CAPE FEAR VALLEY HEALTH	**IRB Guidance:** Informed Consent & Waivers/Alterations of Consent

Requirements for Informed Consent

Federal regulations and the CFVHS IRB require that Principal Investigators provide a process for obtaining subjects' consent prior to their involvement in human subjects research unless the IRB has approved a waiver or alteration of the consent process. Please note that the consent process is not the same as documentation of consent. The consent process must (the following may be achieved via oral presentation, video, or slide show in addition to the informed consent document):

- Begin with a concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the project. This subsection must be organized and presented in a way that facilitates comprehension; • Occur in circumstances that minimize the possibility of coercion and undue influence;
- Conducted in a private and quiet setting;
- Obtained on the most current IRB approved consent form;
- Utilize language to promote the subject's understanding of the information;
- Provide the information that a reasonable person would want to have to make an informed decision about whether to participate, and an opportunity to discuss that information;
- Allow sufficient time for consideration of the information and decision regarding participation. In some cases, this may mean providing all the information and giving the prospective subject time to go home and continue the consent process on another day;
- Not waive or appear to waive subjects' rights; and
- Include each of the required elements and applicable additional elements of informed consent describing the project and the nature of research participation as required by federal regulations, tribal laws, institutional policies and approved by the IRB;
- Include a discussion regarding the use and retention of data, and if they choose to withdraw from a project.

The requirements for the informed consent form differ for Exempt determined research and Non-Exempt (Expedited/Full Board) approved research.

For Exempt Review Determined Research

Before involving a human subject in exempt research, it is ethically important in the responsible conduct of research to obtain the informed consent of potential participants. The informed consent process for exempt research does not need to include all the required elements of informed consent in the Common Rule (45 CFR 45) regulations (as noted below), researchers should employ a consent process when interacting with participants even when conducting registration or exempt research. Understand the IRB will make the final determination on informed consent requirements.

Researchers are strongly encouraged to continue using the guidance information below and one of the ***IRB Informed Consent Form Templates***. At minimum, the informed consent process for exempt research should disclosure of the following to participants:

- That the activity involves research;
- A description of the procedures;
- That participation is voluntary;

- Name and contact information of the Researcher and the IRB Office.

For Non-Exempt (Expedited/Full Board) Review Approved Research

Before involving a human subject in expedited or full board approved research, an investigator shall obtain the legally effective informed consent of the participant or the participant's legally authorized representative (LAR). Informed consent is to be obtained under circumstances that minimize the possibility of coercion or undue influence and that provide sufficient opportunity for the person to review, discuss and consider whether to participate.

Information must be provided in language understandable to the participant and/ or LAR. Potential participants must provide the information that a reasonable person would want to have to make an informed decision about whether to participate.

The informed consent process as a whole must present information in sufficient detail relating to the research and must be organized and present in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.

The informed consent process and forms may not include exculpatory language through which an individual is made to waive or appear to waive any legal rights or release the investigators, institutions, or sponsors from liability for negligence.

Waiver of Informed Consent Process

The IRB may waive or alter the requirement for the Principal Investigator to obtain a potential subject's consent for participation. To approve such a waiver or alteration, the IRB must find justification and document within the Research Plan addressing:

- The project involves no more than minimal risk to the subjects;
- The project could not practicably be carried out without the waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The above waiver conditions must be met for research that involves the use of identifiable private information or identifiable biospecimens and the research could not be practicably carried out without using such information or biospecimens in an identifiable format.

When considering a waiver of the consent process for screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the prospective subject or the subjects legally authorized representative, the IRB must find one of the following:

- The Principal Investigator, or their designee, will obtain information through oral or written communication with the prospective subject or legally authorized representative; or

- The Principal Investigator, or their designee, will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

When considering a waiver of the consent process for Public Demonstration Projects, the IRB must find:

- The research is conducted by or subject to the approval of state or local government officials
- The research or demonstration project is designed to study, evaluate, or otherwise examine:
  - Public benefit or service programs;
  - Procedures for obtaining benefits or services under those programs;
  - Possible changes in or alternatives to those programs or procedures; or
  - Possible changes in methods or levels of payment for benefits or services under those programs; and
  - The research cannot be practicably carried out without the waiver of alteration.

The IRB may not waive the consent process for any research to be conducted under DoD regulations where the research is classified or if subject meets the DoD definition of an experimental subject. Research involving an experimental subject is defined as: An activity, for research purposes, where there is an intervention or interaction with a human subject for the primary purpose of obtaining the effect of the intervention of interaction.

- A waiver of the consent process for such DoD regulated research requires permission of the Secretary of Defense.
  - If a waiver of consent is granted, the Principal Investigator (PI) must identify their process to solicit and obtain consent from an experimental subject's legally authorized representative, and the PI must include a description regarding how the research will benefit the individual subject.
    - The convened IRB will make a final determination if research is intended to be beneficial to the individual experimental subject.
  - The Assistant Secretary of Defense for Research & Engineering may waive the requirement of consent when all of the following elements have been met:
    - The research is necessary to advance the development of a medical product for the Military Services.
    - The research might directly benefit the individual experimental subject.
    - The research is conducted in compliance with all other applicable laws and regulations.

Documentation of Informed Consent

Federal regulations require that subjects provide written consent prior to their involvement in human subjects research unless the IRB has approved a waiver or alteration of the documentation of consent. The following must be included in the Informed Consent Document. The CFVHS IRB has Informed Consent Templates which can be found on the IRB website and all documents include the required language.

Key Information Summary

The informed consent form must begin with a concise and focused presentation of key information that is most likely to assist the prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the consent process and form must be organized and presented in a way that facilitates comprehension. To accomplish this, a section is added at the beginning of the informed consent form or script that is used to facilitate this process.

How each Principal Investigator applies the key information requirement, and to what level of detail, is dependent on the complexity of the research involved. Federal regulations suggest the following elements be included as Key Information:

- A statement that the project is research and participation is voluntary.
- A summary of the research, including:
    - Purpose
    - Duration
    - List of procedures.
- Reasonable, foreseeable risks and discomforts.
- Reasonable, expected benefits.
- Alternative procedures or courses of treatment, if applicable.

Elements of Informed Consent

In addition to the Key Information, the informed consent process and form must contain basic elements of informed consent and additional elements, when applicable, to allow participants to make an informed decision about whether to participate.

Basic Elements

Basic elements must be included in the information provided to participants unless elements are waived by the IRB under specific conditions.

The basic elements of informed consent are incorporated into the IRB consent form templates, excluding the following:

- Assent forms for 7 -10 years of age and 11-13 years of age,
- Verbal consent script,
- Online consent,
- Project Information Sheet.

Basic Elements *required by the federal regulations* are:

1. A statement that the project involves research.
2. An explanation of the purpose of the proposed research.
3. The expected duration of the subject's participation.
4. A description of the procedures to be followed.
5. Identification of which procedures are experimental. For studies that are not greater than minimal risk and are not HHS-funded, this element may be omitted.
6. A description of reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable.
7. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that if it is an experimental treatment or procedure, no benefits can be guaranteed.
8. A disclosure of appropriate alternative procedures or treatments, if any, which are available and might be advantageous to the subject. One alternative might be to choose not to participate in the research.

For studies that are not greater than minimal risk and are not HHS-funded, this element may be omitted.

9. A statement describing the manner and extent, if any, to which confidentiality of records identifying the subject will be maintained, a statement that the IRB and other entities may inspect the records, and, if the research is Food and Drug Administration (FDA)-regulated, FDA may inspect the records.
10. For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs and if so, what they consist of or where further information may be obtained. For studies that are not greater than minimal risk and are not HHS-funded, this element may be omitted.
11. A description of whether reimbursement for time, inconvenience, etc. will be given, including the schedule of payments.
12. Information regarding who to contact for answers about the research and in the event, there is a research-related injury (this is generally the principal investigator (PI) or another staff member closely associated with the project). A separate contact, typically this is the Office of Research Support, must be named for questions concerning the subject's rights to provide input, comments, or complaints.
13. A statement that the subjects' participation is voluntary, that refusal to participate will not involve penalty or loss of benefits to which the subject is entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled.
14. If the research involves collection of identifiable private information or identifiable biospecimens, one of the following statements must be included as appropriate:
    a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or LAR, if this might be a possibility; or
    b) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

Note: for FDA regulated *applicable clinical trials* the following statement must be included:

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Additional Elements

When appropriate, additional elements of informed consent must be provided to participants and or LARs. They are as follows:

1. A statement that the particular treatment and/or procedure may involve risks to the subject (or to the embryo or fetus, if the subject becomes pregnant) that are currently unforeseeable. This element should be included when the research involves an investigational drug or device or involves procedures for which the risk profile is not well known.

2. Anticipated circumstances under which the subject's participation may be terminated by the PI, with or without the subject's consent. Include when there are known circumstances under which the subject's participation may be terminated by the PI or sponsor.

3. A description of additional costs for which the subject will be responsible, that may result from participation in the research project. Include when there are additional costs to subjects, over and above standard of care, e.g., additional MRIs, radiographs, DEXA scans, additional visits that may not be covered by insurance/Medicare/Medicaid.
4. A description of the consequences of a subject's decision to withdraw from the research and procedures for orderly and safe termination of participation by the subject. This element should be included when there is a likelihood that abrupt termination from the research is likely to result in adverse events to the subject.
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject. Include when there is likelihood that interim findings might indicate increased risk and a reasonable person would wish to reconsider participation.
6. The approximate number of subjects that will be involved with the project, totally and at CFVHS.
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subjects will or will not share in this commercial profit.
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
10. Other additional information may be required by the IRB.

Other requirements

Department of Defense (DoD)

In addition to the required elements and any applicable additional elements, consent forms for research funded or supported by the Department of Defense must include:

- A statement that the DoD or a DoD organization is funding the research project.
- A statement that representatives of the DoD are authorized to review research records.
- A statement as to whether any compensation, and/or whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.

Department of Justice (DOJ) In addition to the required elements and any applicable additional elements, consent forms for research supported by the Department of Justice must include the following statements:

- The name of the funding agency
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- Confidentiality may only be broken if the subject reports immediate harm to participants or others. The participant must be informed about any disclosure and the risk of harms from the disclosure.

- PIs do not have to report child abuse unless the participant signs another consent form allowing the child abuse reporting.
- In studies supported by the NIJ, the subjects must be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If the identity of the individual cannot be maintained the participants must be explicitly notified. In some circumstances, the IRB may approve a consent procedure and form that omits some or alters some or all of the elements of informed consent.

Documentation Requirements

Informed consent must be documented by the use of written informed consent form approved by the IRB and signed (including electronic format) by the subject or the subject's LAR. A written copy shall be given to the person signing the form and sufficient time allowed to read or have the form read to them.

Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the Principal Investigator to obtain a signed and dated consent document for some or all subjects, if it finds one of the following justified in the Research Plan:

- That the only record linking the subject and the project would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the project, and the subject's wishes will govern; **or**
- That the project presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the project context; **or**
- That the subjects are members of a distinct cultural group or community in which signing forms is not the norm. This is limited to minimal risk research projects and requires an appropriate alternative method for recording that informed consent was obtained..

In cases in which the documentation requirement is waived, the IRB may require the PI to provide subjects with a written statement regarding the project (project information sheet).