

Sample Consent Form (for Adult Participants)

Agreement to Participate in Research

Responsible Investigator(s): _____

Title of Protocol: _____

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]**.
3. **[Include a description of any reasonably 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).]**
6. Although the results of this study may be published, no information that could identify you will be included. **[Note: In certain unusual situations, you may prefer to attach a full "release to publish" statement]**
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]**. 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]**. Questions about research subjects' rights or research-related injury may be presented to Pamela Stacks, Ph.D., Associate Vice President, Graduate Admissions and Program Evaluations, at (408) 924-2480.
9. No service of any kind, to which you are otherwise entitled, will be lost or jeopardized if you choose to "not 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 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 any other participating institutions or agencies.
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.

- This document must be on SJSU Department Letterhead, unless a waiver is given by 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.
- 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 _____

(Remember to erase this instruction box.)

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.

Signature

Date

Investigator's Signature

Date

Sample Consent Form (for Child Participants)

Agreement to Participate in Research

Responsible Investigator: _____

Title of Protocol: _____

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]***.
3. ***[Include a description of any reasonably 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 discernible benefits are expected. General feelings of reward from being of help to research are not considered to be direct benefits. However, you may add that these are possible, indirect benefits, if applicable.]***
5. ***[Alternative procedures, if not participating (if applicable).]***
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 to researcher: In certain unusual situations, you may prefer to attach a full "release to publish" statement.]***
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]***. 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]***. Questions about research subjects' rights or research-related injury may be presented to Pamela Stacks, Ph.D., Associate Vice President, Graduate Admissions and Program Evaluations, at (408) 924-2480.
9. No service of any kind, to which you and/or your child/ward are otherwise entitled, will be lost or jeopardized if you choose to "not 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 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 any other participating institutions or agencies.
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.

- This document must be on SJSU Department Letterhead, unless a waiver is given by 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.
- 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 _____

(Remember to erase this instruction box.)

- 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.
- 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

Investigator's Signature

Date

Sample Signature Format for Research Involving Children or Wards

(Intended to replace the usual signature lines shown at the end of the SJSU Sample Consent Form)

Name of Child or Ward (please print clearly)

Parent's (or Guardian's) Signature

Date

Relation to Child or Ward

Full Mailing Address

Investigator's Signature

Date

Sample Letter for Studies Involving Mailed Questionnaires

(Note: should be on SJSU Letterhead from researcher's department)

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 other participating institutions).

[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 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. If you have questions or complaints about research subjects' rights, or in the event of a research-related injury, please contact Pamela Stacks, Ph.D., Associate Vice President for Graduate Admissions and Program Evaluations at (408) 924-2480.

Sincerely,
[Your Name]
[Position]

Sample of Consent Elements to include in a letter of informed consent/cover letter (not to be signed by participants)

Note: must be on SJSU Department Letterhead.

Advice: format the text 2.5 inches from the left side of the paper, to match the letterhead design width.

These are the basic items that even unsigned letters are generally required to have, in some form:

- **(Responsible Investigator)**.....*Identify yourself (by name, on the form) as the person responsible for the study.*
- **(Title of Protocol)**.....*or a "layperson's" version of the title, if it is too complicated for the readers*
- You have been asked to participate in a research study investigating **[*explanation of the purpose of the research*]**.
- 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*]**.
- **[*Include a description of any reasonably 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.*]**
- **[*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.*]**
- Although the results of this study may be published, no information that could identify you will be included.
- Questions about this research may be addressed to **[*name of the responsible investigator, area code, and phone*]**. Questions about research subjects' rights or research-related injury may be presented to Pamela Stacks, Ph.D., Associate Vice President, Graduate Admissions and Program Evaluations, at (408) 924-2480.
- No service of any kind, to which you are otherwise entitled, will be lost or jeopardized if you choose to "not participate" in the study.
- Your consent is being given voluntarily. You may refuse to participate in the entire study or in any part of the study. 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.
- You will receive a copy of this letter of consent for your records.

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, it is 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 principal investigator. ***Under appropriate circumstances, a "cover letter" addressing all issues pertinent to a consent form, and signed by the principal investigator, may serve as evidence of informed consent.***

If any potential subject is less than eighteen years old, a parental consent form is normally 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, the Verification of Translation Accuracy form must be completed.