# Model Consent Language and Formatting

Use this type of CHILD ASSENT FORM for research projects that involve:

* Research participants who are MINORS (age 7-13). Since minors typically may not provide informed consent for themselves, a parent/guardian needs to provide consent for the minor to participate. The researcher must get both the parental consent/permission (which is a separate document, not listed in this file), and the assent of the minor for the minor to participate.
* Interview, Survey or Observation in a setting where there is no reasonable expectation of privacy, etc.
* Research study is generally biomedical, conducted in a clinical setting
* Always have two copies of the informed consent for each potential participant. One signed copy is kept by the PI or research team, and the other copy is to be given to the enrolled participant after written consent is given.

## Assent to Participate in a Research Project:

**Study Title:** Genes and Brain Development in Healthy Children

**Study Doctor:** [Name]

We are asking you to take part in a research study to help us learn more about how brains develop in healthy children.

Before you decide whether to take part in this study, it is important that you know:

* It is your choice to be a part of this study or not;
* If you decide to join the study, you can stop at any time; and
* Your parent or legal guardian must also agree for you to be in this study.

# **What will you be asked to do if you join this study?**

You will go to The Queen’s Medical Center for the study visits. It will probably take two or three visits to finish. Here is what you will be asked to do:

***Medical Exam:*** First, you and your parent will be asked about your background and your health. A doctor will check things like your height, weight, moods, nerves and muscles. If you are a girl and have started your period, we will test your urine to see if you are pregnant. If you are pregnant, you cannot be in the study.

***Saliva Test:*** You will be asked to give some saliva (spit) by spitting about one-teaspoon of saliva into some tubes.

***Brain and Nerve Tests:*** Some tests will measure how your brain and nerves are working. These will be paper-pencil and computer tests.

***Brain scan:*** For the brain scan, you will lie down on a bed, which will slide into a small tunnel. A scanner inside the tunnel will take pictures of your brain. During the scan, you can watch a video, listen to music, or take a nap.

**Will anything happen to you that may make you feel uncomfortable or unsafe?**

***In-Person Research Risk:***

For the safety and protection of yourself, the research team and others, we strongly recommend that you wear a well-fitting mask that covers nose and mouth [(CDC guidance)](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html) during each research-related encounter to reduce the spread of common respiratory diseases such as the Rhinovirus (common cold), the Influenza (Flu), Respiratory Syncytial Virus (RSV), and Coronavirus Disease of 2019 (COVID-19). Members of the research team will wear a well-fitting mask that covers nose and mouth at all times.

***Medical Exam:*** Some people feel embarrassed when a doctor examines them or asks them personal questions. You do not have to answer any questions that make you uncomfortable.

***Pregnancy Test (for girls):*** If your urine test shows that you are pregnant, this might be upsetting to you and your family. If you wish, you and your parent or legal guardian will be given information about options you may want to consider.

***Brain and Nerve Tests*:** If you get frustrated during the tests, we will stop and take a break, talk about what is frustrating you, or do other tests.

***Brain Scan:*** We will make sure it is safe for you to have a brain scan. Metal things in your body or clothes could be unsafe, so you must tell the doctors if you do. We will be asking you to remove things like jewelry, retainers, glasses, watches, or electronic equipment or toys.

The brain scan will not hurt. Some people feel nervous during the scan; however, you will be sleeping, watching a movie, or listening to music. Since loud sounds from the scanner might bother you, earplugs and head phones will be used.

***Saliva Test:***Spitting a lot of saliva can make your mouth dry, so we will give you water to drink after the saliva collection.

**Who will be given information about you?**

Personal information about you will be kept private by the study staff. If a test shows that you are pregnant, this information will be shared with your parents or legal guardian. If the researchers believe that there is a problem or you have been hurt, they will report this information to people whose job it is to protect you.

**Will you be given money for being in this study?**

You, your parent, or your legal guardian will be given money for your time for being in the study:

* **$25** for the medical exam;
* **$25** for the saliva sample, the brain and nerve tests; and
* **$25** for the brain scan.

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

You don’t have to be in the study if you don’t want to. It’s up to you. Even if you start, you can stop later if you want. No one will be mad at you.

***How do you get your questions answered?***

You may contact the UH Human Studies Program at 808.956.5007 or [uhirb@hawaii.edu](mailto:uhirb@hawaii.edu). to discuss problems, concerns and questions, obtain information, or offer input with an informed individual who is unaffiliated with the specific research protocol. Please visit <https://research.hawaii.edu/orc/human-studies/participant-information/> for more information on your rights as a research participant.

**Agreement to take part in the study:**

Signing your name below means that you agree to be in this study. You and your parents will be given a copy of this form after you have signed it.

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

Your name (print) Your Signature Date

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

Researcher’s Name Researcher’s Signature Date

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

Name of Parent or Legal Guardian (print)