funding Information**   * Check below, * If “Yes”, complete and submit the **Funding and Sponsorship Form** with your ***Application Form***. | |
| No, the research is not funded | |
| Yes, the research is funded. | |
| **Section 4: 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 Site: Click or tap here to enter text. |
| Other CFVHS site: Click or tap here to enter text. | International: specify country: Click or tap here to enter text. |
| Other external site: Click or tap here to enter text. | |
| **Section 5: 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** disclose any real or potential Conflicts of Interest*.* Please see the [IRB website](https://www.capefearvalley.com/research/index.html) for detailed information regarding COI. | |
| No conflicts identified  Yes, conflicts are identified. (Please contact the IRB Office for further instructions) | |
| **Section 6: EXEMPT CATEGORY 4:**   * Select one of the following. | |
| Secondary research for which consent is not required: secondary research uses of ***identifiable private information*** or ***existing 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*.**  **No identifiable PHI, such as a list of MRNs or other identifiers, may be retained anywhere (SlicerDicer, spreadsheet, code sheet, etc.)**  (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. | |
| **Section 7: Project Type**   * *If you plan to collect biospecimens prospectively solely for research purposes as part of this project (e.g., through biopsies), then you cannot use this template.* * Check one of the following | |
| **Retrospective Review** (the information and/or biospecimens already exist at the time this protocol is submitted for initial IRB review)  **Date Range of information/biospecimens to be reviewed:**  Click or tap here to enter text. | |
| **Prospective Review** (the information and/or biospecimens do not exist when this protocol is submitted to the IRB for initial review – for biospecimens, you can use this template only if the specimens are being collected for non-research purposes such as medical treatment/diagnosis) | |
| **BOTH Retrospective and Prospective** **Review**  **Date Range of information/biospecimens to be reviewed:**  Click or tap here to enter text. | |
| **7.1 Estimate the total number of SUBJECTS in this record-review/biospecimen project that you intend to:** | |
| **Screen:** Click or tap here to enter text.  **Use:** Click or tap here to enter text. | |
| **7.1.2 Explain how you determined the number of records/biospecimens to include in the project:** | |
| Click or tap here to enter text. | |
| **Section 8: Project Information** | |
| **8.1 Project Background and Purpose** | |
| **8.1.1 Background with Citations** Provide a brief summary of the literature including references/citations. Explain how the proposed project adds to this literature (project rationale). | |
| Click or tap here to enter text. | |
| **8.1.2 Aim/purpose** Include project aims/purpose, or hypotheses. | |
| Click or tap here to enter text. | |
| **8.2 Study Sample**   * Describe the sample characteristics that will determine which information/biospecimens you analyze for this project (e.g., type of medical conditions/diseases, specific age range, gender, etc.). | |
| **8.2.1 Inclusion/Exclusion criteria)**  Click or tap here to enter text. | |
| **8.3 Procedures and Methodology** | |
| **8.3.1 Provide a brief overview of the procedures/methods used in the research project.** These include variables in the project and how they are measured, as well as data analysis/description.  Click or tap here to enter text. | |
| **8.3.2 List the specific data elements that will be collected or attach your data collection tool to the submission. Please list all data points**  Click or tap here to enter text. | |
| **8.3.3 Data analysis**  **8.3.3.1 Describe plan for data analysis**  Click or tap here to enter text. | |

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| --- | --- | --- |
| **8.3.3.2 Final data will only be reported in:** | | |
| Yes  No | | Aggregate form (ex., group means) for at least 10 individuals |
| Yes  No | | Individual data will be reported |
| **8.3.4 For what purpose were the records/biospecimens created?**   * Select all that apply | | |
| **Information/Data** | | **Biospecimens** |
| Clinical care (electronic medical records)  Quality assurance  Program administration (clinical data bases, if applicable)  Different research project  School or teaching records  Billing or insurance  Hospital or community surveillance  Other: Click or tap here to enter text. | | Clinical pathology specimens  Different research project  Other: Click or tap here to enter text. |
| **8.3.5 Are some or all of the records publicly available?** | | |
| Yes  No | If “Yes,” answer 8.3.1.1 and 8.3.2.2 | |
| **8.3.5.1 Provide internet links to descriptions of the datasets, if available. If you plan to analyze multiple data sets, describe each dataset separately and explain who holds each dataset** | | |
| Click or tap here to enter text. | | |
| **8.3.5.2 If you plan to analyze multiple data sets, describe each dataset separately and explain who holds each dataset.** | | |
| Click or tap here to enter text. | | |
| **8.3.6 If the information is not available publicly, who will provide you with the information/biospecimens or how you will gain access to the information to be collected?**   * Only medical care team members caring directly for the patient are allowed to access review the patient’s records. * Accessing medical information see **Section 8.7** for details | | |
| Click or tap here to enter text. | | |
| **8.3.7 Will you access identifiable information but record the information 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?**   * Accessing medical records and retaining a list of subjects is considered identifiable PHI or if you retain/report any of the 18 PHI identifiers your research data is considered identifiable data, regardless of where or how it is saved. This applies to SlicerDicer Reports retained in Epic and this report is considered research materials. | | |
| Yes  No | | |
| **8.3.8 Does the use of the information/biospecimens require any special permissions, restrictions, and/or agreements?**   * Data providers often require that the researcher enter into a data sharing agreement or other type of agreement setting forth data security requirements and associated non-disclosure agreements, principal investigators must determine if they have the capability to meet the data security requirements. * Examples: a data use agreement (DUA), data transfer agreement (DTA), or material transfer agreement (MTA). * Agreements must be reviewed by Legal Services and signed by the Institutional Official (IO). | | |
| Yes  No  If yes, a DUA, DTA, MTA or other type of agreement must be attached to your submission. | | |
| Click or tap here to enter text. | | |
| **8.4 Data Protection and Privacy** | | |
| **8.4.1 Where and how will you access, transmit, and store the information/biospecimens?**   * Describe if the information provider places any restrictions on how the information can be accessed and where the data can be stored * If you intend to access any clinical information on CFVHS Epic or other clinical systems for research, you must comply with ***CFVHS Policy: Access to Protected Health Information (PHI) without Authorization*** | | |
| Click or tap here to enter text. | | |
| **8.4.2 Describe how you will prevent the identifiable information from being released:** | | |
| Click or tap here to enter text. | | |
| **8.4.3 Describe when the identifiers will be removed from the research information (data), if ever:** | | |
| Click or tap here to enter text. | | |
| **8.4.4 Describe the location of data storage at each stage in the research process. If relevant, include CFVHS locations (with building and room numbers), international sites, and electronic storage locations.**   * Example: “Data will be accessed on a CFVHS owned tablet. Each night, data will be uploaded to a password protected file on the CFVHS secured “Z”: drive via remote access. Printed copies of research information will be stored in the PI’s office located in the Internal Medicine department at CFVMC, in room XXX.” * Data is property of CFVHS and must be stored on a secured CFVHS server in a password protected, encrypted (if containing identifiers) file only accessible by IRB-approved project team members. | | |
| Click or tap here to enter text. | | |
| **8.4.5 Describe if there are plans to store any of the data/specimens long-term.?**   * All research information, including source documents must be retained for a minimum of 3 years or 6 years (if it included identifiable PHI) after project completion * If the information/biospecimens will be destroyed after retaining for the required time, explain the planned methods for destruction? | | |
| Click or tap here to enter text. | | |
| **8.5 Risks**   * Discuss possible risks (both the probability of the risk and the magnitude of the risk) that could occur if there were a breach of confidentiality (social, economic, legal, reputational, or other possible harms to individuals or community/group). * There is always a risk of loss of confidentiality. | | |
| Click or tap here to enter text. | | |
| **8.6 Benefits**   * Discuss potential benefits to society or academia. * There must be a benefit for the IRB to approve the research project. | | |
| Click or tap here to enter text. | | |
| **8.7 HIPAA Authorization and Waiver of HIPAA Authorization**   * For research projects that involve analysis of medical record data or biospecimens held by CFVMC or CFVHS Affiliates: if you are ***accessing*** identifiable protected health information (PHI) the IRB (serving as the HIPAA Privacy Board) will consider whether to waive the requirement for HIPAA Authorization. * Complete and attach ***Appendix A – HIPAA & Use of PHI*** | | |

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| **Section 9: PRINCIPAL INVESTIGATOR and RESIDENT/STUDENT AGREEMENT, if applicable** |
| * 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 submission email. |

----------------------------------------------------------------------Complete Checklist on Next Page--\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Checklist for Exempt Research:**

|  |  |  |
| --- | --- | --- |
| Attached | N/A | Document |
|  | -- | Exempt Research Category 4 Application Form |
|  | -- | Investigator Agreement, signed by the Principal Investigator and, if applicable, the resident/student. |
|  |  | Research Personnel Form, if Section 2 is not complete, and required applicable training documentation. |
|  |  | Human Subject Conflict of Interest Disclosure Form(s) |
|  |  | Funding and Sponsorship |
|  |  | 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 Section 9.3.5 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 |