Informed Consent Minimal Requirements Basic and Additional Elements

	Key information as first paragraph to assist prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. (Ex.: research, voluntary, purpose, duration, procedure, risks, benefits, appropriate alternative procedures)
	A statement that the study involves research.
	An explanation of the purpose of the research.
	The expected duration of the participant's involvement.
	A description of the procedures to be followed.
	Identification of the procedures that may be experimental.
	A description of any reasonably foreseeable risks of discomforts to the participant.
	A description of any benefits to the subject or others which may reasonably be expected from the research.
	A disclosure of appropriate alternative procedures of course of treatment, if any, that might be advantageous to the participant.
	A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained and that notes the possibility that the FDA may inspect the records.
	A statement that participation is voluntary, that refusal to participate or withdrawal from participant in the study will involve no penalty, no loss of benefits to which the participant is otherwise entitled to.
	A statement with information about whom to contact with questions about adverse event: to whom to contact with questions about participant rights and to whom to contact with questions about the study.

Additional elements:

	A statement that a particular treatment or procedure may pose risks for the subject (or fetus) if the subject would become pregnant, that are unforeseeable.
	Additional costs to the subject and under what circumstances.
	The consequences of subject withdrawal from participation (lab tests, follow-ups for safety reasons)
	A statement that if important additional significant new findings arise that may be pertinent to the subject's willingness to participate, that these will be provided to the subject.
	Number of participants.
	Whether clinical results during the study will be shared with the participant or not.
	In research that involves the collection of identifiable private information or identifiable biospecimens, either a statement that even if identifiers are removed the data or biospecimen will not be used in other studies, or alternately, that de-identified data/biospecimens could be used for other unrelated studies, by other or the same researchers, without additional informed consent from the subject or legal representative (if this were a possibility).
	Statement that biospecimens devoid of identifiers, can be used for commercial purposes and the extent of subject rights to commercial profits.
	General description of the types of research that can be carried out with these biospecimens or identifiable data.

	A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.

	The length of time during which private identifiable information/biospecimens may be stored or used for other research.
	Whether the subject (or representative) will be told about the other research in which his/her private identifiable information will be involved or a statement that this information will not be shared with the subject.

Waiver of Consent

An IRB can waive the consent in research involving public benefit programs, procedures for obtaining benefits, possible changes to those programs and research cannot be carried out without the waiver for practical reasons.

An IRB can waive or alter consent if:

1) _____Risk is minimal

2) _____Cannot be carried out for practical reasons, if a consent is taken

3) _____The waiver will not adversely affect the rights or safety of the subjects

4) _____Whenever appropriate, subjects will be given additional pertinent information after participation.

5) _____When research review involves obtaining the information as a 1 shot, without recording identifiers; such that at the end of the day the researcher cannot know what information belongs to whom.

An IRB can waive a signed informed consent form when:

1)The risk is less than minimal

_____

2) _____The only link to the study would be the signed document

3) _____The principal risk is a breach in confidentiality and involves no procedures for which an informed consent would be required

4) _____The IRB can require the researcher to provide written information to the subjects and if the subjects are members of a group, culture where informed consents are not the norm.

Screening, recruiting or determining eligibility. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens with the purpose of screening, recruiting or determining eligibility if:

1) _____The investigator will obtain oral or written information with the prospective participant

2) _____The investigator will obtain identifiable private information or biospecimens by reviewing records or stored biospecimens.

3) _____If an individual were asked to provide broad consent for the storage, maintenance and secondary research use of private identifiable data or biospecimens, the IRB CANNOT WAIVE CONSENT.

Documentation of the Informed Consent

The informed consent must be documented by a written document approved by the IRB, and signed by the participant or the participant's legal representative at the time of the consent. A copy should be given to the person signing the form.

The consent form may be either of the following:

1)_____A written document that embodies the elements of informed consent required by section 50.25/_.116(a)(5). This form may be read to the participant or the participant's legally authorized representative, but in any event, the investigator will provide the participant or the participant's legal representative sufficient time to read the form before it is signed.

_____ 2)Short form written consent document stating that the elements of informed consent required by section 50.25 have been presented to the prospective participant or his/her legal representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the representative in addition to a copy of the short form.

3) Informed consents of clinical trials must be posted on the federal web site.