**Texas Woman’s University Institutional Review Board (IRB)

Guide to Writing a Consent Form**

For studies that require written informed consent, these guidelines provide minimum standards for preparation of the written consent form. **When writing your consent document, make sure that all items on the consent form match the information provided to the IRB in the application form.**

**REQUIRED ELEMENTS OF INFORMED CONSENT**

1. The heading:

 **TEXAS WOMAN'S UNIVERSITY**

 **CONSENT TO PARTICIPATE IN RESEARCH**

2. The title of your study.

3. The names, degrees, TWU email addresses, and office phone numbers of the investigator(s) and faculty advisor (if investigator is a student). Note that the type of degree should be used as opposed to the prefix “Dr.” and that the use of home phone numbers is not recommended.

4. A concise and focused presentation of key information that is organized and explained in a way that facilitates comprehension of the study.

The purpose of this section is to assist a potential subject or legally authorized representative understand reasons why one might or might not want to participate in the research. Please note that the information presented in this section should be discussed in greater detail later in the consent form. Hence, it is important to keep this section brief and simple in language. The length of this section can vary from a paragraph to a maximum of one page depending upon the field/type of study. Possible key informationincludes*,* butis *not limited to,* a summary of the items below. Note that not all of these items may be key information for every study.

* a statement that the study being conducted is for research (required),
* the purpose of the research (required),
* main study procedures or activities required of the subjects (required),
* total time commitment,
* major risks associated with participation in the study,
* significant inclusion or exclusion criteria for participation,
* setting of study,
* benefits of the study, or
* any other study-specific key information.

5. A description of the research study, which must include the following:

* A description of the procedures to be used in the study, including details of the participant’s involvement, and identification of any procedures that are experimental.
* The total time commitment for the participant.
* If audio or video recording will be used, an explanation of the purpose of the recording and who will have access to the recordings.

6. Potential risks

* A description of all potential risks to the participant and the steps that will be taken to minimize those risks.
	+ Include *loss of confidentiality* as a potential risk on the consent form as well as in the application since this can be a risk in every study involving human participants. Describe how the confidentiality of [identifiable private information](https://www.twu.edu/institutional-review-board-irb/definitions/private-information/) will be protected including where this information will be stored. If information will be destroyed as a protection of confidentiality, state how it will be destroyed and provide a timeframe such as “3 years from the end of the study.” Note that if identifiable information will be kept indefinitely, this must be disclosed to the participant. The following statement must be included on all consent forms:

***Confidentiality will be protected to the extent that is allowed by law.***

* + If electronic transmission of information is used (i.e., email, internet, online meeting platforms, etc.), add the following statement:

***There is a potential risk of loss of confidentiality in all email, downloading, electronic meetings, and internet transactions.***

7. Research collecting any [identifiable private information](https://www.twu.edu/institutional-review-board-irb/definitions/private-information/) and/or any [identifiable biospecimens](https://www.twu.edu/institutional-review-board-irb/definitions/identifiable-biospecimen/) must inform the subjects in the study what will happen to their identifiable private information and/or biospecimens. Researchers must include the (1) or (2) below:

1. A statement that identifiers will be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

If you would like to participate in the current study but not allow your de-identified data to be used for future research, please initial here \_\_\_\_\_\_\_\_.

1. A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

8. TWU Disclaimer Statement (add verbatim)

***The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.***

If using a Spanish consent form:

***Los investigadores tratarán de prevenir cualquier problema que pudiera suceder a causa de este estudio de investigación.  Usted deberá hacer del conocimiento de los investigadores tan pronto exista un problema, y ellos le ayudarán.  Sin embargo, TWU no provee servicios médicos ni ayuda financiera para atender daños o heridas que pudieran suceder debido a su participación en este estudio.***

9. A statement that participation is voluntary and participants may withdraw from the study at any time without penalty.

10. A description of any direct benefits or remuneration to the participant as a result of participation in the study. If there are no direct benefits, please state that there is none. If results will be available or provided to participants, include information on when and how the participant will be provided with results of the study, or how participants can ask for copies of the results.

11. Information for contacting TWU with questions

***You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study you should ask the researchers; their contact information is at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the Texas Woman’s University Office of Research and Sponsored Programs at 940-898-3378 or via e-mail at*** ***IRB@twu.edu****.*

If using a Spanish consent form:

***Usted recibirá una copia firmada y fechada de esta forma de consentimiento.  Si tuviera cualquier pregunta acerca de este estudio de investigación, favor de dirigir sus preguntas a los investigadores; sus números telefónicos se encuentran en la parte superior de esta forma.  Si usted tuviera preguntas acerca de sus derechos como participante en este estudio o acerca de la forma en que este estudio se está llevando a cabo, puede ponerse en contacto con la Oficina de Investigación y de Proyectos Auspiciados por Fondos Externos de la Texas Woman's University al número 940-898-3378 o por correo electrónico a*** ***IRB@twu.edu***

If obtaining consent online/electronically:

***You may print a copy of this consent page to keep. If you have any questions about the research study you should ask the researcher; their contact information is at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the TWU Office of Research and Sponsored Programs at 940-898-3378 or via e-mail at IRB@twu.edu.***

12. If the consent form is more than one page long, provide a line in the bottom right corner of each page except the signature page for the participant or parent/guardian to initial to indicate that they have read them. The pages of the consent form must be numbered using the following format: Page 1 of 3, Page 2 of 3, etc., under the line for participant initials.

13. Provide a signature line at the end of the consent form for the participant to sign and date the form. If the participant is a minor, provide a signature line for the parent/guardian to sign and date the form as well as an assent line for the minor if appropriate.

**POTENTIAL ADDITIONAL ELEMENTS OF INFORMED CONSENT**

When appropriate, the following elements(s) shall also be provided to each subject or the legally authorized representative:

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;
7. 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;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, 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).
10. A section may be added at the end of the consent for the address where the results of the study may be sent.