**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.

**IMPORTANT INFORMATION ABOUT THIS RESEARCH PROJECT**

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 viewing different color combinations on a phone app throughout the day may impact your mood.” Or “This study is being done to help us better understand the experiences of refugees living in Tarrant County, Texas.” 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 35 years old and a refugee who lives in Tarrant County.”

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 contribute your perspective to a scientific study involving refugees,” or “if you would like a chance to talk about your disability in a focus group with other disabled individuals.”) 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 sharing your personal experiences with a group” or “if you do not have the time to attend two 3-hour study visits on the UT Arlington campus.”)

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. 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.
2. 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.
3. \_\_\_\_\_\_ (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 (Ex. “There are no direct benefits for participating in this research study; however, the study will contribute to general knowledge and understanding about challenges experienced by refugees living in Tarrant County.”). **Do not list compensation of any kind (cash, course credit, gift cards) in this section.**

 **POSSIBLE RISKS/DISCOMFORTS**

Describe any foreseeable risks and/or discomforts that the subject may experience as a result of participating in this research study. 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.

**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. If there are no alternative procedures offered for this study, state as such.

**Ex:** You have the option to participate in other research studies or complete alternative class assignments in order to fulfill your course research requirements.

**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 and electronic data collected from this study will be stored in a secure location on the UTA campus and/or a secure UTA server 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 OneDrive account for the duration of the study.”]

The results of this study may be published and/or presented without naming you as a participant. The data 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.]

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.

**FOR ALL NIH FUNDED STUDIES:** 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.

**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.*