The University of Tulsa Institutional Review Board (TU IRB)
INFORMED CONSENT FORM (ICF)
GENERAL INSTRUCTIONS * FAQS * ADDITIONAL CONSENT ELEMENTS/SAMPLES

PLEASE READ BEFORE COMPLETING THE CONSENT FORM TEMPLATE

WHICH CONSENT FORM SHOULD I USE? Select the Informed Consent Form(s) appropriate for your study:


Online ICF – For online research of adult subjects (18 years or older) when you can waive documentation of consent (not collecting signed forms) *See frequently asked questions (FAQs) on next page https://35ht6t2ynx0p1ztf961h81r1-wpengine.netdna-ssl.com/wp-content/uploads/2018/01/TU-IRB-Online-ICF-2018CR.pdf


Assent Form – For minor subjects (under 18 years old) OR adult subjects with cognitive impairment and MUST be accompanied with a Parent/Guardian/LAR ICF https://35ht6t2ynx0p1ztf961h81r1-wpengine.netdna-ssl.com/wp-content/uploads/2018/01/TU-IRB-Assent-for-Minors-Form-2018CR.pdf

Broad Consent Form – It is an optional alternative to the informed consent requirements and ONLY used for the store, maintain, and/or use identifiable private information or identifiable bio-specimens for secondary research use (where the identifiable data was collected from either a research study other than the proposed future research or from a non-research purpose) https://35ht6t2ynx0p1ztf961h81r1-wpengine.netdna-ssl.com/wp-content/uploads/2018/01/TU-IRB-Broad-Consent-2018CR.pdf

WHAT ARE THE SHORT FORMS AND WHEN CAN I USE THEM? The SHORT Forms (informed consent forms) are a condensed version of the ICFs and used for no/low risk, simple studies, where the condensed initial paragraph is sufficient to explain the study and no additional information is needed for subjects to make an informed decision about participating.

HOW WILL I KNOW IF THE SHORT FORM IS APPROPRIATE?

Ask yourself: If there is no additional information that I have to explain to participants about their risks, benefits, data/identity protections, and study procedures that you have not already written in the, “WHAT IS THE KEY INFORMATION I NEED TO KNOW TO HELP ME DECIDE…” section, then you can use the appropriate SHORT FORM. If you are still not sure, contact the Research Compliance Coordinator.

- ALWAYS get your IRB application documents from the TU IRB Webpage, to ensure the latest version. Go to: https://utulsa.edu/research/office-research/research-compliance/irb-protection-human-subjects/

- Follow the blue, italicized and/or bracketed [ ] instructions after the title headings of each section on all consent/assent forms. ONLY delete: the blue, italicized and/or bracketed [ ] instructions at the top of each section OR when you’ve been given a choice of statements to use in a section and then delete the rest. Most black text is REQUIRED language and needs to remain in that section.

  You can delete entire sections of the Informed Consent Form ONLY WHEN instructions explicitly state that you may delete the section, if not applicable to your study: *
  
  [This section can be deleted if not applicable to your study]

- Write in clear and concise simple language and keep forms as short as possible. Tailor the language to your participants’ needs, using simple words that your potential participants will understand. If your prospective subjects are the general adult public, use language/vocabulary not above 8th grade reading level. Write in the 2nd person as if they are standing right in front of you and you are answering their questions (“you” are being asked to… “your” responses…)

v2018CR
• The last page of this form has Additional Consent Requests to copy and paste over to your consent form whenever applicable. Examples of research activities that require an additional signature approval include: audio or visual recordings for research purposes or for public use, future contact of participants, etc.

• If you are paying human subjects any dollar amount via check or cash/gift card over $25 [PLEASE NOTE: The TU Controller’s Office requires identifying information to issue checks of any dollar amount or to track payment via cash or gift certificates over $25 to payees. [In those cases, the Confidentiality section of the consent form must inform participants that they will be asked to provide their Name, Address and Social Security Number to receive compensation.] This information will be provided to the Controller’s Office at the time of payment (payment/compensation is made via a check) or at the end of the year. *For privacy protections, do not write the study title on the Controller’s Office paperwork. Just write, “Payments to Human Subjects”. For more information see Payments to Human Subjects Policy: https://35ht6t2yxn0p1ztf961h81r1-wpengine.netdna-ssl.com/wp-content/uploads/2015/01/Pymts-to-Human-Subjects-policy-v.2016.01.07.pdf

9 ADDITIONAL ELEMENTS REQUIRED TO BE ADDRESSED ON THE ICF WHEN APPLICABLE TO YOUR STUDY:

[When any of the 9 items below are applicable to your study, you are REQUIRED to provide additional information on the ICF.] Copy and Paste the section title: “ADDITIONAL ELEMENTS OF INFORMED CONSENT”, and address the item(s) as needed on your consent form:

(1) 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) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s or the legally authorized representative’s consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by 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;

(6) The approximate number of subjects involved in the study *already on the TU Informed Consent Forms;

(7) A statement that the subject’s bio-specimens (even if identifiers are removed) may be used for commercial profit and whether the subject 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 bio-specimens, 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).

(ONLY FOR ANY RESEARCH INVOLVING MORE THAN MINIMAL RISK - FULL BOARD PROTOCOLS) – *[ADD this section to your ICF if applicable to your study]*

WILL I BE COMPENSATED FOR ANY INJURY RELATED TO THIS STUDY OR WILL ANY MEDICAL TREATMENTS BE AVAILABLE IF I GET INJURED? [For research involving more than minimal risk, explain whether or not any compensation or medical treatment is available if injury occurs. If compensation or treatment will be provided, describe the nature of the compensation and/or treatment. If no compensation will be available, make that clear in this section. Explain how the subject can obtain additional information if necessary.]
Are there any alternative procedures or courses of treatment other than participating in this study? [Disclose any appropriate, alternative procedures or courses of treatment (other than participating in this study), that might be advantageous to the subject]

When am I allowed to waive documentation of consent (no signed consent forms, internet research using the online consent form)?

Criteria to Waive Documentation of Informed Consent

§46.117 (C)(1) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or
(ii) 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; or
(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

When am I allowed to alter or waive parts or all of the informed consent?

Criteria to Alter or Waive Parts or All of Informed Consent

§46.116 (F)(3) In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research involves no more than minimal risk to the subjects; and
(ii) The research could not practicably be carried out without the requested waiver or alteration; and
(iii) If the research involves using identifiable private information or identifiable bio-specimens, the research could not practicably be carried out without using such information or bio-specimens in an identifiable format; and
(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Examples of additional signed consent to use as needed

*Copy and paste over to your consent form and change the text to fit your study*

Samples of required additional consents and signature lines —When needed

Below are examples of additional consent where an additional signature line is required. These examples can be copied and pasted into the informed consent form when applicable. (You may change the wording to fit your study)

**Please address if the additional consent is optional or a condition of participation and change the text to fit your study**

Optional consent for future contact

The researcher may wish to contact you in the future about new research studies. Please check the appropriate statements to indicate whether or not you give permission for future contact.

☐ I give permission to be contacted in the future about new research studies.
☐ I do not give permission to be contacted in the future about new research studies.

☐ I give permission to be contacted in the future for information relating to this study.
☐ I do not give permission to be contacted in the future for information relating to this study.

____________________________________________________
Signature of Participant or Legally Authorized Representative

____________________________
Date
AUDIO RECORDING OF STUDY ACTIVITIES: To assist with accurate recording of participant responses, interviews may be audio recorded.  [Explain if names will not be used during recording.]  Participants have the right to refuse to allow such recording without penalty.  Please select one of the following options.

☐ I consent to the use of audio recording.
☐ I do not consent to the use of audio recording.

Signature of Participant or Legally Authorized Representative  Date

________________________________________________________

VISUAL RECORDING OF STUDY ACTIVITIES: To assist with accurate recording of participant responses, interviews may be visually recorded.  [Explain if faces will be blurred out for photos/videos and for audio, address if names will not be used during recording.]  Participants have the right to refuse to allow such recording without penalty.  Please select one of the following options.

☐ I consent to the use of a visual recording.
☐ I do not consent to the use of a visual recording.

Signature of Participant or Legally Authorized Representative  Date

________________________________________________________

CONSENT TO AUDIO AND VISUAL RECORDINGS DURING STUDY ACTIVITIES FOR RESEARCH PURPOSES:
With your permission, you will have the following done during this research (check all that apply):

☐ photography/still visual shots  ☐ visual recording  ☐ audio recording

To assist with accurate recording of participant responses, assessments and follow-up appointments may be visual or audio recorded.  [Explain if faces will be blurred out for photos/videos or if audio and if names will not be used during recording.]  Participants have the right to refuse to allow such recordings without penalty.  Please select one of the following options.

☐ I consent to the use of audio/visual recordings for research purposes.
☐ I do not consent to the use of audio/visual recordings for research purposes.

Signature of Participant or Legally Authorized Representative  Date

________________________________________________________

If you have any questions completing the IRB documents or to submit your completed IRB protocol documents, contact:
Carmen Skaar-Walden, Coordinator of Research Compliance
The University of Tulsa • Office of Research and Sponsored Programs
McClure Hall, Room 205-C • 918-631-3310 • carmen-schaar-walden@utulsa.edu