CAPE FEAR VALLEY HEALTH

IRB Worksheet: Human Subjects Research Determination

Instructions: Use this worksheet to help you determine whether your project constitutes research involving human subjects, according to regulatory definition of these terms and therefore requires review and determination or approval by the IRB.

Special Considerations:

- If your project involves human biological or genetic material, or repositories, please contact the IRB Office for specific instructions (the information provided in this worksheet may not apply to your research).
- In general, activities undertaken for the fulfillment of a single course requirement and not the development of or contribution to generalizable knowledge (e.g., public presentation or publication) do not require IRB review.
- If your answers reveal that your project is human subjects research, you must complete and submit an Exempt Research Protocol Application Form or a New Protocol Application Form to the IRB Office for review prior to commencing any research activities involving interaction with human subjects.

If your answers reveal that your project is not human subjects research, you should submit a Non-Human Subjects Research (NHSR) Application Form to the IRB Office for determination prior to commencing any research activities. The IRB Office will provide you with a formal determination letter documenting that your project is not human subjects research.

If you need assistance please contact the IRB office at 910-615-5839 or irb@capefearvalley.com.

Section 1: Determination of Research (45 CFR.102 (l))

- *Human subjects research regulations apply only to activities that meet the federal definition of* ***research***.
- *Research is a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to "generalizable knowledge"*. Answer questions 1 and 2 below to determine whether your project meets this definition of research.
- The additional following activities are deemed not be research under the federal regulations:
  - Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship) including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
  - Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to all a public health authority to identify, monitor assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
  - Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
  - Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions

1. Is this project a systematic investigation? Systematic means having or involving a system, method, or plan.

- Examples of projects that are systematic include, but are not limited to, those which:
  - Gather information for the purpose of hypothesis building or testing.
  - Ask individuals the same sets of questions or obtain the same kind of information from them.
  - Apply the same measures in gathering the data – whether through interaction, observation, or experiment.
  - Utilize data collection methods that can be replicated

☐ Yes ☐ No

2. Is this project designed to contribute to generalizable knowledge?

- Your project contributes to generalizable knowledge if you intend for finding from the research to applicable to a larger population, or otherwise make the findings of it available for the development of knowledge beyond the scope of the project. The following projects do not usually meet the definition of generalizable knowledge:
  - Quality Improvement/Quality Assurance/Program Evaluations
  - Case Reports with less than 3 subjects
  - Instrument/Questionnaire development

☐ Yes ☐ No

➢ If you answered "No" to either question 1 or 2, STOP. Your project is not considered research and submission to the IRB is required for review and determination, oversight by the IRB is NOT required. Please ***submit Non-Human Subjects Research (NHSR) Application Form*** to the IRB for an official final determination by the IRB.

➢ If you answered "Yes" to questions 1 and 2, continue to section 2.

Section 2: Determination of Human Subjects (45 CFR.102 (e)

➢ *Human subjects protection regulations apply only to research involving* ***human subjects****.*

➢ *Human subject is a living individual about whom an investigator (whether profession or student) conducting research:*

1) Obtains information or biospecimens through ***intervention*** or ***interaction*** with the individual, and uses, studies, or analyzes the information or biospecimens; or
2) *Obtains, uses, studies, analyzes, or generates* ***identifiable private information*** *or* ***identifiable biospecimens****.*

- Answer the questions below to determine if your research involves human subjects.

3. Does the research involve obtaining information (data) about and/or biospecimens from *living* individuals?

- Information about and/or biospecimens from an individual includes, but is not limited to the following:
  - Ideas, attitudes, opinions, feelings, experiences, thoughts, beliefs, assessments, recollections, etc., reported by an individual, even when the individual provides the information while working in a professional capacity.
  - Information about living individuals that was gathered by another research or source.
  - Information about living individuals gathered through the use, analysis or harvesting of cell lines, tissue, or the products of labor and delivery.
  - Samples of material, such as urine, blood, tissue, cells, DNA, RNA, and protein.

☐ Yes ☐ No

➢ If you answered "No" to question 3, STOP. Your project is not considered human subjects research and submission to the IRB is required for review and determination, oversight by the IRB is NOT required. Please submit ***IRB Non-Human Subjects Research (NHSR) Application Form*** to the IRB for an official final determination by the IRB.

4. Does the research involve obtaining information and/or biospecimens through *intervention* or *interaction* with individuals and uses, studies, or analyzes the information and/or biospecimens?

- ***Intervention*** includes:
  - Both physical procedures by which information or biospecimens are gathered (e.g., venipunctureetc.) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., drawing blood from subjects, timing subjects running laps, recording brain activity during sleep, etc.).
- ***Interaction*** includes:
  - Communication or interpersonal contact between investigator and subject (e.g., an interview, online survey, recording posts on blog or listserv, a mailed questionnaire, focus groups, etc.)

☐ Yes ☐ No

5. Will you access, obtain, use, study, analyze, or generate *identifiable private information* and/or *identifiable biospecimens* from individuals?

- ***Private information*** includes:
  - Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
  - Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical records, emails, certain listserv communications, etc.
  - ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- ***Biospecimens*** include:
  - Samples or specimens of material, such as urine blood tissue, cells, DNA, RNA, and protein.
  - ***Identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

☐ Yes ☐ No

- If you answered "No" to either question 4 or 5, STOP. Your project is not considered human subjects research and submission to the IRB is required for review and determination, oversight by the IRB is NOT required. Please ***submit IRB Non-Human Subjects Research (NHSR) Application Form*** to the IRB for an official final determination by the IRB.
- If you answered "Yes to questions 4 or 5 or both, You must submit the appropriate ***Exempt Research Protocol Application Form*** or a ***New Protocol Application Form (Non-Exempt Research)*** to the IRB for review and determination/approval by the IRB.