**TEMPLATE ASSENT FORM (13–17 Year Olds) – BIOMEDICAL STUDY**

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 UNIVERSITY OF CALIFORNIA AT BERKELEY

**ASSENT TO PARTICIPATE IN A RESEARCH STUDY**

***Title of Study***

*[If applicable, designate sub-group after study title, e.g., "13–17 Year Olds"]*

My name is \_\_\_\_\_\_\_\_\_\_. I am a *[student/professor]* in the Department *[or* School*]* of \_\_\_\_\_\_\_\_\_\_ at the University of California, Berkeley. I am doing a research study [*or if student:*  I am working with my teacher, Professor\_\_\_\_\_\_\_\_\_\_,on a research study]. I’d like to tell you about this study and ask if you will take part (be a "subject") in it.

**What is a research study?**

A research study is when people like me collect a lot of information about a certain thing to find out more about it. Before you decide if you want to be in this study, it’s important for you to understand why we’re doing the research and what’s involved.

So please read this form carefully. You can discuss it with your parents or anyone else. If you have any questions about the research, just ask me.

**Why are we doing this study?**

*[Give brief explanation of why study is being done, e.g.:]*

I *[and the other researchers on my team]* are doing this study to find out more about \_\_\_\_\_\_\_\_\_\_ [*explain study purpose in simple terms suitable for this age range*].

**Why are we talking to you about this study?**

*[Give brief explanation of why the individual is being asked to participate in study, e.g.:]*

To learn about \_\_\_\_\_\_\_\_\_\_, we would like to study \_\_\_\_\_\_\_\_\_\_ in people around your age. *[We will do this by comparing some tests of people who have \_\_\_\_\_\_\_\_\_\_ with tests of people who don't*. We're inviting you to participate becauseyou are \_\_\_\_\_\_\_\_\_\_ *or* you have \_\_\_\_\_\_\_\_\_\_*]*.

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

*[List all study procedures/ tests/ activities in chronological order, using bulleted format. Indicate location where procedures will take place (e.g., lab, home, or other setting), and amount of time needed for each procedure. Also note* total *amount of time required for study participation. See below for examples of various procedures.]*

If you agree to be in the study and your parents give permission, we will ask you to:

* Answer questions

*On the first day, you and your parents will come to our lab. We will ask you and your parents to answer some questions about the way you think, act, and feel about things.*

If you don't want to answer any of the questions, you don't have to.

This part will take about *\_\_\_ [minutes/hours]*.

* Do tests/ puzzles/ computer games

Then we will ask you to[*briefly describe study procedures/activities, e.g.*] *take some tests/ solve some puzzles/ play some computer games.*

*Sometimes you will have to make decisions about these words or pictures on the computer. Or you will have to answer questions with a pencil and paper, or by speaking out loud. We will explain exactly what you need to do and when to do it.*

You can take breaks during the *tests and computer games* as often as you need to.

This part will take about \_\_\_ *[minutes/hours]*.

* Blood sample:

We will ask you to give a sample of your blood *[indicate amount in lay terms, e.g., about a teaspoonful]*. This is done by a *[*trained health technician *or* researcher*]* putting a needle into a vein *in your arm* and drawing the blood into a small tube. It will take about *10 to 15 minutes at the most*. [*Explain how many blood draws will be done and when they will occur.*]

*So on the first day*, you will spend about \_\_\_ *[minutes/hours]* on the study.

* Brain scan

[*NOTE: See* [*CPHS Guidelines on Magnetic Resonance Imaging (MRI) in Research*](http://cphs.berkeley.edu/mri.pdf) *and apply to protocol and assent/permission forms as appropriate.*]

*On the second day*, you will get a brain scan called an "MRI," which stands for Magnetic Resonance Imaging.

-When you get an MRI, you lie down on a narrow table that's called a "scanner bed." We slide the bed into a big tube with a magnet in it called the "scanner." The scanner is about 6 feet long by 2 feet wide and is open at each end. The scanner makes pictures of your brain.

-Before you can go into the scanner, we want to make sure it's safe. We will ask you and your parents to read over the MRI screening form with us. This form lists the different things that can make it unsafe for you to be in the scanner, like wearing braces, having a tattoo, or being pregnant.

***Subjects who are able to become pregnant only***:

We don't know if there are risks to an unborn baby from MRI. So **if there is any chance you might be pregnant, you should not participate in this study.**

If you want to make sure that you are not pregnant before taking part in the study, we will have a pregnancy testing kit available that you can administer to yourself in private. You do not need to reveal the results to anyone.

[***Note:*** *Pregnancy testing requirements for other biomedical studies that involve investigational devices or drugs may be determined by CPHS on a case-by-case basis.*]

-If the screening shows it's safe for you to get an MRI, we'll go ahead to the next steps.

1. *First*, we will train you in a "mock" (pretend) scanner. It looks like the real MRI scanner but doesn't have the magnet in it. This lets you get used to what it's like in the real scanner. You will see how it feels to lie down in a narrow space and practice keeping still, which is very important for the real scan. This training will take about \_\_\_ *[minutes/hours]*.

1. *Then, after you take a rest*, we'll ask you to do the real scan. For the real scan, you will lie still on the scanner bed. We will put cushions around the sides of your head to help keep it from moving. Since the scanner can be very noisy, we will give you earplugs to protect your hearing. We will make sure that you are comfortable.
2. We will slowly slide the scanner bed you are lying on into the scanner. Once you are inside… [*explain what will happen/what subject will be asked to do*]*.*
3. *While you are doing these tasks*, the MRI scanner will be making pictures of your brain that measure your brain activity.
4. You can take breaks *from the tasks* as often as you need to.
5. The real MRI scan will take about \_\_\_ *[minutes/hours]*.

*So on the second day,* you will spend about \_\_\_ *[minutes/hours]* on the study.

* Saliva (spit) collection:

We will also ask you to give samples of your saliva (spit). [*Briefly explain reason,\* e.g., to measure cortisol (a chemical that the body produces when a person is in a new or stressful situation). Also describe method for collection and how many times it will be done.*] This will just take a few minutes to do each time.

[\****Note***: *If saliva or other samples are being used for* ***DNA/genetic/genomic testing*** *purposes, see* [*CPHS Guidelines on Genetic/Genomic Research*](http://cphs.berkeley.edu/genetic_genomic.pdf) *for details on consent language, etc*., *and adapt as appropriate*.]

Total time: Altogether, the whole study will take about \_\_\_ *[minutes*/*hours]* of your time *[spread out over \_\_\_ days.]*

[Study location:*Note where study procedures will take place if not already specified above.*]

**Will you get healthier if you are in the study?**

*[Explain possible benefits of the study, both direct/individual (if there are no direct benefits, make this clear) and indirect/general benefits to society or scientific knowledge, e.g.:]*

This isn't a study about getting healthier or a treatment to make you better. But we hope to learn more about \_\_\_\_\_\_\_\_\_\_, *[so in the future we can help people/other children who have \_\_\_\_\_\_\_\_\_\_]*.

**Will any part of the study be uncomfortable or hurt?**

[*List possible risks/discomforts, using bulleted format. See examples below.*]

* Blood drawing**:** Getting your blood drawn can hurt for a few seconds from the needle stick going in, like when you get a shot at the doctor's office. Afterwards, you might get a little bruise. Sometimes an infection can develop there, but that hardly ever happens.
* Brain scan: You might be uncomfortable while you are in the MRI scanner. This happens to some people when they lie very still in a small space.

-The scanner makes a very loud noise when it is turned on. That's why we will give you earplugs to wear while we are taking pictures of your brain.

-You might feel something like a tap on your body or a tingling while the scanner is running. If you do, it shouldn't last very long.

If you do not like being in the scanner for any reason, please [*instruct the subject how to indicate he/she is uncomfortable or wants to take a break, e.g., speak out loud/ into an intercom, squeeze a squeeze-ball*]*,* and we will stop the testing right away.

**Who will know about your study participation?**

*[This section should adapt guidance under "Confidentiality" in the* [*CPHS Template Consent Form - Biomedical Study*](http://cphs.berkeley.edu/CF-Template_Biomed.docx)*. For example:]*

Besides you and your parents [*insert others, if applicable*], the researchers are the only ones who will know about your study participation. If we publish reports or give talks about this research, we will only discuss group results. We will not use your name or any other personal information that would identify you.

[I*f applicable: Unless a court of law requires it or your parents request that we share them with your doctor, we will not give the specific results of your tests, scans, or samples to anyone else*.]

To help protect confidentiality, [*explain security measures to be taken for data, samples, recordings, etc. in simple terms, e.g.:*] we will give your study data a code number, and keep it in a file with a password that only the researchers know. The file will be on a computer that only the researchers are allowed to use.

[*If data/records will be destroyed, state when; if they will be retained, explain for how long and why, e.g.:*] We plan to keep this information for \_\_\_ years, in case we or other researchers want to use it later for other studies. But we will follow the same steps we just described to keep it as confidential as possible. [*If photographs, audio or video recordings will be retained for future use, see sample* [*Media Records Release Form*](http://cphs.berkeley.edu/CF-Sample_MediaRecordsReleaseForm.docx).]

**Will you get paid for being in the study?**

[*If no payment*:] You will not be paid for being in this study. [*Or if payment*:] Your parents [*or, depending on the arrangements*, You] will receive [*e.g., amount of money, gift cards with their value*] as a thank-you for your time and effort to take part in this study. [*Briefly explain how/ when compensation will be dispersed, etc.*]

**Do you have to be in the study?**

No, you don’t. Research is something you do only if you want to. No one will get mad at you if you don’t want to be in the study. And remember, you can always change your mind later if you decide you don't want to be in the study any more.

**Do you have any questions?**

You can ask questions about this study at any time, now or later. You can talk to me, or your parents, or someone else at any time during the study. You can contact me, *[PI or student investigator's name]*, at ***510-000-0000*** or ***email@xxxx.xxx***. *Or you can contact [other research team member's name] at* ***510-000-0000*** *or* ***email@xxxx.xxx***.

If you have any questions or concerns about your rights and treatment as a research subject, you can contact OPHS, the office of UC Berkeley's Committee for the Protection of Human Subjects, at 510-642-7461 or subjects@berkeley.edu*.*

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**ASSENT OF ADOLESCENT (13–17 years old)**

If you decide to participate, and your parents agree, we'll give you a copy of this form to keep for future reference.

***If you would like to be in this research study, please sign your name on the line below.***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subject's Name/Signature (*written by adolescent*) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator/Person Obtaining Assent Date