PEPPERDINE
UNIVERSITY

YOUTH ASSENT TO PARTICIPATE IN RESEARCH (AGES 14–17)

The following instructions and examples are provided to assist in development of the Youth Assent Form. Additional templates and information are available from the IRB and website.

The following should be considered when developing the assent form:

- Assent forms must include clear identification of the responsible institution (Pepperdine University letterhead as shown above can be utilized or Departmental specific letterhead). Assent forms submitted without identification of the responsible institution will result in delay of approval of the project.

- All forms should be submitted suitable for reproduction (printed single sided or available electronically) using at minimum reasonable 12-point font and 1 inch margins.

- Each page of the form should be full without inappropriate divisions: sections can be split (some on one page, some on another page) so that large blank areas do not exist.

- All pages must include page numbers at the bottom and (if applicable), a participant's initial blank.

- An assent document should be written in a manner that is appropriate for the age of the participant, the decision-making capacity of the individual participant and/or the complexity of the project. Typically, information included in an assent form is minimal between the ages of 7-13 years, youth assent forms provide more information for ages 14-17 Again, the amount of information in an assent form should be customized to your study population, the age of the participant and the decision-making capacity of the participant.

- The informational content of the elements of informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This

helps the prospective subject focus on each individual element thereby increasing the validity of the assent process.

- The assent form must be written in simple enough language so that it is readily understood by the least educated of the subjects to be utilized. Normally the highest level of language in the consent form should equate to the youngest of the subjects to be utilized. Scientific terms should be avoided when possible. If scientific terms will be included, the lay term or definition should be provided.

- Please remember, age of majority in California is 18 years old. Anyone younger than 18 requires parental consent/assent or a waiver of parental consent must be approved by the IRB.

- ***Before submitting the assent document for IRB approval, delete this page and all comments/instructions/boxes or non-applicable language.***

(INSERT TITLE OF THE STUDY)

You are invited to participate in a research study conducted by **(insert names and degrees of Principal investigator, including faculty advisor)**, from Pepperdine University. Your participation is voluntary. You should read the information below, and ask questions about anything you do not understand before deciding whether to participate.

Please take as much time as you need to read the consent form. You can decline to participate, even if your parent/legal guardian agrees to allow your participation. You may also decide to discuss it with your family or friends. If you decide to participate, you will both be asked to sign this form. You will be given a copy of this form.

PURPOSE OF THE STUDY

Include why the participant is being asked to be in this research study?

> ***Explain succinctly and simplistically why the prospective subject is eligible to participate. As appropriate, major eligibility criteria may be included in this section.***

Example: We are inviting you to be in this study because you are a teenager, and we are interested in how different kinds of TV affect the way teenagers do things.

In addition, this section should provide a clear and accurate statement of the scientific purpose, the objectives of the research, and the reasons why the study is being conducted. This section should be brief and simple. However, enough detail should be presented so that the youth understands why the study is being performed. Researchers are reminded that if subjects cannot understand the study or procedures, they more than likely will not participate.)

STUDY PROCEDURES

What will be done during this research study?

If you agree to participate, you will be asked to…

Guidelines:

- **Describe the procedures and their duration chronologically using simplistic language, short sentences and/or short paragraphs. The use of subheadings will help to organize this section and increase readability.**
- **If audio or video taping or photography will take place, state so and indicate whether participants can choose to continue with their participation should they decline to be recorded.**
- **Use simple language to indicate exactly what will happen to each participant, where the study will take place, how long each visit will take, how may visits are required, etc. It is more important to tell subjects and/or parents exactly what will happen, than it is to provide an exhaustive and sophisticated scientific justification for the study.**
- **For research involving randomization of participants into different arms of studies, specify the randomization procedures in very simple terms.**
- **Describe the study procedures for each subject population, if the study procedures are different between parent and youth.**

Example: This research will take you about 30-45 minutes to do. First, we will train you on a computer task. Then, you will watch a short TV program. This may be a comedy show or an instructional program or a documentary show. Then you will do a real computer task. This computer task involves choosing between one of four part-time or summer jobs.

Example: If you agree to participate in this study, you will be asked to complete an online survey. The survey will take about 30 minutes to complete. You don't have to answer any questions you don't want to.

Example: You will be asked to do a series of tasks where you will see some photographs, objects and places; and asked to react, think about, or rate your feelings towards the photographs. You will also be asked to complete a series of questionnaires, some will ask you questions about feelings, some will ask whether you agree or disagree with certain statements, and some will ask questions about your general knowledge or vocabulary.

Example: If you agree to participate in this study, you will be asked to complete the following procedures:

> **Online Survey:**
> You will be asked to complete an online survey, which should take no more than 10 minutes to complete.
>
> **Focus Group Interview:**
> You may also be asked to participate in an audio-taped focus group interview. The focus group consists of two or more people and will take about an hour to complete. If you don't want to be taped, you cannot participate in the focus group.
>
> **Individual interviews:**
> You may also be asked to participate in an individual interview. If you do not want to participate in a focus group or want to be audio-taped, you may be asked to participate in an individual interview, anticipated to take no more than an hour to complete.

POTENTIAL RISKS AND DISCOMFORTS

(Describe any reasonable foreseeable risks, discomforts, inconveniences, including physiological risks/discomforts; describe any psychological, social, legal or financial risks to participant and how these will be minimized).

Example: There are potential risks to your participation as one may feel uncomfortable answering some or all of the questions. You do not have to answer any question you don't want to.

Example: There is a mild risk of anxiety, sadness, or other emotional reactions. You may discontinue your participation at any time.

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

(Note that as this is a research study, the benefits are contingent upon the results. The investigator can state what the benefits are anticipated to be, not what they will be. Also the anticipated benefits to society should be stated.)

Example: There are no anticipated benefits to your participation. We hope that this study will help researchers learn more about cognition and emotion. This research may help advance knowledge in the field of cognition and emotion; however, there is no direct benefit to you for participating in this study.

Example: It is hoped that you might learn a new method of relaxing. Researchers hope to help therapists teach their patients how to better deal with stress.

PAYMENT/COMPENSATION FOR PARTICIPATION (IF NOT APPLICABLE DELETE SECTION)

(State whether the participant (parent and/or youth) will receive payment/compensation or any other form of compensation, e.g. small gift, etc. If not, this section can be removed. If participants receive payment, describe amount for each participant; when payment is scheduled; and the pro-rated schedule should the participant decide to withdraw or is withdrawn by the investigator. If participant will be reimbursed for expenses such as parking, bus/taxi, travel companion/assistant, etc., list the payment. Note payment is not contingent upon completion of study procedures.)

Example: You will receive $10 gift card from Target for your time. You do not have to answer all of the questions in order to receive the card. The card will be given to you when you return the questionnaire.

Example: You will receive entry into a drawing for an iPod. The drawing will be held at the end of the study and the winner notified via email.

Example: You will receive one credit for participating in the study; the credit will be issued at the end of your participation, per the subject pool guidelines.

POTENTIAL CONFLICTS OF INTEREST OF THE INVESTIGATOR (IF NOT APPLICABLE DELETE SECTION)

(A "Conflict of Interest (COI)" is a situation in which financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research. If there appears to be a conflict of interest (COI) or there is a COI, include this section. If

there is no COI, this section can be deleted.)

1. **The investigator must disclose all financial or other personal considerations that compromise, or have the appearance of compromising, the investigator's professional judgment in proposing, conducting, supervising, or reporting research. Conflicts include financial as well as non-financial interests. Conflicts include financial interests (stocks, stock options, or other ownership interests, whether traded publicly or not) in a research sponsor or licensee; management roles in a research sponsor, licensee, or other company having an economic interest in the outcome of the research; and using students to perform services in which an investigator maintains an ownership interest or management role.**
2. **In disclosing your proprietary interest and research interest in the informed consent, you may do so in general terms, in a manner consistent with IRB requirements. At a minimum, you must disclose the nature of the interest, such as a paid consultant, a lecturer, a board member, an equity ownership, or a management or supervisory role in the sponsoring company.**

Example 1: If there may be commercial product development in the future, the following statement can be used: The biotechnology company _____ (insert company name) may use your _____ (insert type of samples) for other research studies. Those studies may develop products that can be sold. If they make money from these products, you will not receive any money.

Example 2: If you have a financial interest in the sponsoring company, the following statement should be used.
The investigator has a financial interest in the company sponsoring this study. (Briefly describe your financial interest.) The nature of this financial interest and the design of the study have been approved and allowed by the institutional committees.

CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The members of the research team, the funding agency **(remove references to funding agency if not applicable)** and Pepperdine University Protection Program (HSPP) may access the data. The HSPP reviews and monitors research studies to protect the rights and welfare of research subjects.

The data will be stored **(state where and how the data will be stored.)[If applicable to the study describe the participant's right to review/edit the audio-video-recordings and/or transcripts (parents cannot access their child's responses) and who will have access**

(including transcribers. If the audio-video-recordings will be used for educational purposes, describe how personal identities will be shielded/disguised and, if/when the audio-video-recordings will be erased (approximately). If the audio-video-recordings will be maintained indefinitely, state how confidentiality will be maintained. If information will be released to any other party for any reason, state the person/agency to which the information will be furnished, the nature of the information, and the purpose of the disclosure. Give a brief description of how personal information, research data, and related records will be coded, stored, etc., to prevent access by unauthorized personnel (list the personnel who have access).

(Indicate how long the data will be kept. Please note that data must be kept for a minimum of three years after the completion of the study. The data may be kept indefinitely.)

Example: The data will be stored on a password protected computer in the researcher's office for three years after the study has been completed and then destroyed.

Example: The data will be stored on a password protected computer and/or in a locked file cabinet in the researchers office for three years after the study has been completed and then destroyed.

Example: Upon completion of the data collection and data entry, all hard copies (consent documents, survey instruments, etc.) will be destroyed. The remaining data will be maintained indefinitely; however, the data will not be used in future research studies.

PARTICIPATION AND WITHDRAWAL

Your participation is voluntary. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. **(If appropriate, describe the anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent.)**

ALTERNATIVES TO FULL PARTICIPATION

The alternative to participation in the study is not participating or completing only the items which you feel comfortable.

EXAMPLES:

Example: *Your alternative is to not participate. Your relationship with your employer will not be affected whether you participate or not in this study.*

EMERGENCY CARE AND COMPENSATION FOR INJURY

(This section is required only for studies that are greater than minimal risk (full board); if the study does not qualify for full board review, please delete this section.)

If you are injured as a direct result of research procedures, you will receive medical treatment; however, you or your insurance will be responsible for the cost. Pepperdine University does not provide any monetary compensation for injury.

INVESTIGATOR'S CONTACT INFORMATION

I understand that the investigator is willing to answer any inquiries I may have concerning the research herein described. I understand that I may contact ***(insert name and contact information include email address for faculty supervisor or other collaborator)*** if I have any other questions or concerns about this research.

RIGHTS OF RESEARCH PARTICIPANT – IRB CONTACT INFORMATION

If you have questions, concerns or complaints about your rights as a research participant or research in general please contact Dr. Judy Ho, Chairperson of the Graduate & Professional Schools Institutional Review Board at Pepperdine University 6100 Center Drive Suite 500 Los Angeles, CA 90045, 310-568-5753 or gpsirb@pepperdine.edu.

SIGNATURE OF RESEARCH PARTICIPANT (IF PARTICIPANT IS 14 OR OLDER)

I have read the information provided above. I have been given a chance to ask questions. My questions have been answered to my satisfaction and I agree to participate in this study. I have been given a copy of this form.

AUDIO/VIDEO/PHOTOGRAPHS ***(If this is not applicable to your study and/or if participants do not have a choice of being audio/video-recorded or photographed, delete this section.)***

□ *I agree to be audio/video-recorded /photographed* ***(remove the media not being used)***

□ *I do not want to be audio/video-recorded /photographed* ***(remove the media not being used)***

_____

Name of Participant

_____ _____

Signature of Participant Date

SIGNATURE OF INVESTIGATOR

I have explained the research to the participants and answered all of his/her questions. In my judgment the participants are knowingly, willingly and intelligently agreeing to participate in this study. They have the legal capacity to give informed consent to participate in this research study and all of the various components. They also have been informed participation is voluntarily and that they may discontinue their participation in the study at any time, for any reason.

_____

Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date