# Sample Consent Form (for Adult Participants)

## Agreement to Participate in Research

**Responsible Investigator(s):** _____***[If you are an SJSU student, please indicate this after your name or in an introductory statement in item #1]***

**Title of Study:** _____

1. You have been asked to participate in a research study investigating… ***[explanation of the purpose of the research].***

2. You will be asked to… ***[describe what will be required of subjects, where and when the study will occur, and what materials and/or devices will be employed, including the use of audio/visual recording devices].***

3. ***[Include a description of any foreseeable risk or discomforts to the subjects, or a statement that no risks are anticipated. Please be aware that emotional discomfort is considered to be a risk of which subjects must be informed.]***

4. ***[Include a description of any direct benefits to the subjects or to others which may reasonably be expected from the research, or a statement that no discernable benefits are expected. General feelings of reward from being of help to research are not direct benefits; however, you may add that these are possible, indirect benefits, if applicable.]***

5. ***[Alternative procedures (if applicable; if not applicable, omit this item and re-number all subsequent items). ]***

6. Although the results of this study may be published, no information that could identify you will be included. ***[Note: If identifying information will be included in publication or dissemination, this statement should be revised. In certain unusual situations, you may prefer to attach a full "release to publish" statement. Otherwise please describe the manner in which confidentiality will be maintained. ]***

7. ***[Compensation for participation in the study (amount, nature, and reason), if any. Otherwise, please state that there is no compensation for participation.]***

8. Questions about this research may be addressed to ***[name of the responsible investigator, area code, and phone number; or email address].*** Complaints about the research may be presented to ***[name of the respective department Chair (or of the respective College Dean, if there is no department Chair), title, department/college, area code and phone number].*** Questions about a research subjects' rights, or research-related injury may be presented to Pamela Stacks, Ph.D., Associate Vice President, Graduate Studies and Research, at (408) 924-2427.

9. No service of any kind, to which you are otherwise entitled, will be lost or jeopardized if you choose not to participate in the study.

10. Your consent is being given voluntarily. You may refuse to participate in the entire study or in any part of the study. ***[If you are doing surveys or interviews, add the statement: You have the right to not answer questions you do not wish to answer.]*** If you decide to participate in the study, you are free to withdraw at any time without any negative effect on your relations with San Jose State University or with ***[name any other participating institutions or agencies involved in the study]***.

11. At the time that you sign this consent form, you will receive a copy of it for your records, signed and dated by the investigator.

- **The signature of a subject on this document indicates agreement to participate in the study.**

- **The signature of a researcher on this document indicates agreement to include the above named subject in the research and attestation that the subject has been fully informed of his or her rights.**

_____ _____
Participant's Signature Date

_____ _____
Investigator's Signature Date

***Additional Information/Instructions for Researchers:***

***Instructions on the template are in bold italics. Remember to erase this instruction box and the formatting and instructions for investigators contained in this template. Please provide a consent form that is free from typographical, grammar, and spelling errors, and that is formatted in a manner that is readable and easy to understand. The IRB will not approve consent forms that are cluttered or otherwise unclear.***
***Some additional items to consider when creating your consent form:***

- **Anonymous Data Collection:** If the data to be collected from adults will not contain identifying information (i.e., the researcher will not be able to identify who the participants were), item #11 and the first bulleted statement underneath it can be revised, and the signature line for participants can be omitted (the investigator's signature remains). For example, the statements in item #11 and the first bulleted item may be revised to indicate: "Please keep a copy of this form for your own records. By agreeing to participate in the study, it is implied that you have read and understand the above information. Please do not write any identifying information on the survey/questionnaire." Also see the **Sample Cover Letter - Studies Involving Mailed Surveys/Questionnaires** provided below, which is an optional cover letter that may be used separately or in conjunction with the sample consent form for adults depending on the appropriateness of the situation.

- **Online Data Collection:** Likewise the statement in item #11 and the first bulleted statement underneath it can be revised, and both signature lines can be omitted for online surveys/questionnaires. The elements of informed consent can be incorporated into the text preceding a survey, and the participant is directed to the content of the survey by clicking a "Submit" button. If an online survey is to be conducted, the investigator must submit a printed copy of the consent form and data instrument as it will appear in the final format that is presented to participants. Note that many online survey tools such as Survey Monkey allow investigators to track the IP address or email address of respondents. Because the investigator cannot guarantee anonymity in this case, the investigator should either indicate in the protocol narrative that this feature will be disabled, or must indicate that the identifying data will remain confidential.

- **Written Consent:** While the IRB may waive the need for written consent (e.g., no signature from participants is required on the consent form) in certain cases such as those stated above, the investigator must still generally provide a document containing all of the elements of informed consent as outlined on the consent form to participants for their records. If the participants of the research come from an oral rather than a written tradition, or the research will be conducted via telephone, the investigator must provide documentation with their IRB protocol indicating the manner in which informed consent will be obtained verbally (e.g., a script or interview protocol that incorporates informed consent procedures). In the case of telephone interviews, the investigator should make every effort to provide individuals with the information in writing; the IRB may require written consent, depending on the nature of the interview.

- **SJSU Letterhead:** The consent document must be on SJSU Department Letterhead, unless a waiver is given by the IRB (e.g., it is clearly documented in the protocol narrative that the consent form will be posted online - in the text preceding a survey, for example – or will be emailed to participants).

  For best results on SJSU letterhead, format the text 2.5 inches from the left (to match the design width). Margins of 0.5 inches at the top, bottom, and right are acceptable, and may enable you to fit more text on one page.

- **Initial Lines:** If the consent form is more than one page, each non-signature page must be initialed by the subject. Supply a line at the lower right labeled "Initial" for this purpose, as shown below:

  Example 1: _____ Initial

  OR Example 2: Initial _____

# Sample Consent Form (for Child Participants)

## Agreement to Participate in Research

**Responsible Investigator(s):**_____ ***[If you are an SJSU student, please indicate this after your name or in an introductory statement in item #1]***

**Title of Study:**_____

1. Your child or ward has been asked to participate in a research study investigating…***[explanation of the purpose of the research].***

2. Your child or ward will be asked to ***[describe what will be required of subjects, where and when the study will occur, and what materials and/or devices will be employed, including the use of audio/visual recording devices].***

3. ***[Include a description of any foreseeable risk or discomforts to the subjects, or a statement that no risks are anticipated. Please be aware that emotional discomfort is considered to be a risk of which subjects must be informed.]***

4. ***[Include a description of any direct benefits to the subjects or to others which may reasonably be expected from the research, or a statement that no discernable benefits are expected. General feelings of reward from being of help to research are not direct benefits; however, you may add that these are possible, indirect benefits, if applicable.]***

5. ***[Alternative procedures (if applicable; if not applicable, omit this item and re-number all subsequent items). ]***

6. Although the results of this study may be published, no information that could identify your child or ward, your family, or you will be included. ***[Note: If identifying information will be included in publication or dissemination, this statement should be revised. In certain unusual situations, you may prefer to attach a full "release to publish" statement. Otherwise please describe the manner in which confidentiality will be maintained. ]***

7. ***[Compensation for participation in the study (amount, nature, and reason), if any. Otherwise, please state that there is no compensation for participation.]***

8. Questions about this research may be addressed to ***[name of the responsible investigator, area code, and phone number; or email address].*** Complaints about the research may be presented to ***[name of the respective department Chair (or of the respective College Dean, if there is no department Chair), title, department/college, area code and phone number].*** Questions about a research subjects' rights, or research-related injury may be presented to Pamela Stacks, Ph.D., Associate Vice President, Graduate Studies and Research, at (408) 924-2427.

9. No service of any kind, to which you and/or your child or ward is otherwise entitled, will be lost or jeopardized if you choose not to participate in the study.

10. Your consent for your child or ward to participate is being given voluntarily. You may refuse to allow his or her participation in the entire study or in any part of the study. ***[If you are doing surveys or interviews, add the statement: Your child/ward has the right to not answer questions that he/she does not wish to answer.]*** If you allow his or her participation, you are free to withdraw your child or ward from the study at any time, without any negative effect on your relations with San Jose State University or with ***[name any other participating institutions or agencies involved in the study]***. Your child also has the right to withdraw from the study at any time.

11. At the time that you sign this consent form, you will receive a copy of it for your records, signed and dated by the investigator.

- **The signature of a parent or legal guardian on this document indicates:**
  - **a) approval for the child or ward to participate in the study,**
  - **b) that the child is freely willing to participate, and**
  - **c) that the child is permitted to decline to participate, in all or part of the study, at any point.**

Initial____

***[Note the initial line is at the <u>bottom</u> of the first page, or each non-signature page, which happens to be after item11c in this example. Please demonstrate that you have read the accompanying instructions and understand the purpose of the initial line by placing it at the <u>bottom</u> of each non-signature page of your consent form!]***

- **The signature of a researcher on this document indicates agreement to include the above named subject in the research and attestation that the subject's parent or guardian has been fully informed of the subject's rights.**

_____
Name of Child or Ward

_____ _____
Parent or Guardian Signature Date

_____
Relationship to Child or Ward

_____
Full Mailing Address (optional)

_____ _____
Investigator's Signature Date

***Additional Information/Instructions for Researchers:***

***Instructions on the template are in bold italics. Remember to erase this instruction box and the formatting and instructions for investigators contained in this template. Please provide a consent form that is free from typographical, grammar, and spelling errors, and that is formatted in a manner that is readable and easy to understand. The IRB will not approve consent forms that are cluttered or otherwise unclear.***
***Some additional items to consider when creating your consent form:***

- **Wards**: Parental consent is required for a child's participation unless the minor is legally emancipated from his/her parents. If the minor is a ward of the state, permission must be granted from the judge who is the legal custodian of the child. In this case, the investigator should contact the appropriate court, as many counties have a petition and order for research that must be filed. The investigator must submit evidence of having obtained judicial permission with their IRB paperwork.

- **Minor Assent:** In addition to a signed parental consent form, minor assent is also required. This means that the investigator must explain the research to the minor in an age appropriate manner, and obtain the minor's affirmative agreement to participate in the research. Note that if the minor dissents from participating in research, even if his or her parents or guardian have granted permission, the minor's decision prevails in most cases. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure might include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve, and should be documented in the methods and procedures of the IRB protocol narrative that researchers are required to submit as part of their IRB application.

- **SJSU Letterhead:** The consent document must be on SJSU Department Letterhead unless a waiver is given by the IRB.

  For best results on SJSU letterhead, format the text 2.5 inches from the left (to match the design width). Margins of 0.5 inches at the top, bottom, and right are acceptable, and may enable you to fit more text on one page.

- **Initial Lines:** If the consent form is more than one page, each non-signature page must be initialed by the subject. Supply a line at the lower right labeled "Initial" for this purpose, as shown below:

Example 1: Initial _____ OR Example 2: Initial _____

# Sample Cover Letter - Studies Involving Mailed Surveys/Questionnaires

***[Note: This document can be used only if the researcher is not collecting any identifying information and will be providing participants with a self-addressed envelope with which to return the survey/questionnaire. This letter should be on SJSU letterhead from the researcher's department.]***

Responsible Investigator(s):_____ ***[If you are an SJSU student, please indicate this after your name or in an introductory statement]***

Title of Study:_____

Dear Parent,

I need your help in conducting a study of the effects of child care arrangement on working parents. The results of this study should increase our understanding of the complex relationships between work and child rearing. Attached is a questionnaire asking about your child care arrangements and about stress in your life. Will you please spend 15 minutes to complete the form and mail it before your child begins to attend the ABC Child Care Center?

You should understand that your participation is voluntary and that choosing not to participate in this study, or in any part of this study, will not affect your relations with San Jose State University or with ***[name any other participating institutions or agencies involved in the study]***. You have the right to not answer questions you do not wish to answer.

***[Note: If any question(s) has the potential to cause harm or discomfort to a subject, this information must be clearly stated on the cover letter. Any direct risk or benefit to a subject should also be stated. If no risks and/or benefits are anticipated, this must be stated.]***

The results of this study may be published, but any information that could result in your identification will remain confidential.

If you have questions about this study, I will be happy to talk with you. I can be reached at (XXX) XXX-XXXX (or email address). Complaints about the research may be presented to ***[name of the respective department Chair (or of the respective College Dean, if there is no department Chair), title, department/college, area code and phone number]*****.** Questions about a research subjects' rights, or research-related injury may be presented to Pamela Stacks, Ph.D., Associate Vice President, Graduate Studies and Research, at (408) 924-2427.

***[Include instructions for participants on how to return the survey/questionnaire.]***

Sincerely,
[Your Name]
[Position]

# SJSU POLICY ON INFORMED CONSENT

## Individuals Being Asked to Participate in Research Have the Following Rights

- To be asked to participate, as a subject, in a study involving human subjects in an open, honest, and non-coercive manner.

- To be told the project is research.

- To be told what the study is investigating.

- To be told exactly what will be required, including where and when the study will occur and what materials and/or devices will be employed.

- To be clearly informed of any possible risks or inconveniences, including psychological stress, physical stress, or harm.

- To be told about any possible benefits that might reasonably be expected from participation in the study.

- To be encouraged to ask questions concerning the study before and during the course of the study.

- To be assured that no service to which a person is otherwise entitled will be lost or jeopardized if a person chooses not to participate in the study.

- To be informed that subjects have the right to choose not to participate in the study or in any part of the study. Additionally, if subjects choose to participate in the study, they may withdraw at any time without prejudice to their relations with San Jose State University.

- To receive a copy of the signed and dated consent form, or, if a consent form is not used, to be given a list of appropriate contact numbers to be used in the event of harm or complaints.

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## Basics of Informed Consent

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative as specified by the SJSU policy for the Protection of Human Research Subjects.

Unless waived by the HS-IRB, informed consent shall be documented by the use of a written consent form signed by the subject or the subject's legal representative and the primary investigator. Under appropriate circumstances, a cover letter addressing all issues pertinent to a consent form, and signed by the primary investigator, may serve as evidence of informed consent.

If any potential subject is less than eighteen years old, a parental consent form is required.

Informed consent must be secured in the native language of the subject or from the subject's legally authorized representative unless English is readily understood. If translation to another language is necessary, a Verification of Translation Accuracy form must be completed.
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