



**SAN JOSÉ STATE
UNIVERSITY**

INSTITUTIONAL REVIEW BOARD (IRB) INFORMED CONSENT HANDBOOK

Information and Templates for Investigators



Prepared by the [Office of Research](#)

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Instructions for Investigators – Obtaining Meaningful Consent

The basic elements of informed consent that must be communicated to all subjects – whether verbally or in writing include: 1) Information about the study and what participants will be asked to do, 2) Information about the risks and benefits of the study, 3) Information about measures to protect confidentiality as well as limits to confidentiality, 4) Information about participants' rights (e.g., participation in research is voluntary) and, 5) Information on who to contact for questions, complaints, and problems. In addition to including all of the elements of informed consent as outlined on the templates provided in this handbook, the consent documents need to include the following:

- **Complete information about the study.** If your consent documents contain vague language about the purpose and methods of your research, the IRB will not approve your protocol. It is important to be clear about why a particular phenomenon or behavior is being studied. What do you hope to achieve by conducting the research and what methods do you propose to use? If the topic under investigation is complex, it is still your responsibility to describe it in a manner that would be understandable to participants. If there are methods described in your protocol narrative but not in your consent document – or vice versa – the IRB will not approve the protocol.
- **Layman's language and text that is well-written and has been proofread.** Any complex discipline-specific or theory-specific jargon needs to be written in a language and at a reading level of a general audience. Do not expect subjects to be familiar with practices within your discipline. Do not prepare a protocol or consent form that contains official-sounding verbiage that you think the IRB wants to hear. The use of first person on consent forms is also not recommended because it is often used in documents that are binding contracts. All of the elements of informed consent that appear on the templates in this handbook need to be included, but you may word the information in a way that is appropriate to the audience. If you choose to simplify the language on the consent form to suit the audience that does not mean that grammar errors will be tolerated in the document.
- **Alternative methods for obtaining consent from study participants with limited reading skills or who are illiterate.** When a written consent form is not appropriate for a specific individual or population, verbal consent may be approved by the IRB. A script of what will be said and information about how consent will be documented needs to be included. A list of contact information should still be provided in writing when verbal consent is obtained. Note that the option to obtain consent verbally is not appropriate for subjects who are literate but whose primary language is not English (see below); this option is also not appropriate simply because obtaining written consent would be inconvenient for the research team.

The IRB does waive the need for written consent in some situations, when the investigator requests it, such as for telephone interviews or anonymous surveys. A waiver of written consent means that participants do not need to sign the consent form; however, participants should still be provided with information in writing, except in cases where they have limited reading skills.

- **Translations presented in the primary language of participants.** The investigator is responsible for determining whether translations will be needed and for providing consent forms in the primary language of participants. In some settings, such as in k-12 schools, translations may be used routinely. If translations will be used, a verification of translation accuracy form needs to be included as well as an English version of the consent form. An investigator may create her/his own translations as long as someone not involved with the research verifies the accuracy of the translation.
- **Information about the limits to confidentiality, such as mandated reporting.** Be certain to find out whether you are a mandated reporter. If you are a mandated reporter, the consent form needs to indicate that you are required to report cases of abuse, neglect, and intent to harm self or others, when applicable. Other limits to confidentiality include the potential for re-identification in small and specific data sets and the lack of privacy in focus groups or other settings where data is collected from a group; in such circumstances the researcher cannot guarantee that everyone will honor confidentiality agreements. The confidentiality section of the protocol narrative and the consent form must explain the measures that will be used to protect confidentiality, report any foreseeable limits to confidentiality, and explain how and when records containing any identifying research data will be destroyed.
- **Access to appropriate supportive services, when applicable.** Research projects in the social and behavioral sciences typically pose less physical risk than biomedical research, but the research is not risk free. The primary risks associated with research in the social and behavioral sciences can include anxiety, shame, stigmatization, embarrassment, emotional distress, psychological trauma, and loss of privacy. When the research deals with an emotionally sensitive topic (e.g., suicide, abuse, trauma), information on available support services and resources should be provided to participants. This information can be included as a separate document attached to the consent form.
- **Clean and clutter-free presentation.** In addition to being well-written, the format of the consent form should not be neglected. Use a consistent font size that is easy to read, and avoid excessive combinations of formatting such as bold, italics, and underline. Do not print the consent form onto letterhead until you are sure the text will be aligned properly. Make sure to use complete sentences. If numeric itemization is used, make sure that it is logical. Keep in mind that participants are not aware of IRB requirements and that, above all, the consent document must make sense to them.

Parental Consent

Written consent must be obtained from the legal guardian of any research subject under the age of 18 unless the minor is legally emancipated from his/her parents. The SJSU IRB does not waive the need for written consent from parents and does not allow passive consent (i.e., an “opt-out” option). 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.

The basic elements of informed consent that must be communicated on the parental consent form are the same as those on an adult consent form except that the wording addresses the minor’s participation (e.g., “Your child or ward is being invited to participate in a research project”...etc.). Refer to the Consent Form Template for Parents/Guardians of Participants Who Are Minors in this handbook and to the example consent forms for parents included in Appendix B for details on the wording and format of the document.

Minor Assent

In addition to a signed parental consent form, minor assent is also required when the subjects are capable of providing it. This means that the investigator must explain the research to the minor in an age appropriate and developmentally 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. 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, how long it will take, whether it might involve any 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 section of the protocol narrative. If assent will be obtained verbally, a script outlining what will be said should be included with the IRB protocol. Examples of written assent forms and scripts are provided in Appendix C of this handbook.

Additional Tips for Investigators

Anonymous Data Collection

If the data to be collected from adults will not contain identifying information (i.e., the investigator will not be able to identify who the participants are and will not be able to link responses to individuals), the signature line for participants can be omitted. The standard text in the signature section of the consent form can be replaced with: "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 Letter Format for Mailed Surveys included with the sample consent forms for adults in Appendix A of this handbook. This letter may be used in place of the consent form template for adults so long as all of the elements of informed consent are included.

Online Data Collection

Likewise, the standard text in the signature section of the consent form can be revised, and both signature lines can be omitted for online surveys/questionnaires. The elements of informed consent as outlined on the templates in this handbook 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.

Letterhead

The use of SJSU letterhead for the consent documents is not required as long as all of the pertinent contact information, as outlined on the templates below, is provided. However, it is highly encouraged that faculty investigators use letterhead. If you choose to use letterhead, please make sure to align the informed consent text so that the document is readable. Text should not bleed into the logo column and should be evenly spaced with a reasonable font size. Students can contact their department for copies of official letterhead. Please do not create your own letterhead. If you do not have access to official letterhead, simply use blank paper.

Multiple Consent Forms

If your research involves the use of multiple consent forms for different groups of subjects, please label each consent form with the corresponding subject group so that IRB members can easily distinguish between consent forms.

[**Consent Form Template for Adults** – Instructions on this template are in brackets. Remember to erase these instructions and brackets when preparing your consent forms. Make sure that your consent form has been proofread for typographical, grammar, and spelling errors. Refer to the consent form samples in Appendix A for examples of wording.]

REQUEST FOR YOUR PARTICIPATION IN RESEARCH

TITLE OF THE STUDY

NAME OF THE RESEARCHER [In addition to your name, also include your title or affiliation in this section, for example, Ph.D. or San Jose State University graduate student. If you are a student, include your faculty supervisor’s name also.]

[You may include an introductory statement about yourself and your research preceding the consent information. The introductory statement is optional.]

PURPOSE

[Describe what your study is about and why the study is being conducted.]

PROCEDURES

[Describe what participants will be asked to do, where and when the study will occur, the duration, and what materials and devices will be used – including the use of audio/video recording devices. You may want to have separate check box at the end of the consent form explicitly requesting permission to conduct audio or video recordings.]

POTENTIAL RISKS

[Describe any foreseeable risk or discomforts to the participants. Include information on how risks will be mitigated as well as any appropriate supportive services that are available, when applicable.]

POTENTIAL BENEFITS

[Describe any possible direct benefits to participants, such as health, educational, or social benefits. Describe any indirect benefits, such as the possibility that participants may help contribute to generalizable knowledge or that the research may help populations outside of the study group.]

COMPENSATION

[Provide information about the amount, nature, and reason for any compensation being offered for participation. Otherwise, state that there is no compensation for participation.]

CONFIDENTIALITY

[Describe the manner and degree to which confidentiality will be maintained. Explain if there are any limits to confidentiality – for example, if you are a mandated reporter. Avoid using the word “anonymous” unless you are certain that the research team will not be receiving any identifying information from participants and will not be able to connect responses to individuals. If identifying information will be included in publication or dissemination, the degree to which participants will be identified and how they will be identified should be stated.]

PARTICIPANT RIGHTS

[The following sample text summarizes participants’ rights.]

Your participation in this study is completely voluntary. You can refuse to participate in the entire study or any part of the study without any negative effect on your relations with San Jose State University or [name any other participating institutions]. You also have the right to skip any question you do not wish to answer. This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You will not waive any rights if you choose not to participate, and there is no penalty for stopping your participation in the study.

QUESTIONS OR PROBLEMS

[The following sample text summarizes the contacts that need to be included on the consent form.]

You are encouraged to ask questions at any time during this study.

- For further information about the study, please contact [name of researcher and contact information – phone or email or both].
- Complaints about the research may be presented to [name and contact information for your department chair or college dean if there is no chair].
- For questions about participants’ rights or if you feel you have been harmed in any way by your participation in this study, please contact Dr. Pamela Stacks, Associate Vice President of the Office of Research, San Jose State University, at 408-924-2479.

SIGNATURES

[See instructions preceding this consent template for circumstances in which there may be variations to this section. A waiver of written consent can be granted for anonymous surveys or in cases where verbal consent is obtained. If the need for written consent is not waived by the IRB the following text and signature lines should be used.]

Your signature indicates that you voluntarily agree to be a part of the study, that the details of the study have been explained to you, that you have been given time to read this document, and that your questions have been answered. You will receive a copy of this consent form for your records.

Participant Signature

Participant’s Name (printed)	Participant’s Signature	Date
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Researcher Statement

I certify that the participant has been given adequate time to learn about the study and ask questions. It is my opinion that the participant understands his/her rights and the purpose, risks, benefits, and procedures of the research and has voluntarily agreed to participate.

Signature of Person Obtaining Informed Consent	Date
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[Consent Form Template for Parents/Guardians of Participants Who Are Minors – Instructions on this template are in brackets. Remember to erase these instructions and brackets when preparing your consent forms. Make sure that your consent form has been proofread for typographical, grammar, and spelling errors. This consent form is similar to that used for adults, but the wording refers to “Your child or ward...” rather than addressing the participant directly. Written consent for a minor’s participation cannot be waived. If parents are also participants in the research, a separate consent form for adults should be used for them. Refer to the consent form samples in Appendix B for examples of wording for parental consent and to Appendix C for examples of wording for minor assent.]

REQUEST FOR YOUR CHILD’S OR WARD’S PARTICIPATION IN RESEARCH

TITLE OF THE STUDY

NAME OF THE RESEARCHER [In addition to your name, also include your title or affiliation in this section, for example, Ph.D. or San Jose State University graduate student. If you are a student, include your faculty supervisor’s name also.]

[You may include an introductory statement about yourself and your research preceding the consent information. The introductory statement is optional.]

PURPOSE

[Describe what your study is about and why the study is being conducted.]

PROCEDURES

[Describe what the parent’s child will be asked to do, where and when the study will occur, the duration, and what materials and devices will be used – including the use of audio/video recording devices. You may want to have separate check box for parents at the end of the consent form explicitly requesting permission to conduct audio or video recordings.]

POTENTIAL RISKS

[Describe any foreseeable risk or discomforts to the parent’s child. Include information on how risks will be mitigated as well as any appropriate supportive services that are available, when applicable.]

POTENTIAL BENEFITS

[Describe any possible direct benefits to the parent’s child, such as health, educational, or social benefits. Describe any indirect benefits, such as the possibility that participants may help contribute to generalizable knowledge or that the research may help populations outside of the study group.]

COMPENSATION

[Provide information about the amount, nature, and reason for any compensation being offered for participation. Otherwise, state that there is no compensation for participation.]

CONFIDENTIALITY

[Describe the manner and degree to which confidentiality will be maintained. Explain if there are any

limits to confidentiality – for example, if you are a mandated reporter. Avoid using the word “anonymous” unless you are certain that the research team will not be receiving any identifying information from participants and will not be able to connect responses to individuals. If identifying information will be included in publication or dissemination, the degree to which participants will be identified and how they will be identified should be stated.]

PARTICIPANT RIGHTS

[The following sample text summarizes participants’ rights.]

Your child’s participation in this study is completely voluntary. You may refuse to allow his or her participation in the entire study or any part of the study without any negative effect on your relations with San Jose State University or [name any other participating institutions]. Your child also has the right to skip any question that he or she does not wish to answer. This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to allow your child to participate. You will not waive any rights if you choose not to allow your child to participate and there is no penalty for stopping your child’s participation in the study. Your child may also decide to stop at any time.

QUESTIONS OR PROBLEMS

[The following sample text summarizes the contacts that need to be included on the consent form.]

You are encouraged to ask questions and to have your child ask questions at any time during this study.

- For further information about the study, please contact [name of researcher and contact information – phone or email or both].
- Complaints about the research may be presented to [name and contact information for your department chair or college dean if there is no chair].
- For questions about participants’ rights or if you feel your child has been harmed by participating in this study, please contact Dr. Pamela Stacks, Associate Vice President of the Office of Research, San Jose State University, at 408-924-2479.

SIGNATURES

[The following text and signature lines should be used.]

Parent/Guardian Signature

Your signature indicates that you voluntarily agree to allow your child to be part of the study, that the details of the study have been explained to you and your child, that you have been given time to read this document, and that your questions have been answered. You will be given a copy of this consent form, signed and dated by the researcher, to keep for your records.

Name of Child or Minor

Parent or Guardian Name (Printed)

Relationship to Child or Minor

Parent or Guardian Signature

Date

Researcher Statement

I certify that the minor's parent/guardian has been given adequate time to learn about the study and ask questions. It is my opinion that the parent/guardian understands his/her child's rights and the purpose, risks, benefits, and procedures of the research and has voluntarily agreed to allow his/her child to participate. I have also explained the study to the minor in language appropriate to his/her age and have received assent from the minor.

Signature of Person Obtaining Informed Consent and Assent

Date

Appendix A

Example Consent Forms for Adults

The following examples contain variations in wording and formatting but are provided to demonstrate consent forms that are written in a language applicable to a general audience. Please defer to the consent form templates provided in this handbook when preparing your consent form, as they have been designed to be easily accessible and contain the specific verbiage and contact information that SJSU requires. Some of the contact information on the examples has been changed or omitted to protect the researchers. We recommend the use of clear, distinct headings presented in the order provided on the templates rather than numerical or bulleted formatting for the presentation of the main elements of informed consent.

Example #1 – Distinct Heading Format

CONSENT FORM FOR PARTICIPATION IN RESEARCH

TITLE OF STUDY

Examining Authentication Interfaces

NAME OF RESEARCHERS

Jeremiah Still, Ph.D. and Mary Still, Ph.D.

Department of Psychology, San Jose State University

You have the opportunity to complete this research study for course credit as designated by your instructor. Please take your time in deciding if you would like to participate. You may complete an alternative assignment for equal course credit by reading and summarizing a scholarly journal article.

You must be at least 18 years old to participate in this study.

PURPOSE

The purpose of this research is to investigate how you memorize passwords and explore your ability to recall text-based passwords versus recognizing picture-based passwords. The results of this study will be used to improve password-based login systems.

DESCRIPTION OF PROCEDURES

You will interact with a computer throughout the experiment. In the first part of the study you will be asked to memorize both words and pictures. Next you will play a single game of Bejeweled. Then, you will recall or recognize the study's passwords. At the completion of the experiment you will be asked questions about your experience recalling or recognizing the learned passwords.

RISKS

There are no known risks to participating in this study beyond those risks you would encounter logging in to a computer-based system.

BENEFITS

By completing this study you may help improve the usability of authentication systems. We hope by increasing the usability of authentication systems, users' private data will become more secure.

COMPENSATION

The only compensation you will receive for your participation is course credit as designated by your instructor.

PARTICIPANT RIGHTS

Your participation in this study is completely voluntary and you may refuse to participate. If you agree to participate, you have the right to stop at any time with no penalty. You also have the right to skip any survey question that you do not wish to answer.

CONFIDENTIALITY

The results of the study will not be associated with you in any way. We are required to keep a copy of this informed consent document, but it will be kept separate from the study results. No records are kept that allow your name to be associated with your responses in the study or on the survey. Your responses will be anonymous.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study.

- For further information about the study, please contact Jeremiah D. Still, Ph.D.: professor1@university.edu or at (123) 456-7890.
- Complaints about the research may be presented to Ronald Rogers, Ph.D., Chair of the Department of Psychology: professor2@university.edu or (123) 987-6543.
- For questions about your rights or to report research-related injuries, please contact Pamela Stacks, Ph.D., Associate Vice President of The Office of Research: (408) 924-2479.

PARTICIPANT SIGNATURE

Your signature indicates that you voluntarily agree to participate in the study, that the details of the study have been explained to you, that you have been given ample time to read this document, and that your questions have been satisfactorily answered. You may request a copy of this consent form for your records.

Participant’s Name (printed)

Participant’s Signature

Date

INVESTIGATOR STATEMENT

I certify that the participant has been given adequate time to read and learn about the study and all of his/her questions have been answered. It is my opinion that the participant understands the purpose, risks, benefits, and the procedures that will be followed in this study and has voluntarily agreed to participate.

Signature of Person Obtaining Informed Consent

Date

Example #2 – Question and Answer Format

REQUEST TO PARTICPATE IN RESEARCH

TITLE OF STUDY

Nurses' Job Likes and Dislikes on Hospital Short-Stay Units

NAME OF RESEARCHER

Hiyam Bitar, Graduate Student
Dr. Toby Adelman, Supervising Professor

San Jose State University
School of Nursing

This research study is meant to assess job likes and dislikes of nurses working on hospital Short-Stay units. The study is being conducted by Hiyam Bitar, a nurse employed at a Northern California hospital, and a graduate student at San Jose State University.

Nurses' participation in this study is voluntary. You are being asked to participate in this study because you are a registered nurse who works on the Short-Stay unit at the chosen hospital. Please take your time to make your decision about participation. If you have any questions you may ask the researcher.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to explore what nurses report as job likes and dislikes on hospital Short Stay units.

WHO PAYS FOR THIS STUDY?

This study is conducted by a student and has not received any funding.

WHAT WILL HAPPEN IF I TAKE PART IN THE RESEARCH STUDY?

If you consent to participate in the study, you will fill out a satisfaction questionnaire, which has two parts. The first part is a short demographic survey that asks about your age, gender, educational background, the years you have worked at your present job, and the years that you have worked as a nurse. The second part is composed of 100 questions and explores what you like and dislike about your job. The questionnaire will be administered at your work place, for your convenience.

WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

Yes, your information will be kept confidential. You will not be asked for your name or any information that could identify you. Organizations that may look at and/or copy research records to make sure that the study was done properly include:

- San Jose State University, College of Applied Sciences and Arts
- San Jose State University, Institutional Review Board

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for the length of time it takes you to answer the survey questions, approximately 60 minutes.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to withdraw from the study or stop at any time while taking the survey. Just tell the researcher of your decision.

Also, the study researcher may stop you from taking part in the study at any time if she believes it is in your best interest.

WHAT RISKS CAN I EXPECT FROM BEING IN THE STUDY?

There are no anticipated risks associated with this study. No information that could result in your identification will be released or reported.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

While there are no direct benefits to you, the information that is collected in this study may help Short-Stay unit managers to improve nurses' job satisfaction.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not be charged for participating in the study.

WHAT WILL I GET FOR TAKING PART IN THE STUDY?

You will receive a \$25 gift card from Target.

WHAT ARE MY RIGHTS IF I TAKE PART IN THE STUDY?

Participating in the study is your choice. You may participate or not. You may also stop taking part in the study at any point in time as you are answering the survey questions.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

The researcher, Hiyam Bitar, is ready to answer any question you may have. Contact Hiyam Bitar at (123)456-7890 or at myname@school.edu.

Concerns or complaints about the research may be directed to Dr. Toby Adelman, department chair of the School of Nursing at San Jose State University, at (987)654-3210.

Questions about a research subjects' rights or a research-related injury may be presented to Pamela Stacks, Ph.D., Associate Vice President, the Office of Research, at (408)924-2479.

CONSENT

Your consent is your choice. You may want to participate in the entire study or in a part of the study. You have the right to not answer any question you do not wish to answer. You may withdraw from the study at any time with no effect on your relations with San Jose State University. You have the right to decline participation in the study.

Your completion and return of the survey indicates your willingness to participate. You may keep this consent document for your records. Please refrain from writing your name on the questionnaire. Your name will not be collected to ensure confidentiality of the survey.

Example #3 – Online Survey Format

CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

TITLE OF STUDY

The Effect of High Impact Practices on Academic Success: A Study of Students Who Transfer into San Jose State University

NAME OF RESEARCHERS

Dr. Mark Van Selst, San Jose State University
Cirenia Huerta, SJSU Graduate Student
Department of Psychology

THE PURPOSE OF THIS STUDY

You are being asked to participate in a research study investigating the effect of participation in “High Impact Educational Practices” on academic success. High Impact Educational practices provide opportunities that increase student engagement, persistence, and learning. The particular practices include linked courses, learning communities, diversity experiences such as study abroad, and undergraduate research. If you decide to participate in the study, you will complete a few short questions about the sort of educational experiences you have had at your prior community college or university. The questions will also include self-reporting your grade point average and course selection at SJSU.

THE PROCEDURES TO BE FOLLOWED

The survey is available online at: <http://www.linkto.yoursurvey.com>

Please read through the following information about your rights as a research participant. If you agree to take the survey, please hit the agree button at the bottom of this page.

POTENTIAL RISK

There are no direct foreseeable risks anticipated other than those normally encountered in your daily life.

POTENTIAL BENEFITS

There are no foreseeable benefits anticipated.

COMPENSATION

There is no compensation for participation this study.

CONFIDENTIALITY

Although the results of this study may be published, no information that could identify you will be included. Your responses will be coded and kept in a password protected computer.

YOUR RIGHTS

Your participation in this study is voluntary. If you choose to participate, you may quit the survey at any time without negative consequences. You can also choose not to answer any survey questions that you do not wish to answer. No service to which you are otherwise entitled will be lost or jeopardized if you choose not to participate in the study or quit partway through the study.

CONTACT INFORMATION

Questions about this research may be addressed to the researcher, Dr. Mark Van Selst (Department of Psychology, San Jose State University, 408-987-6543).

Complaints about the research may be presented to Dr. Ron Rogers (Chair, Department of Psychology, 408-123-4567).

For questions about research subjects' rights or to report research-related injuries contact Dr. Pamela Stacks (Associate Vice President, Office of Research, 408-924-2479).

AGREEMENT TO PARTICIPATE

Please select from the choices below. If you click agree, it is implied that you have read the information above about the research, your rights as a participant, and give your voluntary consent. Please print out a copy of this page and keep it for your records

I AGREE TO PARTICPATE IN THE
RESEARCH.
CONTINUE TO SURVEY

I DO NOT AGREE TO PARTICPATE IN
THE RESEARCH.
EXIT

Example # 4 – Letter Format for Mailed Surveys

REQUEST FOR YOUR PARTICIPATION IN A RESEARCH STUDY

Name of Researcher: Jane Doe, Graduate Student
Dr. James Brown, Faculty Supervisor
Department of Education
San Jose State University

Title of Study: Child Care and the Working Parent

Dear Parent,

I need your help in conducting a study about 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 choosing not to participate in this study will not affect your relations with San Jose State University or with ABC Child Care Center. The risks associated with participation in this study are minimal. Some of the questions ask about your level of stress and stress management. You can skip any question that you do not want to answer. While there are no direct benefits associated with participating in the study, your responses may help the ABC Child Care Center staff in providing more targeted services to parents.

The results of this study will be shared with researchers at SJSU, staff at the ABC Child Care Center, and may be also published in academic journals. However, the survey is anonymous and no information that could identify you directly will be shared.

If you have questions about this study, I will be happy to talk with you. I can be reached at (123) 456-7890 or Jane.Doe@sjsu.edu. Complaints about the research may be presented to Dr. Mary Smith, chair of the Education Department. If you have questions about your rights as a research participant, or need to report a research-related injury, please contact Dr. Pamela Stacks, Associate Vice President, Office of Research, at (408) 924-2479.

If you would like to participate in this study, please complete the attached questionnaire and mail it back in the enclosed self-addressed envelope. You may detach this letter and keep it for your records. Thank you for contributing to this study!

Sincerely,
Jan Doe

Appendix B

Example Consent Forms for Parents/Guardians for Participants Who Are Minors

The following examples contain variations in wording and formatting but are provided to demonstrate consent forms that are written in a language applicable to a general audience. Please defer to the consent form templates provided in this handbook when preparing your consent form, as they have been designed to be easily accessible and contain the specific verbiage and contact information that SJSU requires. Some of the contact information on the examples has been changed or omitted to protect the researchers. We recommend the use of clear, distinct headings presented in the order provided on the templates rather than numerical or bulleted formatting for the presentation of the main elements of informed consent.

Example # 1 – Distinct Heading Format
(See the accompanying assent document for this study in Appendix C)

REQUEST FOR YOUR CHILD’S PARTICIPATION IN A RESEARCH STUDY

TITLE OF THE STUDY

Facilitating Children’s Learning of Augmentative and Alternative Communication Systems

NAME OF RESEARCHER

Dr. Wendy Quach, Department of Communicative Disorders and Sciences
San Jose State University

PURPOSE OF THE RESEARCH

You are invited to permit your child to participate in a research study to evaluate an augmentative and alternative communication (AAC) model that has features that are designed to assist learning of the operation and use of AAC systems in young children. AAC systems such as symbol books, sign language, or computers are used for people who have difficulty communicating using verbal speech. The first phase of this study is to explore how typically developing children learn to use technology. Your child may be eligible to participate because he/she is between 5 – 8 years old and is typically developing. The following information is provided to help you make an informed decision about whether or not to allow your child to participate. If you have any questions, please do not hesitate to ask.

PROCEDURES

To determine your child’s eligibility for participation, you will be asked to complete a short questionnaire about your child’s hearing, vision, speech, language, and cognitive development. In addition, a short screening will be administered to your child to determine his/her ability to recognize words at the first grade level. This will take place at San Jose State University. Children who do not have typical hearing, vision, speech, language and cognitive development will not be eligible for participation in the study.

In this study, your child will be randomly assigned to one of two instructional techniques. S/he will participate in five sessions, 30-minutes each. In all sessions, your child will sit face to face with a communication partner and use the AAC model to speak sentences.

In all sessions, your child will see words, phrases, or sets of symbols that he/she may use to create a message. Your child’s communication partner will see the same items. During all sessions, your child’s interactions using the AAC model will be videotaped and analyzed. Participation in this study will take a total of approximately 2.5 hours of your child’s time. The study will help determine how different methods of instruction affect learning of AAC systems.

RISKS AND/OR DISCOMFORTS

The risks or discomforts associated with this research are minimal. Your child may experience frustration while learning tasks; however, children will have ample opportunity to learn the tasks because there are 3 teaching sessions. You or your child may also choose to discontinue participation in the study at any time.

BENEFITS

Children may benefit from participation in this study through exposure to potentially useful assistive technology options. This study may also benefit persons with severe disabilities by helping in the development of a new technology through computers and communication devices that support conversational interactions.

COMPENSATION

No compensation is being offered for participation in this study.

CONFIDENTIALITY

The information obtained in this study may be published in scientific journals or presented at scientific meetings, but no information that could identify your child will be shared. Your child's identity will remain strictly confidential. Results of the study will be reported collectively and will not contain information that could be traced back to individual participants.

The study data will be stored in a locked cabinet in the researcher's lab and will be kept for three years after the study is complete. After the study results are published, the data will be destroyed at the end of the 3 years.

PARTICIPANTS' RIGHTS

You are free to decide whether or not to permit your child to participate in this study. You may refuse to allow his or her participation in the entire study or any part of the study without any negative effect on your relations with San Jose State University. Your child may also decide to stop at any time.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to allow your child to participate. You will not waive any rights if you choose not to allow your child to participate and there is no penalty for stopping your child's participation in the study.

OPPORTUNITY TO ASK QUESTIONS

You and your child may ask any questions about this research and have those questions answered before agreeing to participate. You or your child may also ask questions during the experiment.

- For further information about the study, please contact Dr. Wendy Quach at (408) 123-4567
- Complaints about the research may be presented to Dr. Michael Kimbarow, Chair of the Department of Communicative Disorders and Sciences, at (408) 987-6543
- For questions about participants' rights or if you feel your child has been harmed by participating in this study, please contact Dr. Pamela Stacks, Associate Vice President of the Office of Research, San Jose State University, at 408-924-2479.

DOCUMENTATION OF INFORMED CONSENT**Parent/Guardian Signature**

Your signature indicates that you voluntarily agree to allow your child to be part of the study, that the details of the study have been explained to you and your child, that you have been given time to read

this document, and that your questions have been answered. You will be given a copy of this consent form, signed and dated by the researcher, to keep for your records.

Name of Child or Minor _____ Parent or Guardian Name (Printed) _____

Relationship to Child or Minor _____ Parent or Guardian Signature _____ Date _____

Researcher Statement

I certify that the minor’s parent/guardian has been given adequate time to learn about the study and ask questions. It is my opinion that the parent/guardian understands his/her child’s rights and the purpose, risks, benefits, and procedures of the research and has voluntarily agreed to allow his/her child to participate. I have also explained the study to the minor in language appropriate to his/her age and have received assent from the minor.

Dr. Wendy Quach _____ Date _____

Example # 2 – Letter Format

REQUEST FOR YOUR CHILD'S PARTICIPATION IN A RESEARCH STUDY

Responsible Researchers: Dr. Maureen Smith and Dr. Ravisha Mathur
Department of Child & Adolescent Development
San Jose State University

Title of the Study: Young Children and Their Imaginary Companions

Dear Parents,

We would like to request your child's participation in a research study investigating their real and imaginary companions. Dr. Maureen Smith and Dr. Ravisha Mathur from the Department of Child and Adolescent Development at San José State University are conducting this study. The purpose of the study is to compare children's best friendships with children's imaginary companionships. In addition, we are investigating how these companions and friends develop and what function they play in your child's everyday life (e.g., how these companions affect your child's functioning in school and his/her other relationships).

Your child will be either interviewed (if he or she is a kindergartner) or be asked to complete a survey. We will ask questions like, "Do you have a pretend friend?" as well as asking them to respond to statements about their friends, " _____ would like me even if others did not." Finally, we will also ask them to participate in a pretend phone task, where they "talk" to their friends (either real or imaginary) on the telephone. This interview and/or survey will take about 50 minutes to complete.

Children participating in the study are not expected to experience any risks beyond those normally encountered in daily life. We have used similar questionnaires in the past and, although there are no direct benefits to the children participating and no direct compensation, many children have said they had fun doing them and enjoy answering the questions.

The study will be completed at school. All information from the study will only be seen by the research staff and will be kept confidential. The names of individual students will not be included in any reports of the study. That is, no information that could identify your child, your family, or you will be included in any reports of this research study. You should know, however, that we are required by law to report any disclosure of child abuse to the appropriate authority.

Participation is voluntary and there is no penalty if you and your child decide not to participate. If you decide to allow your child to participate, your child does not have to answer any question that he or she does not wish to answer. Also, you or your child may withdraw from the study at any time. There is no penalty for choosing to not participate.

If you have any questions about this study at any time, we would be happy to speak with you. We can be reached at (408) 567-1234 or (408) 876-5432. If you have any complaints, please contact Dr.

Toni Campbell, Department Chair of Child and Adolescent Development at (408) 321-1234. If you have questions about the rights of research participants, or in the event of a research related injury, please contact the Associate Vice President of the Office of Research, Pamela Stacks, Ph.D., at (408) 924-2427.

If you are willing to let your child participate in the survey, please sign this page, fill in the information requested, and return to your child’s teacher. A second copy of this form, signed and dated by the researchers, is attached for your records.

Sincerely,

Maureen Smith, Ph.D.

Ravisha Mathur, Ph.D.

Parent/Guardian Signature

Your signature indicates that you voluntarily agree to allow your child to be part of the study, that the details of the study have been explained to you and your child, that you have been given time to read this document, and that your questions have been answered. You will be given a copy of this consent form, signed and dated by the researcher, to keep for your records.

_____	_____	
Name of Child or Minor	Parent or Guardian Name (Printed)	
_____	_____	_____
Relationship to Child or Minor	Parent or Guardian Signature	Date

Researchers’ Statement

We certify that the minor’s parent/guardian has been given adequate time to learn about the study and ask questions. It is our opinion that the parent/guardian understands his/her child’s rights and the purpose, risks, benefits, and procedures of the research and has voluntarily agreed to allow his/her child to participate. We have also explained the study to the minor in language appropriate to his/her age and have received assent from the minor.

_____	_____	_____
Maureen Smith, Ph.D.	Ravisha Mathur, Ph.D.	Date

Example Assent Documents for Minors

Assent documents will vary depending on the age group and developmental ability of the minor. For adolescents, a written document seeking participants' signatures may be used. For young children, assent may be obtained verbally, and a script of what will be said should be included. Some of the contact information on the examples has been changed or omitted to protect the researchers.

Example # 1 – Simple Assent Form for Younger Children

REQUEST FOR YOUR PARTICIPATION IN A RESEARCH STUDY

NAME OF THE STUDY

Facilitating Learning of AAC Systems in Young Children

NAME OF THE RESEARCHER

Dr. Wendy Quach from San Jose State University

Dear Student,

You are invited to take part in this research study that takes place over 5 sessions. We are asking you because you are 7 or 8 years old.

In this study, we will show you how to use a new computer to make sentences to talk. There will be words or pictures to use when you make sentences. To do the study, we will videotape you while you use the new computer to make it talk. At the end of some sessions, we will ask you questions about how well you can operate the computer.

Being in this study will give you a chance to see and try out some new computers that can talk. It may also help us make new computers for people to use when they are talking.

We will also ask your parents for their permission for you to do this study. Please talk this over with them before you decide whether or not to participate. You may ask any questions at any time.

You do not have to be in this study if you do not want to. You can also stop at any time, if you want to. If you check "yes," it means that you have decided to participate and have read everything that is on this form. You and your parents will be given a copy of this form to keep.

_____ Yes, I would like to be in the study.

_____ No, I do not want to be in the study.

Name of Participant and Signature

Date

Signature of Researcher

In my judgment the minor/youth is voluntarily and knowingly giving assent to participate in this research study.

Wendy Quach, Ph.D., Principal Investigator

Date

Phone: (408) 123-4567

Example # 2 – Assent Form for Adolescents

REQUEST FOR YOUR PARTICIPATION IN A RESEARCH STUDY

TITLE OF THE STUDY

Exploring the Role of Parental Involvement in Juvenile Justice Outcomes

NAME OF THE RESEARCHERS

Dr. Emily Bruce and Dr. Maureen Smith
San Jose State University

WHAT THE RESEARCH IS ABOUT

You are invited to participate in a research study investigating how parent involvement (for example, being present during court hearings) affects the outcome of cases for youth.

WHAT YOU WILL BE ASKED TO DO

You will be asked to do three things: (1) Fill out a short set of questions that ask you about things like your age and ethnicity; (2) Fill out a short questionnaire that asks you about the kinds of social support you get from friends and family; and (3) participate in a focus group with other youth in custody where you will be asked to talk about things like what you know about the juvenile court process and whether having a parent with you in court makes a difference.

You will answer the questions and participate in the focus group during a regularly scheduled class taught by FLY. The focus group should take about an hour. If you decide not to participate, FLY will arrange for another activity for you during that time.

RISKS AND BENEFITS OF PARTICIPATION

We do not anticipate that there are any risks associated with participating in this study. You may benefit from being part of the study by learning more about your beliefs about the court and parent support as well as from learning more about other youth like you and their experiences. Your participation may also benefit other youth who may enter the juvenile court system by helping us figure out how to increase the support you get in the court system.

INCENTIVES FOR PARTICIPATION

There will be no compensation for participating in this study. However, as a thank you for your time and help, there will be pizza and other snacks during the focus groups.

CONFIDENTIALITY

Although the results of this study may be published, no information that could identify you or your parents will be included. We will only report information in a way that could not be traced back to a specific individual. To ensure the privacy of the information you provide, we will store all research materials in a password protected and encrypted file on a password protected computer that only the research team has access to.

The only exception to our confidentiality agreement is if there is a disclosure of abuse, or intent to harm self or others. We are required by law to report these disclosures to the appropriate authority. We can also not guarantee that other participants in the focus group will keep the information that is shared confidential, but we will go over confidentiality standards at the beginning of the focus group and ask everyone not to share others' personal information outside of the group.

WHO TO CONTACT IF YOU HAVE QUESTIONS

If you have questions at any time during the study, the people listed below can be contacted.

Questions about this research may be addressed to Maureen Smith, Ph.D., at 408-123-9876. Complaints about the research may be presented to Toni Campbell, Ph.D., Chair of the Department of Child and Adolescent Development, at 408-987-6543. For questions about your rights or to report a research-related injury, contact Pamela Stacks, Ph.D., Associate Vice President, the Office of Research, at 408-924-2479.

WHAT YOUR RIGHTS ARE

No service of any kind to which you are otherwise entitled will be lost or at risk if you decide not to participate in this study. Your assent (agreement) is voluntary. You may refuse to participate in the entire study or in any part of the study. You have the right to not answer any questions you do not wish to answer. If you decide to participate in the study, you are free to quit at any time without any negative effect on your relations with San Jose State University, The Santa Clara County Juvenile Justice Court and Probation Department, or FLY.

SIGNATURES

Your signature indicates that you voluntarily agree to participate in the study, that the details of the study have been explained to you, that you have been given time to read this document, and that your questions have been satisfactorily answered. You will receive a copy of this consent form for your records.

Participant's Name (printed)

Participant's Signature Date

RESEACHER STATEMENT

In my judgment the minor/youth is voluntarily and knowingly giving assent to participate in this research study. Consent from the parent or guardian has also already been sought and obtained.

Maureen Smith, Ph.D. Date

Example # 3 – Assent Script for Getting Verbal Assent from Children

Study Title

Reading Fluency

Name of Researcher

Douglas Wright, Graduate Student, Department of Education
Dr. Jane Doe, Professor in the Department of Education
San Jose State University

Why am I meeting with you?

I want to tell you about something I'm doing called a research study. A research study is when a person or group of people collect a lot of information to learn more about something. I am doing a study because I'm also a student and I want to learn if the interactive PowerPoint presentations I have created on the computer can help increase both how fast you read and how well you understand what you're reading. This is called reading fluency. After I tell you about the study, I will ask if you would like to be in the study or not.

Why am I doing this study?

I want to find out if using the interactive PowerPoint presentations I put together on the computer works better than using the standard way we practice reading fluency to increase the number of words you read per minute. I want to find out which method is most effective. To do this, I am getting information from all of the students in the fourth grade at your school who would like to be a part of the study.

There will be about 80 students in the whole study. The study will begin as soon as I get your permission and your parents' permission to let you participate. The study will go on every school day for about three weeks.

What will happen to you if you are in this study?

If you agree to be in this study, you will randomly be placed into one of two groups.

In one group, we will practice reading fluency with the use of the interactive PowerPoint presentations for about 10 minutes each morning. I will use the computer and display pictures that may help you figure out the definitions to about 6 key vocabulary words from our English Language Arts theme stories. I will first ask you to take a guess and tell the person sitting next to you what you think the definition to the given word is based on the picture that you see. After you have guessed, I will show you the definition and we will read it aloud together.

Next, I will display one by one some important vocabulary words from the story we are working on for that particular week. Each word will be displayed one at a time. I will read it first, so you know how it's pronounced. Then everyone in the group will read the word together and aloud so I can hear you and make sure it is being pronounced correctly.

If you are part of the other group in the study, that means you will practice reading fluency the same way we have been doing it since the beginning of the school year. You will practice every school day morning for about 10 minutes. You will have a reading fluency partner. You will read while your partner keeps track of the number of words you read correctly. Then your partner will read while you keep track of the number of words your partner reads correctly. Your teacher will tell you when to begin and when to stop each time you read.

What will happen after 3 weeks of the study?

After three weeks, you will take the same kind of reading fluency test you usually take to see how many words you can read per minute. Your teacher will give you something to read and ask you to read as quickly as you can in one minute. Your teacher will record the number of words you read correctly.

After all of the fluency scores for all students who are participating in the study have been collected, the fourth grade teachers will meet to look at the information.

If the students in the first group do much better than the students in the second group, then their teachers will have the opportunity to be shown how to use the interactive PowerPoint presentations and they will be able to use them in their classroom with their own students.

If the students in the second group have better scores than the students in the first group, then all of the students who were in the first group will be able to come to an after school class for about 10 minutes each school day for only 3 weeks to practice their reading fluency skills in the traditional way so that they have a chance to catch up to the other kids in the second group.

When I share the results of this study with my school and with the public, I will not use any students' names or individual test scores. Nobody will be able to tell whether you participated in the study or not.

What happens if you don't want to participate?

You don't have to be in the study if you don't want to. It won't affect your grade in the class and there is no punishment for not participating. If you are not in the study, you can still be in the class, but I will not use your test scores as part of my study. Whether or not you are in the study is completely your choice.

If you decide that you want to be in the study, your participation may help teachers provide better instruction about reading and this may help other students.

Do you have any questions?

You can ask me questions any time. You can ask now. You can ask later. You can talk to me, or you can talk to the principal. They know all about the study. You can also talk about the study with your parents.

Do you want to be in the study?

Signature of the Person Conducting the Assent Discussion

I have explained the study to _____ (*print name of child*) in language he/she can understand, and the child has agreed to be in the study. Consent from the parent or guardian has also already been sought and obtained.

Printed Name of Person Conducting Assent Discussion

Signature of Person Conducting Assent Discussion

Date

Appendix D
SJSU Policy on Informed Consent

The complete wording of the SJSU policy on informed consent can be found in S08-7, Policy for Protection of Human Research Subjects, Section VI. F. This handbook has incorporated policy recommendations into its instructions. The policy itself can be accessed on the SJSU Academic Senate website: <http://www.sjsu.edu/senate/docs/S08-7.pdf>