

***Informed Consent Template - General***

Informed consent is required to provide potential subjects or their legally authorized representatives with the information necessary for them to make a decision about participating in research.

Information in the consent document must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level. The reading level can be higher if the target population tends to have a higher literacy rate than the general population.

1. Regulations require that research projects with long informed consent documents begin with a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study.

Many IRB studies have brief consent documents (2 or 3 pages) that meet this new requirement without the need for a separate key information section. However, if your project is complex, involves numerous research procedures, or the consent document is more than 3 pages in length, this information section is required.

A template for key information sheets may be found on the UT IRB Website [Forms Page](https://research.utexas.edu/ors/human-subjects/irb-forms/) in the “Standard Consent Language” document.

1. Text in [brackets] represents information about your study that you must add (in plain text).
2. A backslash indicates that you must make a selection depending on the procedures for your study (e.g., “will/will not”).
3. Additional instructions or sample text are provided in blue boxes.
4. **Before you upload your consent document to IRBaccess, delete this cover page, brackets, and boxes.** The finished document should reflect what you will give to the subject. To delete the boxes, select all text and delete.
5. Use a file name for each consent document such that it clearly identifies type of consent and for which subjects it is intended (e.g. child assent, parental permission, adult consent, etc.).
6. Many studies at conducted at UT Austin involve the use of similar instruments, measures, and devices. The Office of Research Support & Compliance maintains a library of standard consent language for researchers to use. See the “Standard Consent Language” document located on the UT IRB Website [Forms Page](https://research.utexas.edu/ors/human-subjects/irb-forms/) for sample language and definitions.

For more information on plain language go to <http://www.plainlanguage.gov/>.

**DELETE THIS INSTRUCTION PAGE FROM THE CONSENT FORM PRIOR TO SUBMITTING TO THE IRB**

UT Austin IRB Approved

Protocol Number:

Approved:

Title of the Project:

Principal Investigator: [Name, credentials, institutional affiliation]

Faculty Advisor: [Name, credentials, institutional affiliation]

Study Sponsor: [If any]

*Include Faculty Advisor information if you are a student, resident, or post-doc.*

*Include the full name of the Study Sponsor. If there is no Sponsor, delete this item.*

**Consent to Participate in Research**

**Invitation to be Part of a Research Study**

You are invited to be part of a research study. This consent form will help you in choosing whether or not to participate in the study. Feel free to ask if anything is not clear in this consent document.

**What is the study about and why are we doing it?**

The purpose of the study is [describe the study purpose].

*Include in this section a full and complete description of the purpose of the study and any necessary background information regarding why you are conducting the study.*

**What will happen if you take part in this study?**

If you agree to take part in this study, you will be asked to [provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how)].

*Include in this section a full and complete description of the study procedures explained from the participant’s perspective. After reading this section, the participant should have a good understanding of what they will experience and be asked to do.*

*If the study involves the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the type of questions that will be asked or describe the sensitive topic areas that are involved.*

**How long will this study take and how many people will be in the study?**

Participation in this study will take [add amount of time] and include [##] of participants.

**What risks and discomforts might you experience from being in this study?**

There are some risks you might experience from being in this study. They are [describe specific risks and indicate what the study team will do to minimize those risks].

*Include in this section a full and complete description of all reasonably foreseeable risks and discomforts the participants might experience. It is not acceptable to say that there are no risks.*

*Primary risks include psychological or informational risks. Informational risks could include those involving breach of confidentiality. Psychological risks (e.g., those associated with the completion of a particularly sensitive survey) could be mitigated by providing subjects with contact information for counseling resources.*

*If there is a risk of loss of confidentiality state so, but do not include information regarding how researchers safeguard against this risk. This will be addressed later.*

*Many studies at UT Austin involve the use of similar instruments, measures, devices, etc. The Office of Research Support & Compliance maintains a library of standard/sample language that successfully conveys these risks to participants. See the* ***Standard Consent Language*** *document located on the* [*Forms Page*](https://research.utexas.edu/ors/human-subjects/irb-forms/) *for sample language and definitions.*

**How could you benefit from this study?**

You will receive no direct benefit from participating in this study; however, [explain benefits to society].

**What data will we collect from you?**

As part of this study we will collect [describe data being collected].

**How will we protect your information?**

We will protect your information by [explain]. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

**[OR]** [Describe limitations to confidentiality, if any.]

Information about you may be given to the following organizations:

* The study sponsor and/or representative of the sponsor **[delete if there is no sponsor]**
* Representatives of UT Austin and the UT Austin Institutional Review Board
* Other collaborating organizations **[list other orgs or delete if not applicable]**
* Officials of the Department of Health and Human Services or the Federal Food and Drug Administration **[FDA may be deleted if this is not an FDA regulated study]**
* **[If research is conducted in foreign countries include the following:]** This research is also being conducted in foreign countries, so personal information pertaining to you may be shared or copied by authorized agents of governmental agencies in those countries.

*Include one of these statements:*

*Option 1:*

We will share your data with other researchers for future research studies that may be similar to this study or may be very different. The data shared with other researchers may include information that can directly identify you. Researchers will not contact you for additional permission to use this information.

*Option 2:*
We will share your data with other researchers for future research studies that may be similar to this study or may be very different. The data shared with other researchers will not include information that can directly identify you.

*Option 3:*
The data that we will collect about you will not be shared with any other researchers.

*Option 4 (include only if data will be added to a registry/repository):*

If you agree, we plan on sharing your data or samples with other researchers. Those researchers in turn may share your data or samples with additional researchers. Their storage/sharing policies are outlined on a separate form. Future research studies may be similar to this study or may be very different. The data shared with other researchers may include information that can directly identify you. Researchers will not contact you for additional permission to use this information.

*Include of the following:*

We plan to publish the results of this study. To protect your privacy, we will/will not include any information that could directly identify you.

**What will happen to the information we collect about you after the study is over?**

We will/will not keep your research data to use for [insert: future research or describe other purpose]. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

**[OR]** Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

**How will we compensate you for being part of the study?**

You will receive [nature and total amount of incentive/compensation] for your participation in this study. [Describe how compensation will be determined if the subject withdraws from the research before the end of the study.]

You will be responsible for any taxes assessed on the compensation.

**[OR]**

You will not receive any type of payment for your participation.

**What other choices do you have if you do not take part in this study?**

*Describe alternatives to participation if applicable.*

*For studies that involve recruitment via the PSY301 subject pool, describe the alternative assignment available.*

***Delete this section if not applicable to the study.***

**Your Participation in this Study is Voluntary**

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin [add as appropriate: and your school, your doctor, or healthcare provider, etc.]. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you decide to withdraw before this study is completed, [provide details about disposition of data]

**Contact Information for the Study Team and Questions about the Research**

***Include the following information:***

*1. Contact information for UT Principal Investigator and*

*2. Contact information for an alternate contact if available (e.g., faculty sponsor if student investigator is conducting the study, a medically responsible investigator, or a research coordinator)*

*3. Contact information for who to contact in case of an injury if applicable and if different from the UT PI*

*Provide at least 2 methods of directly contacting the PI (e.g. mail, phone, email, pager).*

*The PI’s mailing address must be provided if HIPAA Authorization language is included in this consent form.*

If you have any questions about this research, you may contact:

[Name of PI]

Phone:

Email:

Or

[Name of secondary contact person(s)]

Phone:

Email:

**Contact Information for Questions about Your Rights as a Research Participant**

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin

Institutional Review Board

Phone: 512-232-1543

Email: irb@austin.utexas.edu

Please reference study number XXXX-XX-XXXX.

**Your Consent**

*Required for projects obtaining a signature only – delete this paragraph for projects that will request a waiver of documentation.*

*For projects involving a waiver of documentation, delete the paragraph and signature lines and include the following:*

Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records [or you can print a copy of the document for your records]. If you have any questions about the study later, you can contact the study team using the information provided above.

*For subjects completing online survey(s), delete the paragraph and signature lines and include the following:*

By clicking the button below, you are agreeing to be in this study. If at any time you wish to stop participating, simply close your browser window.

*For projects adhering to GCP requirements, add an additional line for signature of person obtaining informed consent and the date.*

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Signature of Person Obtaining Consent Date

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

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Printed Subject Name

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Signature Date

**Legally Authorized Representative Permission**

***Delete this section if not applicable to the study.***

By signing this document, you are agreeing to the person’s named below participation in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [the person named below] to take part in this study.*

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Printed Subject Name

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Printed Legally Authorized Representative Name and Relationship to Subject

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Signature Date