CAPE FEAR VALLEY HEALTH	**IRB Guidance:** Recruitment of Human Subjects

The purpose of this guidance is to explain the process and requirements for IRB review and approval of recruitment methods and materials used to recruit potential research subjects for participation in a research project.

Recruitment Methods

Record Reviews

1. Potential subjects may be identified by Investigators using medical records, clinical databases or research databases. This process is often identified as "a record review" and requires IRB approval prior to review of records.
2. Investigators should identify the following for the IRB within the submission:
    - Are the potential subjects under their care?
    - Who will review the records?
    - What identifying information will be collected to assist with the recruitment process?
3. The IRB can approve research in which the investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without first obtaining informed consent if either of the following conditions are met:
    - The information will be obtained through oral or written communication with the prospective subject, OR
    - By accessing records or stored biospecimens.
4. Cape Fear Valley Heath Systems (CFVHS) sites are considered a covered entity and must abide by the federal regulations regarding Health Insurance Portability and Accountability Act (HIPAA). The steps in accessing potential subject records vary if the potential subject is the Investigator's patient or not.
    - Investigators and project teams should indicate in their IRB submission if they wish to screen or recruit subjects from review of medical records.

Approach Letters/Emails or Phone calls

1. Approach letters/emails/calls are seen as a first step of the informed consent process and the subject selection process and should contain the information as outlined in ***IRB Guidance: Use of Advertisements***.
2. To avoid an invasion of privacy, it may be necessary for an investigator to enlist the cooperation of other professionals and organizations as intermediaries in contacting a potential subject and obtaining consent to release his or her contact information to the investigator. This is appropriate when an investigator has not had prior contact with prospective research subjects and has not obtained their names from a publicly available source.
3. Approach letters/emails should be printed on either departmental or project-based letterhead and signed by the PI. When using email, they should be sent via an approved listserv or the Investigator’s CFVHS email address.

Use of a Public List

When the investigator obtains names through a public list (e.g., telephone book), the name of the source should be included in the initial approach communication/contact (letter/email or phone call).

Academic Colleague to Colleague Letters/Emails or Professional to Professional Letters/Emails

An investigator can solicit help from outside institutions or entities with recruitment. These soliciting letters/emails providing basic information to colleagues/professionals affiliated with outside institutions or organizations regarding a CFVHS Investigator's project do not require IRB approval. The use of potential participant recruitment letters/emails should be explained in the recruitment procedures to be used for the project and the actual recruitment letters/emails must be uploaded for IRB approval.

Advertisements/Flyers/Posters/Radio/TV

1. Federal regulations require IRBs to review the information contained in advertisements to determine that the procedures for recruiting subjects are not unduly influential or coercive and do not promise a certainty of cure beyond what is outlined in the consent and the protocol. See ***IRB Guidance: Use of Advertisements*** for specific language which may or may not be allowed in advertisement materials.
2. Advertisements used to recruit subjects include, but are not limited to:
    - Newspaper
    - Radio
    - Televisions
    - Bulletin boards
    - Posters
    - Flyers/Brochures that are intended for potential subjects.
3. IRB review is necessary to ensure that the information is not misleading to subjects, especially when the project may involve subjects considered vulnerable.

Internet Recruitment (e.g. web postings, websites, social networking sites online environments)

1. If an Investigator chooses to use the Internet for recruitment, CFVHS IRB review and approval of the method and content is required. Investigators must describe in their submission where and what listing is being used. In addition, the Investigator must assure that the information shared for Internet recruitment is in accordance with their signed clinical trial agreement or grant. Refer to ***IRB Guidance: Use of Advertisements*** for a description of what information may be included with internet recruitment.
    - If the proposed recruitment website or posting includes risks and/or potential benefits or compensation information, the material must be reviewed and receive IRB approval prior to posting.
    - If the proposed recruitment website will collect any personal identifiable information from potential subjects, this must be reviewed and approved by the

IRB prior to posting, along with a description of how the information will be collected and protected from breaches of privacy.

2. Federal guidance regarding website recruitment states that if a project's recruitment material (e.g. website or web posting) contains only basic descriptive information, IRB approval is not required. CFVHS IRB considers the following posting services not to require prospective IRB approval (although the use of websites for recruitment should be included in the recruitment procedures to use for the project):
    - The National Cancer Institute's cancer clinical trial listing (PDQ)
    - The government-sponsored AIDS Clinical Trials Information Service (ACTIS),
    - ClinicalTrials.gov.

Recruitment of Vulnerable Populations

Projects which will include or target vulnerable populations must include the appropriate safeguards to ensure the rights; welfare and safety of these subjects are protected. For more information about these safeguards and vulnerable populations refer to the following ***IRB Guidance documents:***

- *Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*
- *Use of Legally Authorized Representatives (LARs)*
- *Research Involving Minors/Children*
- *Recruitment & Enrollment of Non-English Proficient or Limited-English Proficient Subjects*

Other Federal Agency Requirements

Several Federal Agencies have additional requirements to ensure the protection of human subjects for projects being funded or conducted under their oversight. For projects receiving funding from the Department of Defense (DoD) or a component of the DoD, the following elements must be addressed in the IRB application submission:

- When research involves U.S. military personnel additional protections for military research subjects to minimize undue influence include:
    - Officers are not permitted to influence the decision of their subordinates.
    - Officers and senior non-commissioned officers may not be present at the time of recruitment.
    - Officers and senior non-commissioned officers have a separate opportunity to participate.
    - When recruitment involves a percentage of a unit, an independent ombudsman is present.
    - When research involves U.S. military personnel, limitations on dual compensation:
        - Prohibit an individual from receiving pay of compensation for research during duty hours.
        - US military personnel may be compensated for research if the subject is involved in the research when not on duty.