

The IRB has the authority to determine whether a project engages Cape Fear Valley Health System (CFVHS) in human subjects research according to our Federalwide Assurance for the Protection of Human Subjects (FWA). Cape Fear Valley Health System is “engaged” in research when its employees or agents, including students, for the purposes of the research project by acting on behalf of the institution when they:

1. Obtain data or biospecimens about human research participants through intervention or interaction with the participants.
2. Obtain identifiable private information or identifiable biospecimens about human research participants, through direct or indirect interaction.
3. Obtain informed consent of human subjects for research; or
4. Obtain an award through a grant, contract, or cooperative agreement directly from the Department of Health and Human Services (DHHS or HHS) or the Food and Drug Administration (FDA).

An institution’s *employees or agents* refers to individuals who:

1. Act on behalf of the institution.
2. Exercise institutional authority or responsibility; or
3. Perform institutionally designated activities.

Employees and agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

CFVHS’s FWA applies to non-exempt federally funded research and certain federally regulated research. Please note that an IRB determination of **exempt status**, generally does not require an engagement determination and therefore, usually does not require an IRB authorized reliance agreement to be executed between CFVHS and non-CFVHS sites for multi-site or collaborative projects that are federally funded or are required to be federally regulated. Some federal sponsors or agencies may require a determination of engagement and an IRB authorized reliance agreement prior to granting of the award. Check with the IRB and your sponsor early in the funding process for collaborative site research.

If you are planning on collaborating with non-CFVHS sites/institutions/facilities and these sites are engaged in research, use the decision tree at the end of this document to determine further actions to be taken.

Examples of when Cape Fear Valley Health System is Engaged in Human Subjects Research

CFVHS is engaged if its employees or agents are conducting the research such as but not limited to obtaining consent, performing research procedures, administering test article, obtaining identifiable information or identifiable biospecimens, etc. The following examples are not meant to be all-inclusive. If you have any questions, contact the IRB office.

- CFVHS physician performs invasive or noninvasive procedures (collection of blood, utilizing physical sensors, manipulating the environment) for research purposes.
- CFVHS staff member interacts with a subject through direct communication, such as administering a survey for research purposes.
- CFVHS medical resident, on behalf of the principal investigator obtains informed consent of human subjects, for research that will be conducted at CFVHS.

- CFVHS medical student obtains private information or specimens from any source for research purposes. This includes but is not limited to observing or recording private behavior, using, studying, or analyzing private information or specimens provided by another institution or already in the possession of the investigator.
- CFVHS faculty member will help collect and measure air samples on a collaborative project looking at the quality of air/pollution in individual's homes. The CFVHS faculty member will not be recruiting or consenting subjects but rather will collect samples, have access to data and will help with publications.
- CFVHS employee worked on a project while completing their PhD at another university. Part of the study included therapy session treating alcoholism among children of alcoholics. Study is an ongoing, multi-year project which they are no longer involved with recruiting/consenting/administering of measures but has access to identifiable data. They wish to help analyze data and publish with and separately from their colleagues.
- CFVHS faculty member will help a colleague at another institution recruit students to participate on study looking at eating habits and keeping food diaries. The CFVHS Faculty will help recruit/consent students. They will not administer the intervention but have access to de-identified data and they plan to publish separately.
- CFVHS receives money through a grant, contract, agreement as the primary awardee or a subcontract to assist on a funded project, even if the research is conducted by employees or agents of another institution.
- CFVHS faculty sub awardee will be a consultant as to provide expertise, will develop survey measures, will code and analyze *identifiable* data or a CFVHS faculty member will help a colleague at another institution recruit students to participate on study looking at studying habits and keeping studying diaries. The faculty member will not administer the intervention but have access to de-identified data and they will publish separately.
- CFVHS provides research intervention of participants previously enrolled/treated at another research site, unless the research intervention being tested or evaluated is limited to a one-time or short-term basis.

Examples of when CFVHS Is Not Engaged in Human Subjects Research Activities

- CFVHS employee informs prospective participants with written information about research, which may include a copy of the relevant informed consent document, and other IRB- approved materials but do not obtain participants' consent or act as authoritative representatives of the investigators.
- CFVHS staff obtaining and appropriately documenting prospective participants' permission for investigators to contact them.
- Institutions that permit use of their facilities: A CFVHS Investigator distributes a survey at a local community center. (The community center is not engaged in human subjects research).
- Institutions that release identifiable private information or identifiable biospecimens such as a high school releases student tests scores to an investigator from CFVHS.
- CFVHS resident obtains coded private information from another institution while maintaining the link but are unable to discover the identity of the subjects because there is an agreement that the link will not be release to the student or anyone on the study team.

- Distribution of research study information to prospective subjects: A CFVHS physician informs patients about a research study being conducted by a resident in the Psychology Department. The physician is not an investigator on the protocol. (The physician is not engaged in research).
- Allowing another institution to use CFVHS facilities for research interventions (i.e., to conduct a specific research procedure only).
- Obtaining private coded information (data or specimens) that the Investigator is unable to readily ascertain the identity (e.g., Investigator receives no link). Note that the release or receipt of such information may be subject to additional institutional requirements prior to release to the Investigator.
- CFVHS medical student accesses or utilizes individually identifiable private information only while visiting an institution that is engaged in the research, provided the research project is overseen by the IRB of the institution that is engaged in research.
- Institutions who employees or agents perform commercial or other services for investigators if **all** the following conditions are met:
 - a) The services performed do not merit professional recognition or publication privileges.
 - b) The services performed are typically performed by those institutions for non-research purposes; and
 - c) The institution's employees or agents do not administer any study intervention being tested or evaluated under the IRB approved protocol.

Examples:

- A transcription company whose employees transcribes research study interviews as a commercial service.
- A qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service.

Cape Fear Valley Health System (the assured institution) may extend its FWA to other collaborative sites/investigators or may cede (defer IRB review to an external IRB depending on whether a project is federally funded or not