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| **FSU IRB Standard Written Consent Template**  **for Social, Behavioral and Educational Research (SBER)**  **DIRECTIONS**:   1. The purpose of this template is to provide sample text for creating an informed consent form for adults. 2. Delete this entire section, the page break following these directions, and any other green text box in this template BEFORE submitting your consent form to the IRB/OHSP, otherwise your consent will be returned to you to conform accordingly. 3. This template is only for use in SBER studies that involve no biomedical procedure, such as any procedure used to diagnose, cure, mitigate, treat or prevent disease or other condition; use of any drug, device, biologic or supplement; and collection, storage, maintenance or use of any biospecimens. 4. Modify this consent so that it accurately depicts your own study. Instructions in thegreen text box include areas where you will need to explain the specifics of your study or edit the text. The [red text in brackets] must be replaced with study specific information, or removed. Other red text provide options that should be selected where applicable, and/or may be deleted if not otherwise applicable to your study. The remaining black text in regular font may be modified BUT ONLY IF the changes are appropriate and still meet the [required elements for informed consent](https://www.research.fsu.edu/research-offices/ohsp/policies-and-procedures/) (e.g., replace the term “You” with “Your child” or “You and your child” throughout this template if only the parent’s child will be asked to take part in the study or if both a parent and their child will be asked to take part in the study, respectively). Also, if you are not video- or audio-recording participants, you can delete all statements related to recording. Importantly, fill in any passages introduced by a \_\_\_\_ [blank], referring to the instructions in the related green text box.   There may be additional information you need to provide to explain your study or to better inform and protect your participants. The FSU IRB will so inform you pursuant to its review of your study and this consent document.  If you have more than one consent form, please clearly label each form by inserting a distinguishing header or footer to identify the intended subject sample (e.g., *Employee Consent* vs *Employer Consent*; *Coaches Consent* vs *Athletes Consent*; “*Instructor Consent*” vs “*Student Consent*”). However, there may be no need to use more than one consent form if different subject sample groups will be taking part in the same study activity (e.g., surveys, focus groups or interviews, even if there are some differences in specific questions or measures).  Ensure consistency between the consent form and the description of the study and the consent process in your protocol; if there is substantive inconsistency, both will be returned to you with instructions to render consistent.  As you are writing the consent document, remove any green text box areas and all instructional text contained inside the text boxes. There should be no instructional text (including these instructions) in the final version of your informed consent forms. |

***Title of the Study***: *[Full title of research study; spell out abbreviations on first use]*

***Principal Investigator***: [*First Last, credentials and FSU affiliation*]

***Faculty Advisor*** [*IF the PI is a student then insert Advisor First Last, credentials and FSU affiliation; otherwise delete this Faculty Advisor section*]

You are being invited to take part in a research study. Please find below information about this research for you to think about before you decide to take part. Ask us if you have any questions about this information or the research before you decide to take part.

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| **Key Information for You to Consider** |
| * **Statement of the Research Study.** You are being invited to volunteer to take part in our research study. It is up to you whether you choose to take part or not. There will be no penalty or loss of benefits to you if you choose not to take part or decide later not to take part. * **Purpose**. The reason that we are doing this research is \_\_\_ [*insert a concise description; more details may be provided in the following pages*] * **Duration.** We think that taking part in our study will last \_\_\_ [*insert the study subject’s overall time commitment required to take part in the research and complete study activities*] * **Research Activities.** You will be asked to \_\_\_ [*insert a very brief description of what will occur, paraphrasing the detailed information below under “What will happen during this research”; e.g., answer online or paper survey or interview questions, take computer tests or complete exams, watch videos or look at pictures online or in a lab, take notes about your day or what you’ve done, participate in activities or exercises, etc.*]   **Risks:** The risks or discomforts to you of taking part in this study include \_\_\_ [*insert a very brief description of the foreseeable risks, paraphrasing the detailed information below under “What are the risks or discomforts associated with this research?”; e.g., you may become uncomfortable at answering some questions, some activities may make you sore or tired, some videos or pictures may be disturbing to see, unauthorized persons may see your confidential information etc*.]  **Benefits:** As a result of taking part in this research, we think that you may \_\_\_ [*insert a very brief description of how the research subject may directly benefit from taking part in the study, and/or insert a statement of the importance of the knowledge that may result from study findings, paraphrasing the detailed information below under “How might I benefit from this research?”; e.g., you may find out more about yourself or your condition, you may learn some new skills about dealing with XYZ, you will help researchers learn more about XYZ so that service or treatment can be improved. If no direct benefits to study subjects are anticipated, insert a statement to that effect. Receiving cash, gift cards or prizes, even if to defray study subjects’ expenses or costs of taking part in the study, are categorically not benefit and should not be described here or below as such*] |

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| Important and to reduce consent length: for consent forms that are four or more pages, provide as indicated above a concise overview of the key information that may influence a potential participant’s decision to participate in the research. **Delete this section if the consent form is less than 4 pages, or do not repeat key information under the sections below if the key information would otherwise satisfy the requirement for more detailed information.** |

What is this study about?

Researchers at Florida State University are studying \_\_\_\_\_. Researchers are interested in finding out [*tell the subject the purpose of the research*.] You are invited to take part in the study because \_\_\_\_ [*describe the inclusion criteria* (*e.g., you receive services or are involved in activities about which we have an interest in studying; you indicated an interest in taking part in studies like ours; you are between 18-24 years of age; you receive Social Security benefits; you are a student here at FSU; you are a leader of \_\_\_\_; you were recently seen as a client at \_\_\_\_*)]. You are one of \_\_\_\_ persons to take part in this study. Your involvement in the study is expected to last [*hours/days/months/weeks/years, until a certain event*].

[*Include if you have a conflict of interest. Otherwise delete*.] We want to inform you that researchers involved with this study have certain interests that may directly and significantly affect the design, conduct, or reporting of this research. The interest is: [*Insert the conflict(s) of interest, including identifying the researcher(s) with the conflict(s) of interest. Use HRP-502COI – TEMPLATE – COI Consent Language Template for the types of conflict(s) of interest to disclose to human subjects and sample language to insert regarding those conflict(s) of interest; the template is available in RAMP IRB or on the OHSP Templates & Required Forms page*.]

[*If not already mentioned in the paragraph above about conflicts of interest, then here include for sponsored/extramurally funded research e.g., National Science Foundation, a Center or Institute of the National Institutes of Health, other federal funding agency, private or public foundation, pharmaceutical or drug company, medical device manufacturer, other corporation, including such funding provided to another non-FSU grantee or contract organization but which is providing a subaward to FSU. Otherwise delete*.] This research is being funded by [*insert name of funding entity*].

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| If your consent includes the key information section above, then this section should include more thorough, detailed explanation of the purpose and intent of the research.  If multiple institutions are involved in the research, include the names of the institutions. |

What will happen during this research?

If you agree to be in this research, your participation will include \_\_\_.

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| This section should detail the procedures that participants will undergo for all aspects of the research. The procedures should be explicitly stated in order of when they will occur as part of the study. Consider using bulleted lists, diagrams, or timelines to increase understanding of study procedures and their sequencing.  If the study includes audio and video recording, this should be explained here. Ensure it is clear to the participant which aspects of the procedures are optional, if any. |

We will tell you about any new information that may affect your willingness to continue to take part in this research.

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| If applicable, the above statement should explain whether any relevant research results will be provided to the participant. It should also be explained under what conditions these results may be shared. |

[*Include if information about the study’s purpose is in any way not exactly as described in the protocol or if any information about the study’s purpose, activities or inquiries will be withheld from study subjects.]* You may not be made aware of some features about the study, such as its exact purpose, study questions and materials, or your responses that we would like to collect. At the end of your participation in this study or if you withdraw from this study we will provide you with additional information.

What will you do to protect my privacy?

The results of the study may be published or presented, but no information that may identify you will ever be provided or released in publications or presentations. We will take steps to protect your privacy and confidentiality. These steps include \_\_\_. Despite taking steps to protect your privacy or the confidentiality of your identifiable information or biospecimens, we cannot guarantee that your privacy or confidentiality will be protected. For example, if you tell us something that makes us believe that you or others have been or may be physically harmed, we may need to report that information to the appropriate agencies. [*Describe other limits to subjects’ privacy and confidentiality*]

Individuals and organizations responsible for conducting or monitoring this research may be permitted access to and inspect the research records. This includes the Florida State University Institutional Review Board (FSU IRB), which reviewed this study. [*List other organizations or entities that may inspect research records, such as any study sponsor*]

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| Describe in this section the steps that you will take to protect a participant’s confidentiality, including, e.g., what and how individuals will have access to the subjects’ identifiable information/biospecimens (e.g., only members of the study team; only the PI; no one); where and how long the identifiable information/biospecimens will be retained; how records of subjects’ names or any other identifiable information/biospecimens will be kept separate from study data; how identifiable information/biospecimens will be secured/encrypted when stored, at rest, used, analyzed or when transmitted; de-identification of all participant’s identifiable information/biospecimens as soon as practicable but before the study is completed; replacement of identifiers with random codes; the plan to destroy the identifiable information/biospecimens; the plan to destroy any linking keys as soon as practicable but no later than after linkage; use of Certificates of Confidentiality; and/or use of data sharing/confidentiality agreements or similar covenants.  Other individuals and organizations to list in this statement would include parties such as the IRB, faculty advisors, collaborating institutions/organizations, state or federal agencies, sponsors, etc. |

If identifiers are removed from your identifiable private information or identifiable biospecimens that are collected during this research, that de-identified information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

[OR]

The information or samples collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers areremoved.

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| For all studies, include one of the two prior statements above. Delete “or biospecimens” if not applicable. |

What are the risks of harms or discomforts associated with this research?

The risks of harms or discomforts associated with the research are \_\_\_\_.

[*Include the following statement for research that involves procedures whose risk profile is not well known, including any experimental procedures*] In addition to the risks of these harms or discomforts, this research may have risks of harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you.

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| Harms or discomforts may by nature be psychological (e.g., emotional distress, anxiety); physical (e.g., drug toxicities, exposure to radiation, research-related injuries); legal (risk of criminal or civil liability); social (e.g., a person’s reputation, social standing, retaliation); and economic (impact upon employment, insurance, research costs). Harms and discomforts may result from unauthorized or unintentional disclosure of identifiable, private information; distress or terror from exposure to troubling or gruesome events or images; being asked questions about sensitive topics or highly personal matters; or finding out about the their results or outcomes from tests or assessments. State the realistic risk of harms or discomforts involved in the research. You must indicate the probability (the odds of a harm or discomfort materializing) and magnitude (the severity of the harm or discomfort).  The risks of harms and discomforts should always match those stated in the IRB application. |

How might I benefit from this research?

Personal benefits you may get from this study are \_\_\_\_.

[OR]

There may be no personal benefit from your participation but the knowledge received may be of value to society.

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| State the realistic benefits a participant can expect in they choose to participate in the research. These must always be consistent with those addressed in the IRB application. Personal benefits that a participant might expect may include learning more about their own condition, circumstances or situation (such as for example through the results of tests or assessments); improving certain of their own skills or abilities (such as for example as the result of education or training); increased understanding or knowledge about issues or other matters that may be important to participants (such as for example by being provided with information, assistance or other resources); and/or access to care or services that may not otherwise be available to the participant (e.g., preventative services; referral to health, human or social services; diagnostic tests or exams).  Never include payments, monetary compensation or in-kind gifts if participants are being reimbursed or otherwise paid for their time, effort, and expense. Compensation is not considered a benefit of research and should be addressed separately. |

**What is the compensation for the research?**

[*Include if subjects will be paid, earn course or other credit, reimbursed, or provided with any financial or other incentive, token or gift. Otherwise delete*.] If you agree to take part in this research study, you will be provided with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [*indicate type of incentive and amount as applicable*] for your time and effort. [*Indicate if applicable how any amount is pro-rated for research visit or activity completion, and whether refusing to answer any question or withdrawing from or discontinuing taking part in the study or any study activity will reduce or preclude subjects from earning part or all of such incentive*.]

[*Include if student subjects will be provided with course credit for taking part in the study, as an alternative to completion of a course, paper or other credit-earning activity. Otherwise delete*.] Earning course credit by taking part in this study is an alternative to the requirement that you otherwise complete a course, paper or other credit-earning activity.

[*Include if subjects will not be paid*] You will not receive any compensation for your participation in this study.

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| If participants will be compensated: In addition to stating the amount, also describe how (e.g., cash, gift cards, credit) and when they will receive compensation (e.g., after specific activities or visits, at the end of the study). |

What will happen if I choose not to participate?

It is your choice to participate or not to participate in this research. Participation is voluntary. Alternatives to participation are \_\_\_\_\_\_\_.

[*Include for student subject pools for which course or other academic credit may be earned by taking part in the study*.] Earning course or other academic credit by taking part in this study is an alternative to the requirement that you otherwise complete a course, paper or other credit-earning activity.

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| Always provide a statement to the effect that it is the participant’s choice whether to participate or not to participate in this research.  Consider also whether there are alternatives to participation (e.g., participating in an alternate program or activity) and clearly describe them in this section.  If research is based in schools, please explain how a student’s decision to not participate will affect their experience in the classroom. |

Is my participation voluntary, and can I withdraw?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. Your decision whether to participate will not affect your relationship with \_\_\_\_ [*researchers, FSU, other organizations, etc*.]. There are no penalty/consequences/loss of benefits to which you are otherwise entitled, if you do not participate.

You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty/consequences/loss of benefits to which you are otherwise entitled.

If you withdraw from the study, the data collected to the point of withdrawal will \_\_\_.

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| Always provide a statement to the effect that taking part in the study is voluntary.  Tailor the statement regarding penalties/consequences/loss of benefits so that the statement is relevant to your study.  Include one of the last two statements about whether data collected to the point of withdrawal may be used:   * Describe what will happen to data collected to the point of withdrawal. Will the data be used, used only if already in an aggregate analysis, or not used? Will you keep the data, or delete? |

Can I be removed from the research without my OK?

We may remove you from the research study without your approval. Reasons we would do this include \_\_\_.

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| Delete this section if not applicable. If applicable, describe reasons why the participant may be withdrawn (e.g., disrupting other study participants during lab exercises, focus groups, other study activities; not following study instructions). |

Who do I talk to if I have questions?

If you have questions, concerns, or have experienced a research-related injury, contact the research team at:

Name of PI

Telephone Number (with Area Code)

FSU E-mail Address

[IF the PI is a student, then insert name, telephone number and FSU email address of PI’s Faculty Advisor]

The Florida State University Institutional Review Board (“IRB”) is overseeing this research. The FSU IRB is a group of people who perform official independent review of research studies before studies begin to ensure that the rights and welfare of participants are protected. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Florida State University IRB

2010 Levy Drive, Suite 276

Tallahassee, Florida 32306

850-644-7900

humansubjects@fsu.edu

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| For research conducted internationally, list as applicable and below your own contact information the international location study team’s local contact information. Also for research conducted internationally, list as applicable and below the FSU IRB contact information the international location’s IRB or Ethics Committee local contact information). U.S. federal law and FSU policy requires that when certain research is conducted in foreign countries, that the foreign countries’ protections for research participants are at least equivalent to U.S. protections. |

**STATEMENT OF CONSENT**

I have read and considered the information presented in this form. I confirm that I understand the purpose of the research and the study procedures. I understand that I may ask questions at any time and can withdraw my participation without prejudice. I have read this consent form. My signature below indicates my willingness to participate in this study.

I consent to participate in this study.

Printed Name of Adult Participant

Signature of Adult Participant Date

I agree to be audiotaped

YES (initial) \_\_\_\_ NO (initial) \_\_\_\_

I agree to be videotaped

YES (initial) \_\_\_\_ NO (initial) \_\_\_\_

I agree to allow use of audio/video in presentations or publications

YES (initial) \_\_\_\_ NO (initial)

I agree to use of audio/video for educational purposes including \_\_\_\_\_

YES (initial) \_\_\_\_ NO (initial) \_\_\_\_

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| Include any of the additional permission statements, such as permissions to be audio- or videotaped, otherwise delete. |

**Researcher’s Signature**

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians’ questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

Printed Name of Research Team Member Obtaining Consent

Signature of Research Team Member Date