**The University of Tulsa Institutional Review Board (TU IRB)**

**INFORMED CONSENT FORM (ICF)**

**GENERAL INSTRUCTIONS \* ADDITIONAL CONSENT ELEMENTS/SAMPLES**

**PLEASE READ BEFORE COMPLETING THE CONSENT FORM TEMPLATE**

**SELECT THE INFORMED CONSENT(S) APPROPRIATE FOR YOUR STUDY:**

[**General Informed Consent Form**](https://utulsa.edu/wp-content/uploads/2019/01/TU-IRB-General-ICF-v1.14.2019.docx) –For **adult subjects** **(18 years or older)** [Sample General ICF](https://utulsa.edu/wp-content/uploads/2019/07/Sample-General-ICF.pdf)

[**Online Informed Consent Form**](https://utulsa.edu/wp-content/uploads/2019/01/TU-IRB-Online-ICF-v1.14.2019.docx) **–** For **online research of adult subjects (18 years or older)** when you can waive documentation of consent ***(not collecting signed forms)*** [Sample Online ICF](https://utulsa.edu/wp-content/uploads/2019/07/Sample-Online-ICF.pdf)

[**Parent/Guardian/LAR Informed Consent Form**](https://utulsa.edu/wp-content/uploads/2019/01/TU-IRB-Parent.Guard_.LAR-ICF-v1.14.2019.docx) – For ***adult parent/guardian of a minor subject*** OR a ***Legal Authorized Representative (LAR)******of an adult subject with cognitive impairment****.* ***This form MUST be accompanied with an Assent Form if the minor or cognitive impaired adult subject is able to consent*.**
[Sample Parent/Guardian ICF](https://utulsa.edu/wp-content/uploads/2019/07/Sample-Parent-Guardian-ICF.pdf)

[**Assent Form**](https://utulsa.edu/wp-content/uploads/2019/01/TU-IRB-Minor-Assent-Form-v1.14.2019.docx) – For ***minor subjects (under 18 years old)* OR *adult subjects with cognitive impairment and MUST be accompanied with a Parent/Guardian/LAR ICF.*** [Sample Assent Form](https://utulsa.edu/wp-content/uploads/2019/07/Sample-Assent-Form.pdf)

**Debrief and Second Consent Form –** For **adult subjects (18 years or older)** with an **element of deception** [Sample Debrief & Second ICF](https://utulsa.edu/wp-content/uploads/2019/07/Sample-Debrief-and-Second-ICF.pdf)

[**Broad Consent Form**](https://utulsa.edu/wp-content/uploads/2019/01/TU-IRB-Broad-Consent-v1.14.2019.docx) **–** It is an ***optional*** alternative to the informed consent requirementsand **ONLY used to 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).

**GENERAL INSTRUCTIONS FOR USING CONSENT FORMS**

* **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…)
* 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://35ht6t2ynx0p1ztf961h81r1-wpengine.netdna-ssl.com/wp-content/uploads/2015/01/Pymts-to-Human-Subjects-policy-v.2016.01.07.pdf).
* ALWAYS get your IRB application documents from the TU IRB Webpage, to ensure the latest version. Go to [IRB Protection of Human Subjects](https://utulsa.edu/research/office-research/research-compliance/irb-protection-human-subjects/).

 **WHEN DO YOU NEED TO ADD ADDITIONAL ELEMENTS OF CONSENT TO YOUR INFORMED CONSENT FORM TEMPLATE?**

**ADDITIONAL ELEMENTS REQUIRED TO ADDRESS ON THE ICF WHEN APPLICABLE TO YOUR STUDY:**

1. **Read the full list of additional elements of consent to see if any are applicable to your study. If applicable, go to link for the particular section for additional and add that information.**
2. **In your consent form it should be titled ‘Additional Elements of Informed Consent” title below and provide the additional information requested**

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)** 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;

**(7)** A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;

**(8)** 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).

**(9) IF INJURY IS POSSIBLE DUE TO PARTICIPATING IN YOUR STUDY:**

**WILL YOU BE COMPENSATED FOR ANY INJURY RELATED TO THIS STUDY OR WILL ANY MEDICAL TREATMENTS BE AVAILABLE IF YOU GET INJURED?** *[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.]*

**(10) 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]*

 **(11) DO YOU WANT TO CONTACT THE RESEARCH PARTICIPANT FOR FUTURE RECRUITMENT?**

*[Copy and paste the optional consent below into your form template]*

**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.

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Signature of Participant or Legally Authorized Representative Date

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**(12) DO YOU WANT TO RECORD PORTIONS OF THE SESSION?** *[ Choose one of the recording options below that best fits your study and copy/paste it onto your form template. Change the language to fit your study.]*

**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. *[Explain if subjects can participate in the study if they do not consent to the recording.]* 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 |

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**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 if names will not be used during recording.]* Participants have the right to refuse to allow such recording without penalty. *[Explain if subjects can participate in the study if they do not consent to the recording.]* 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.

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| --- | --- | --- |
|  |  |  |

Signature of Participant or Legally Authorized Representative Date

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**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. *[Explain if subjects can participate in the study if they do not consent to the recording.]* 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 |

**WHEN ARE YOU ALLOWED TO WAIVE DOCUMENTATION OF CONSENT (no signed consent forms)?**

**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 ARE YOU 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:**

1. The research involves no more than minimal risk to the subjects; **and**
2. The research could not practicably be carried out without the requested waiver or alteration; **and**
3. 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**

1. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

**If you have any questions completing the IRB documents or to submit your completed IRB protocol documents, contact:**

researchcompliance@utulsa.edu, 918-631-3310