

## Florida Department of Health Informed Consent Checklist

### Describe the Process of Consent (Required)

Does the person who would conduct the consent interview have sufficient experience?

Is the location or setting adequate to insure informed consent?

- yes
- no

Who would provide consent or permission

What information will be conveyed to the prospective participant or guardian?

What steps are taken to minimize the possibility of coercion or undue influence?

Describe whether there is a waiting period between the consent interview and obtaining consent, and whether it is adequate

What is the language used by those obtaining consent?

What is the language understood by the prospective participant or legal guardian?

Plain Language: Will the individuals communicating information to the participant or the legally authorized representative during the consent process provide information in language understandable to the participant or the representative?

- yes
- no

Exculpatory language: does the consent include exculpatory language (for example, that DOH is not liable if the participant developed health problems during the course of the study, and would not provide compensation or provide any medical treatment without charge for any medical intervention)

- yes
- no

## Describe the Consent Document (Required)

### Required Elements:

A statement that the study involves research

- yes
- no

An explanation of the purposes of the research

- yes
- no

The expected duration of the subject's participation

- yes
- no

A description of the procedures to be followed

- yes
- no

Identification of any procedures which are experimental

- yes
- no

A description of any reasonably foreseeable risks or discomforts to the subject

- yes
- no

A description of any benefits to the subject or to others which may reasonably be expected from the research

- yes
- no

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

- yes
- no

A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

- yes
- no

For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

- yes
- no

An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject

- yes

no

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

yes

no

### Additional Elements as Appropriate

A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

yes

no

Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

yes

no

Any additional costs to the subject that may result from participation in the research

yes

no

The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

yes

no

A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject

yes

no

The approximate number of subjects involved in the study

yes

no

For FDA-regulated research, does the informed consent document include a statement informing participants that the FDA may inspect their records?

yes

no

### Additional DOH requirements

Consent documents inform participants or prospective participants and their representatives that they may voice concerns or ask questions by contacting the following:

- The Principal Investigator;
- The DOH IRB, including the toll-free contact number;
- The Investigator's local IRB if not the DOH IRB; or
- If the research site is in a county health department facility, the Medical Director of the

facility.

Research related injury: Does the consent include information disclosing provisions for medical care or other care or services for research-related injury for consistency with provisions in the contract or funding agreement?

- yes
- no

Does the informed consent document include information about how study participants with concerns or complaints can contact the DOH IRB?

- yes
- no

## Documentation of Informed Consent

Written

- yes
- no

Short form written consent presented orally with written summary (applicable only for non-FDA research)

- yes
- no

For short form consent, are the following present? (applicable only for non-FDA-regulated research)

- All required elements above have been presented orally in a script that will be reviewed by the IRB
- The subject signs the short form
- The investigator describes a process for having a witness to the oral presentation of information and for having the witness sign both the summary and short form
- The investigator has provided a written description for review by the IRB
- The investigator describes plans to provide copies of the description and short form
- The person obtaining consent signs a copy of the summary

## Waiver of informed consent (DHHS-regulated research)

The only record linking the subject and the research 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 research, and the subject's wishes will govern; or

That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

## Waiver of Signed Consent (FDA-regulated research)

- the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or
- separate Emergency Use form has been completed (IRB Chair only)

### Alteration of Elements of Informed Consent (DHHS-regulated research only--does not apply to FDA-regulated research)

- The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.
- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

For Parental Permission and Minor Assent--See IRB Wise application concerning Research Involving Children, Subpart D