Informed Assent Directions:

Suggested headings for the assent form are in **bold**. Instructions about information to be provided are in plain type; consult §116 and §117 of the revised Federal Policy for additional information about informed consent.

Examples of language a researcher might use in a consent form have the "Sample" watermark. These examples are often shorter than what may be necessary to fully describe your study. If assurances mentioned in the examples cannot be made for your study, the limitations and related risks for participants should be fully explained. Please be certain that the content, format, and reading level of the assent form are appropriate for the participants in your study, especially as may be needed for younger children or persons with limited cognitive abilities.

The beginning of the assent form should include a concise explanation, in easily understood language, of:

1. the fact that assent is being sought for research and that participation is voluntary;

2. the purpose and procedures of the research and how much time altogether this will require from the participant;

3. reasonably foreseeable risks or discomforts to the participant;

4. reasonably expected benefits for the participant or others; and

5. alternative procedures or treatments, if any, that might be advantageous to the participant.

Assent to Participate in Research

- You have been asked to volunteer for this research because your school has a program to encourage healthy behaviors among teenagers. You can choose to participate or choose not to participate. Either way, you will not lose any rights or benefits.

- The researchers are studying healthy and unhealthy activities of teenagers and the impact of school programs that encourage healthy behaviors. You will be asked to answer survey questions about your background, lifestyle, and physical and mental health, before and after your school's program. You may also be asked to participate in a focus group. Your parents will be asked to give researchers permission to see the immunizations listed in your medical record. The total time will be about 1 hour if you are doing only the two surveys or 2 hours if you also participate in a focus group.

- Although researchers will try to protect your information, there is a possibility that health and other information about you might become known to others. Information that could identify you will be separated from the rest of your data and stored separately.

- You are not likely to benefit directly from participating in this research. The overall health of teenagers may benefit if new knowledge is gained from the study.

- This study only gathers information about teenagers. Your alternative is to not participate.

What is the name of the study? Promoting Healthy Behaviors in Teenagers
Who is the main person doing the research? Brian Winterbottom, Ph.D.
Where does the researcher work? UCLA Department of Psychology

1. What is the study about? What will I be asked to do? How long will it take?

The goal of this study is to learn about healthy and unhealthy activities of teenagers and measure the impact of school programs that encourage healthy behaviors. You have been asked to participate because your school has a program to encourage healthy behaviors among teenagers. About _____ people from the _____ area will take part in this study. Half of them will only be asked to complete a survey about activities in their daily lives before and after their school's program. The other half will be asked to participate in a focus group at their school, lasting about 1 hour, in addition to completing the two surveys. We will also ask for permission to see your medical records, but only for information about immunizations you have received in your lifetime. Your parents will need to sign a separate document that allows us to do this. The survey will include questions about your background (such as racial or ethnic group), lifestyle (such as eating habits and exercise), and physical and mental health (such as illnesses, body image, and feelings you have about yourself and others). This will take about 30 minutes each time you do the survey. The focus group will discuss some of these topics in more detail.

2. Is there anything in the research that might harm me or make me feel bad or uncomfortable?

Some of the survey questions may ask for very personal information (such as family income level, your sexuality, use of drugs, etc.), but you don't have to answer any questions you don't want to answer. Focus group participants will be asked to avoid discussing with others anything that was said in the group. Although only information about immunizations will be requested from your medical records, other information might be included in what is sent. The researchers have extensive procedures designed to protect your privacy. They will separate any information that identifies you from the rest of your data and store those identifiers separately. Results used for analysis will not include your name or other identifiers. However, if some of the information about you were to become available to others, it could be embarrassing or even affect things like your future employability or access to insurance.

If all members of the focus group agree, we would like to make a video recording to better understand what people said in the discussion. No names or other identifiers will be stored with the recordings, although your faces will be visible. The recordings will be destroyed after they have been analyzed, no later than 1 year after the focus group. Please initial your choice below:

_____ I agree to allow a video recording of the focus group.

_____ I do not want a video recording to be made of the focus group.

3. How will researchers protect the information they obtain about me?

Your name and contact information will be destroyed when the research is finished, or no later than 3 years after your participation. Your answers on the survey and what you and others say in the focus group will not include your identity. The risk of researchers releasing information about you by mistake is small, but the researchers cannot guarantee that this will never happen. They also cannot guarantee that focus group participants will never talk to others about what was discussed. Your data will not be shared with other researchers. The data (but not any video recordings) may be presented at scientific or professional meetings or published in scientific journals. You will not be identified by name in any of those reports.

4. Will I benefit from participating in the research?

You are not likely to personally benefit from participating in this research. The investigators hope the results will lead to a better understanding of the healthy and unhealthy things teenagers do in their daily lives.

5. Will it cost me anything to participate?

There is no cost to you other than the usual data charges you might have for online access to the survey.

6. Will I receive any compensation for participating in the study?

Focus group participants will receive a $20 gift card at the end of the focus group session. A $10 gift card will be sent to all participants after they complete both surveys.

7. If I am hurt while participating in the research, what will be done?

There is no risk of physical harm from participating. You will receive a list of counseling services for teenagers. If any topics discussed in the research are particularly troubling, please talk to an adult you trust, choose a counseling service on the list, or ask the researchers for help. Many, but not all, of the counseling services are available without charge.

8. Who is paying for the cost of the study?

The costs of this study are being paid by the Alfred P. Sloan Foundation. The researchers do not have any financial incentives or conflicts of interest.

9. Who will answer any questions I have about the research?

If you have questions about this research, please contact the main researcher, Brian Winterbottom, at (310) 123-4567 or by email at bwinterbottom@ucla.zzz. You may also ask the UCLA Human Research Protection Program about your rights as a research participant. Their phone number is (310) 123-7689 or send email to participants@research.ucla.zzz.

10. Can I choose whether or not to participate?

It is entirely your choice whether or not to participate in this research. Your parents have said it is OK to participate, but no one will be upset if you choose not to. You may stop participating at any time. You don't have to answer any questions you prefer not to answer. You don't have to sign anything you don't want to sign. You will not lose any rights or benefits by choosing to participate or not to participate. Your school's program for healthy behaviors will be available whether or not you participate in this research.

11. What are my rights as a research participant?

A summary of your rights as a research participant is attached to this assent form.

12. My signature if I am willing to participate:

I agree to participate in this research and have received a copy of the Participant's Bill of Rights for Medical [or Non-Medical] Research.

Printed Name of Participant	Signature of Participant	Date Signed
Printed Name of Representative	Signature of Representative	Date Signed

Additional Information for Researchers

Regarding item 1 in the assent form, the revised Federal Policy asks for identification of any procedures that are experimental. If any procedures or treatments are not considered, for example, to be standard, established, or commonly accepted for the research situation, this needs to be explained to participants. Of course, researchers will generally not want to use the word “experimental” to describe other manipulations of the research situation, as this would bias the behavior of participants.

Regarding item 3 in the assent form, an alternative disclosure about confidentiality might look like this:

> Your name and contact information will be destroyed when the research is finished, or no later than 3 years after your participation. Your answers on the survey and what you and others say in the focus group will not include your identity. The risk of researchers releasing information about you by mistake is small, but the researchers cannot guarantee that this will never happen. They also cannot guarantee that focus group participants will never talk to others about what was discussed. The data (but not any video recordings) may be presented at scientific or professional meetings or published in scientific journals. You will not be identified by name in any of those reports. The researchers may use your data and video recordings in other research without asking your permission. The researchers may also share your data (but not video recordings) with other researchers, after removing information that identifies you, also without asking your permission. You should understand that it might become possible in the future to discover your identity when your data is used, despite what the researchers do to remove information about you.

The revised Federal Policy lists the following additional elements that are to be provided in the assent form when appropriate:

1. A statement that the research procedures may involve unforeseeable risks to the participant (or to the embryo or fetus, if pregnant).

2. Circumstances under which the participant’s participation may be terminated by the investigator.

3. Consequences of a decision to withdraw from the research, and the procedures for doing so.

4. A statement that significant new findings which might affect willingness to participate will be provided if they occur.

5. The approximate number of participants in the study.

6. A statement that biospecimens (even if de-identified) may be used for commercial profit and whether the participant will share in those profits.

7. Under what conditions any clinically relevant results, including individual results, will be disclosed to participants.

8. Whether research with biospecimens will or might include whole genome sequencing.