

## INFORMED CONSENT

### AS OF JANUARY 21, 2019, the following will be in effect regarding informed consent:

- A. The purpose is to enhance participant autonomy and to make informed consent process more meaningful by ensuring they have the key information to make an informed choice to participate based on their own values
- B. The *reasonable person* standard must be used to determine what information to include on the consent form.
- C. Information must be presented in sufficient detail, and organized and presented in a way that facilitates the participant's understanding of why one may or may not want to participate in the research. This means that a list of facts will be insufficient.
- D. Verbiage should reflect how the person should think about what participation in the research would mean to them. The goal is to make the informed consent easier for the participant to process what is involved with participation in the research.
- E. The PI must be fully aware that Informed consent is not valid unless the prospective subject understands the information that has been provided. This is a major responsibility of the PI to ensure.

The following considerations will guide the PI in determining the appropriate way to present the information.

- 1) characteristics of the proposed subject population's levels of cognition and literacy,
- 2) the complexity of the information to be conveyed,
- 3) each subject's emotional state, and
- 4) the setting under which the consent process will take place.

F. *Informed consent is an ongoing process:*

The PI and research team involved in sample recruitment, consenting and data collection must be fully aware that a participant's initial decision to take part in research is not binding. Especially for protocols involving any type of sensitive topic, the PI should periodically ask if the participant is fine to continue in the study. Participants may choose to stop participating for any reason or without cause.

G. Certain key information must be provided first on the form, especially if this is a clinical trial in which consent forms tend to be lengthy.

- Key information can include, **in simple language**, about why one might want or not want to participate. This often includes information about purposes, risks, benefits and alternatives (when appropriate).
- This must be presented in a concise, focused manner.
- Information from a research proposal or application should not be copied and pasted into a consent form as this is typically higher level language.

H. If there is ANY chance that participant data could be used for future research and will be stripped of identifiers prior to that, this must also be explicitly stated in the consent form.

I. The following 3 elements must be included in any consent form if applicable:

- i. Notice about possible commercial profit: A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- ii. Notice about whether clinically relevant research results will be given to participants
- iii. Notice about whether research might include whole genome sequencing for biospecimens

J. For federally-funded clinical trials, one IRB-approved consent form used to enroll participants must be posted on a designated federal website

- i. Must be posted after recruitment closes, no later than 60 days after

- the last study visit
- ii. Federal department or agency may permit or require redactions.

K. Waiver of Consent for research with identifiable private information or identifiable biospecimens.

- i. The IRB must determine that the research cannot be *practicably* carried out without using such information or biospecimens in an identifiable format, and that the IRB determines that benefits outweigh risks of identifiability of biospecimens.
- ii. However, out of respect for participant autonomy, non-identifiable data should be used whenever possible.

L. Waiver of Consent for Screening, Recruiting, or Determining Eligibility

- i. The IRB may approve a proposal to obtain information or biospecimens to screen, recruit, or determine eligibility of prospective subjects without informed consent, if obtained through:
- ii. Oral or written communication with subject or LAR
- iii. Accessing records or stored identifiable biospecimens

## I. **GENERAL REQUIREMENTS**

1. Except as described in Section III below, PIs may not enroll human subjects in research unless they have obtained the legally effective, written, informed consent of the subject or the subject's legally authorized representative who is responsible for clinical decision authorization *prior* to enrollment of the subject in the research.
2. PIs submitting protocols where health information of participants is involved must also refer to the HIPAA Policy in Research. PIs and anyone else involved with the study must be cognizant of the federal regulations regarding protection of health information for participants in research. Participants will need to sign a HIPAA Consent Form in addition to the written informed consent form.
3. PIs are responsible for insuring that subjects, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence.
4. Information given to potential subjects or their representatives must be in language that is understandable to the subject or representative.
5. A typical informed consent should be written at no higher than an 8<sup>th</sup> grade level of reading, and tailored to less than that as appropriate. The IRB uses the Flesch-Kincaid Grade Level readability formula on

<https://readabilityformulas.com/freetests/six-readability-formulas.php> to assess readability.

6. Any time literacy levels are questioned and understanding of the informed consent process by a potential participant may be questionable, the PI should assure verbal understanding of the potential participant of the following: general purpose of the research; voluntary nature of participating and ceasing participation with no adverse consequences; who to contact other than the PI if questions about the research; expectations of potential participation; and risks.
7. No process of obtaining consent may include exculpatory language through which the subject waives any of his/her legal rights, or releases or appears to release the PI, sponsor, or institution or its agents from liability for negligence.
8. The IRB must approve the consent form before it is used, and it must approve any changes made to a previously approved consent.
9. Subjects must be given a copy bearing the IRB approval stamp.
10. The IRB has the authority to observe the consent process and may do so without prior notification to the PI.

## **II. ONGOING INFORMED CONSENT**

Informed consent is communication process that continues during the entire study. Many of the elements of informed consent previously discussed apply throughout the study. The PI and research team should:

- Feel confident that the participant maintains the ability to understand information, make an informed decision, and voluntarily continue to participate.
- Provide written and oral information about emerging study details in a manner understandable to the participant.
- Be satisfied that the participant understands the information provided, has had an opportunity to discuss the information and ask questions, and understands that he or she may withdraw from the study at any time.

When changes in the study occur, and/or significant new findings develop during the course of the study that may affect the participant and his or her willingness to continue participation, additional informed consent may be necessary. Continuation of the study may require having participants sign a new consent form (obtaining re-consent). All proposed changes in the protocol and the consent must be submitted to the IRB. PIs should consult the IRB for the requirements for study changes and re-consent procedures.

1. The IRB has a sample consent forms which contains all the required

elements of consent: (a) for anonymous surveys; (b) expedited research; (c) full board .

2. The UT Tyler IRB requires that all consent forms be written in the second person, e.g., “you should understand that...”
3. The signature page may be written in the first person, e.g., “I understand that...” The following are the required elements (extracted from 45 CFR Part 46.116 and 21 CFR 50.25):
4. Basic Elements of Informed Consent:
  - a. A statement that the study involves research, an explanation of the purposes of the research, the duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
  - b. A description of any reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable;
  - c. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that since it is an experimental treatment or procedure, no benefits can be guaranteed;
  - d. A discussion of possible alternative procedures or treatments, if any, that might be advantageous to the subject. One alternative might be to choose not to participate in the research;
  - e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA, the sponsor, the UT Tyler IRB, or others may inspect the records;
  - f. For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if a research-related injury occurs and, if so, what they consist of, or where further information may be obtained;
  - g. An explanation of whom to contact for answers to pertinent questions about (i) the research (generally the PI or another staff member closely associated with the study), (ii) the rights of the research subject (usually the IRB chairperson), and (iii) any research-related injury to the subject (generally the PI or another staff member closely associated with the study). For item (iii), this should be a telephone number or numbers whereby the research subject can reach an appropriate person 24 hours a day, not just during normal working

hours; and

- h. 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.
- i. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is becomes pregnant), which are currently unforeseeable;
- j. Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent;
- k. A description of any additional costs for which the subject will be responsible, that may result from participation in the research study;
- l. The consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject;
- m. 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;
- n. A description of any compensation or reimbursement for time, inconvenience, travel, and other similar costs to the subject; and
- o. The anticipated number of subjects that will be involved with the study, both totally and at UT Tyler.

#### **IV. WAIVER OF INFORMED CONSENT**

The IRB may waive the requirements for obtaining informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed above, provided that:

Subject's signature can be waived if:

- i. Subjects are members of a distinct community in which signing forms is not the norm

- ii. Research involves no more than minimal risk
- iii. An alternative method for documenting consent is used

The 4 criteria for waiver of consent:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB may waive requirements for obtaining signed informed consents under the following circumstances:

- i. 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, or
- ii. The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.
- iii. Subjects are members of a distinct community in which signing forms is not the norm
- iv. An alternative method for documenting consent is used

There are more stringent and specific requirements for the IRB waiver of informed consent in emergency situations in which the research involves more than minimal risk to the subjects. Information on the requirements and procedures may be obtained from the IRB Chair.

## **V. DOCUMENTATION OF INFORMED CONSENT**

1. Documentation of Consent  
(added in the appropriate section below)
2. Electronic Signatures on Consent Forms are acceptable
3. Legally Authorized Representatives (LAR)

Current policy reflected in #1 below

**VI. RECORD RETENTION REQUIREMENTS FOR SUBJECT CONSENT FORMS**

1. The PI shall maintain, in a designated location, all executed subject consents.
2. These consent forms are to be available for inspection by authorized officials of the UT Tyler administration and IRB, as well as the FDA, DHHS, and other regulatory agencies and sponsors.
3. For FDA regulated test article studies, all signed subject consent forms shall be retained by the PI for the appropriate period(s) specified below.

Drugs: Three (3) years following the date a marketing application is approved or the study is discontinued.

Devices: Three (3) years after a study is terminated or completed, or longer if the records are needed to support FDA approval.

4. Should a PI depart from UT Tyler prior to the completion of an activity, the PI is responsible for initiating mutually satisfactory arrangements with his or her department and the UT Tyler administration as to the disposition of executed subject consents.

**VII. INFORMED CONSENT OBTAINED BY TELEPHONE**

An oral approval does not satisfy the [21CFR56.109\(c\)](#) requirement for a signed consent document, as outlined in [21CFR50.27\(a\)](#). However, it is acceptable to send the informed consent document to the subject by facsimile or standard mail and conduct the consent interview by telephone when the subject can read the consent as it is discussed. If the subject agrees, he/she can sign the consent and return the signed document by facsimile or standard mail.

When the subject makes the first study visit, informed consent must be obtained again. This is to ensure that the patient understands the study and in fact still wants to participate. Both informed consents should be kept on file.

Any questions regarding this process should be directed to the IRB Chair.