**REMINDER: Delete all guidance text found in red BEFORE IRB submission. The consent form should be written in 2nd person language (“you” statements) that is straightforward and easily understandable for the age, cultural background, and mental capacity of your intended participants. Consents for adults should generally be written at an 8th grade reading level.**See OHRP for more helpful guidance: <http://www.hhs.gov/ohrp/policy/ictips.html>.

**KEEP THE CONSENT FORM CONCISE, BRIEF, AND CLEAR.** Try to focus on what is important to the participant in making a decision about whether or not to participate.

**TITLE OF RESEARCH PROJECT**

Enter the project title – it **must** match the title used in your online IRB protocol submission.

**RESEARCH TEAM**

Provide the name, department, and contact details of the Principal Investigator (PI). If you are a student PI, also include the name, department, and contact information of your faculty advisor. Listing other research team members is optional and not recommended for protocols with frequent personnel changes, as this will necessitate modification submissions.

**SUMMARY OF IMPORTANT INFORMATION ABOUT THIS RESEARCH PROJECT**

|  |
| --- |
| *Per federal regulations, this section must be BRIEF and CONCISE – see* [*45 CFR 46(a)(5)(i)*](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)*.*  The research team above is conducting a research study about \_\_\_. Provide an explanation of the purposes of the research in simple, non-technical language; **Ex**: “The purpose of this research is to determine whether or not exercise may reduce stress in college students.” Or “This study is being done to help us understand how your immune system might influence your blood pressure and cardiovascular system.” You can choose to participate in this research study if you are explain the study inclusion & exclusion criteria briefly here, **i.e**. “between 18 and 25 years old; have no chronic health conditions; are not currently on any medications; and you have exercised fewer than two times a week for the past three months.”  The research study visits will be conducted at [location] and will include [very short, concise summary of procedures]. Completing the study will take about [insert amount of time / # of visits]. Possible risks of this study are [very concise list of greatest risks].  You might want to participate in this study if you (explain reasons why a person might want to participate, such as “if you want to potentially help others with your medical condition by contributing to scientific knowledge about your disease,” or “if you would like a chance to help UTA researchers understand more about the human body and develop scientifically sound ways to reduce stress in college students.”) However, you might not want to participate in this study if you (explain reasons why someone might reasonably not want to participate, such as “if you are uncomfortable with sharing your medical or sexual history with researchers”, “if you do not want to expose your body to the small amount of radiation that occurs during a DEXA scan,” “if you are afraid of taking the drugs used in this study,” or “if you do not have the time to attend two 3-hour study visits on the UT Arlington campus.”)  If you are interested in learning more about this study, please continue to read below. |

This study has been reviewed and approved by an Institutional Review Board (IRB). An IRB is an ethics committee that reviews research with the goal of protecting the rights and welfare of human research subjects. Your most important right as a human subject is informed consent. You should take your time to consider the information provided by this form and the research team, and ask questions about anything you do not fully understand before making your decision about participating.

**TIME COMMITMENT**

Explain how many study visits, interactions, or follow ups are expected for each subject, including the amount of time required for each visit and how long their total participation is expected to take (weeks, months, years, etc.) over the entire duration of the study.

**Ex:** Participation in this study will last approximately 30 minutes.

**Ex:** You will be asked to participate in 2 study visits on the UTA Campus in Arlington, Texas, and each visit will last approximately 30 minutes. The visits will be about 1 week apart.

**RESEARCH PROCEDURES**

Provide a description of all procedures to be followed by the subjects in sufficient detail for a lay-person to understand what to expect throughout the study. Identify any procedures which are experimental (i.e. not validated or are currently under investigation).

**Ex:** If you decide to participate in this research study, this is the list of activities that we will ask you to perform as part of the research:

1. Come to the SEIR building first floor clinical research labs.
2. Read through this Informed Consent and talk with the research team to make sure that any questions you may have are answered; then make your choice about whether to participate.
3. If you agree to participate, you will be asked to allow a member of the research team to take your height, weight, and blood pressure.
4. A member of the research team who is trained in drawing blood will then ask you to sit comfortably while he or she inserts a needle into your arm and collects a small amount of your blood in a tube.
5. \_\_\_\_\_\_ (Describe all procedures in a simple list fashion – add tables or other figures if needed to make the procedures clear & understandable)

**If audio/visual recordings will be used**

Include a statement explaining the recording procedures and how the recordings will be utilized for data analysis (including any potential future use). **Ex:** The interview will be audio recorded using an encrypted handheld digital recorder. After the interview, the recording will be transcribed, which means they will be typed exactly as they were recorded, word-for-word, by [a member of the research team / a professional transcription service].

**POSSIBLE BENEFITS**

Explain possible benefits to others or the contribution of knowledge to society, and describe how the research may reasonably benefit the participant directly (i.e., receiving test or lab results or monitored exercise; providing free DEXA scans and the body composition printout; etc). If the research will not benefit the participant directly, state this. **Do not list compensation of any kind (cash, course credit, gift cards) in this section.**

Please note that UT Arlington is not a healthcare provider, and the procedures involved in this research study are not intended to provide medical treatment. There is no expectation or guarantee of improvement or benefit for your health or any medical condition as a result of this research. If you are hoping to receive medical care, you should go to a medical doctor or other healthcare provider.

**POSSIBLE RISKS/DISCOMFORTS**

Describe any foreseeable risks and/or discomforts that the subject may experience as a result of participating in this research study. Clearly specify the physical risks associated with all biomedical procedures. Explain any safeguards that are in place to minimize these potential risks. If the only perceived risks and/or discomforts to participating in the study are those that participants would experience in their everyday lives, state as such.

*If participation will continue over time*, state: “any new information developed during the study that may affect your willingness to continue participation will be communicated to you.”

**Ex:** You might experience (list the foreseeable risks/discomforts) during this research study. (Provide an explanation of the safeguards in place to minimize the potential risks/discomforts). Remember that you have the right to quit any study procedures at any time without penalty, and may do so by informing the research team.

**Ex:** This research study is not expected to pose any additional risks beyond what you would normally experience in your regular everyday life. However, if you do experience any discomfort, please inform the research team.

**Ex:** We will do our best to protect your data and biospecimens during storage and

when they are shared. However, there remains a possibility that someone could identify

you. There is also the possibility that unauthorized people might access your data and

biospecimens. In either case, we cannot reduce the risk to zero.

While you are in the study, it is important that you report any illness or injury that occurs to the research team **immediately**. The University of Texas at Arlington does NOT offer compensation for any injuries resulting from your participation in this research. If you suffer a research-related injury, any resulting medical costs will be your responsibility or that of your insurance / third-party payer. However, as a research subject, you will not lose any of your legal rights.

**COMPENSATION**

Specify the type and amount of compensation offered for participation, if any (including extra credit and non-financial payments), and explain when and how subjects can expect to receive it. If compensation is affected by withdrawal from the study, specify as such, **Ex**: If you choose not to complete all study procedures, you will still receive (compensation type/amount). If no compensation will be offered for participation in this study, state this.

Also, per UTA Accounting Services policy, please add the statement below to all consent forms with payments of monetary value (cash, gift cards, iPads, etc):

“The Internal Revenue Service (IRS) considers all payments made to research subjects to be taxable income. Your personal information, including your name, address, and social security number, may be acquired from you and provided to UTA’s accounting office for the purpose of payment.  If your total payments for the year exceed $600.00, UTA will report this information to the IRS as income and you will receive a Form 1099 at the end of the year. If you receive less than $600.00 total for payments in a year, you are personally responsible for reporting the payments to the IRS.”

**ALTERNATIVE OPTIONS**

Explain any alternative procedures or courses of action that will be offered or that the subject might find beneficial or advantageous, such as options for medical care or alternative treatments. If there are no alternatives to the procedures offered for this study, state as such.

**Ex:** You have the option to participate in other research studies or to go to a regular physician to obtain information about your health condition.

**Ex:** There are no alternative options offered for this study.

**CONFIDENTIALITY**

The research team is committed to protecting your rights and privacy as a research subject. All paper, specimens, and electronic data collected from this study will be stored in a secure location on the UTA campus and/or a secure UTA server. IRB-required documentation will be maintained for at least three (3) years after the end of this research. [If audio/visual recordings will be used, describe the storage and disposition; **Ex:** “The recording will be immediately destroyed after transcription.” OR “The recordings will be kept with the other electronic data in a secure UTA sanctioned storage device for the duration of the study.”]

[Any blood or tissue samples that you provide will be [explain whether they will be sent to an external lab for analysis, and/or whether all or some of the sample will remain frozen in a secure location at UTA for further analysis]*.* We expect to destroy what is left of your samples after [provide an approximate time frame, or revise this to explain that you intend to keep the samples indefinitely].]

The results of this study may be published and/or presented without naming you as a participant. The data and / or samples collected about you for this study [choose one: may, will] be used for future research studies that are not described in this consent form. If that occurs, an IRB would first evaluate the use of any information that is identifiable to you, and confidentiality protection would be maintained. [If you know that you intend to share identifiable data with individuals outside the UTA research team or use identifiable data for future studies, you must explain how it will be used or with whom the data will be shared. For NIH studies, please be sure to explain the controls that are described in your approved [data management and sharing plan](https://resources.uta.edu/research/regulatory-services/human-subjects/guidance-for-researchers/index.php).

While absolute confidentiality cannot be guaranteed, the research team will make every effort to protect the confidentiality of your records as described here and to the extent permitted by law. In addition to the research team, the following entities may have access to your records, but only on a need-to-know basis: the U.S. Department of Health and Human Services and the FDA (federal regulating agencies), the reviewing IRB, and sponsors of the study.

**WITHDRAWAL OF PARTICIPATION OR CONSENT**

If you decide later to withdraw from the study and/or no longer wish to have us store or share your data or biospecimens, you should contact the Principal Investigator of the research team. If requested, we will do our best to retrieve any data and biospecimens that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data and biospecimens we will not be able to retrieve them. In addition, if the data and biospecimens have already been used for new research, the information from that research may still be used. We will [fill in what will happen to the data/specimens after they are retrieved] any data or biospecimens we have or are able to retrieve. [As an alternative, you may wish to provide subjects with a yes/no option of whether or not their data/specimens can be shared beyond your research. If you take this approach, be sure to address how the subjects will express/document their choice during the consent process.]

**FOR ALL NIH FUNDED STUDIES:**

**COCs:** Please include the following additional text regarding the new NIH policy on Certificates of Confidentiality:

“To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can’t be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding. However, there are circumstances where the Certificate does not protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies;

- when information must be disclosed to meet FDA requirements;

- if you give someone written permission to receive research information, or if you voluntarily disclose your study information;

- if the researcher reports that you threatened to harm yourself or others;

- in cases of child abuse or elder abuse reported by the researcher;

- if the investigator reports cases of contagious disease (such as HIV) to the state.”

**CLINICALTRIALS.GOV**If the study will be posted on ClinicalTrials.gov, this statement must be included with no changes per federal law: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

**CONTACT FOR QUESTIONS**

Questions about this research study or reports regarding an injury or other problem may be directed to [PI/Faculty Advisor name and contact information]. Any questions you may have about your rights as a research subject or complaints about the research may be directed to the Office of Research Administration; Regulatory Services at 817-272-3723 or [regulatoryservices@uta.edu](mailto:regulatoryservices@uta.edu).

**As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature & Name of Research Team Member Conducting Consent Process DATE**

**CONSENT**

By signing this form, you are confirming that you understand the study’s purpose, procedures, potential risks, and your rights as a research subject. By agreeing to participate, you are not waiving any of your legal rights. You can refuse to participate or discontinue participation at any time, with no penalty or loss of benefits that you would ordinarily have. Please sign below if you are at least 18 years of age and voluntarily agree to participate in this study.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE OF VOLUNTEER                                                             DATE**

*\*If you agree to participate, please provide the signed copy of this consent form to the research team. They will provide you with a copy to keep for your records.*