General instructions: Researchers should tailor the assent form to the age and developmental level of the subjects. While the adult / parental consent forms must have all categories, the child assent form may be made shorter and simpler if the child would not be able to understand the more detailed information. Use wording that is as simple as possible. Recommended wording follows. Examples and explanations are italicized.

What is a research study?

We’re asking you to be in a research study. Research is a way to help us learn new things. Only people who decide they want to help will be in the study. We’ll tell you about the study and then you should take time to make your decision. You should talk to your parents or your guardian before you decide.

Why is this study being done?

Explain the study purpose in simple language.

Example A. This study is to find out if the type of toothbrush you use makes a difference in how many cavities you get.

Example B. This study is to find out what type of cancer treatment works best.

Example C. This study is to find out if teaching children to relax is the best way to treat children who have been touched by adults or had sex with adults.

What will happen to me?

Explain the methods in simple language.

Example A. A dentist will check your teeth and fix any cavities. You’ll use one type of toothbrush for six months. The dentist will again check your teeth and fix any cavities. You’ll use a different type of toothbrush for the next six months. The dentist will check your teeth and fix any cavities one more time.

Example B. You’ll be given a second medicine while you are getting your regular cancer treatment. Half of the children will get the real study medicine and half will get a fake medicine. The fake medicine is a pill that looks like the study medicine but isn’t a real medicine. You won’t know if the pill is the real medicine or the fake medicine. Even your parents and your doctor won’t know until the study is over whether you got the real or fake medicine. The study will see if children who got the real medicine got better any faster than those who took the fake medicine.
You won’t get any extra tests because you’re in the study. The doctors will look at your medical chart and write down facts.

Example C. You’ll see a psychologist who will ask you questions about how you feel. A psychologist is a type of doctor who helps people with their feelings. The psychologist will give you one of two types of treatment to help you. It might be a treatment where you learn to relax when you think about the hurt that the adult caused you. It might instead be a treatment where you talk about your feelings without teaching you to relax. At the end of the study, the psychologist will ask you the same questions about how you feel, to see if you are feeling better.

**What are the good things about being in this study?**

**Explain benefits. Include payment. Number the items or use bullets if there are multiple benefits. Benefits and risks can be combined into one section.**

**Example A** There are four good things that might happen.

1. You may find out which type of toothbrush you like.
2. You may get fewer cavities because of using the special toothbrushes.
3. You’ll be given the toothbrushes, but you won’t be given anything else.
4. Your parents won’t have to pay for you to get your teeth checked and your cavities filled.

**Example B.** We can’t promise you that being in this study will help you. You may get better or you may get worse. The doctors might find out if this type of medicine helps other children with your type of cancer.

**Example C.** You’ll get help with your feelings about how you were hurt if you are a part of this study, but we can’t promise that the help will make you get over your pain. Your parents will pay for your seeing the psychologist. They don’t get anything free if you help with the study. The psychologist might find out something that can help other children who have been hurt.

**Will being in the study hurt me?**

**Explain risks. Number the items or use bullets if there are more than two risks.**

**Example A.** It is possible that you might get more cavities using the new toothbrushes than if you stick with the one you use now.

**Example B.** Some children don’t feel good after they take the medicine. They might feel these things:

- Upset stomache
- Headache
- Feel like they have a cold.
Example C. We don’t think that being in this study can hurt you. If you tell the psychologist about other people who have hurt you, the psychologist will have to tell your parents. But that is true if you are in the study or not.

How long will I be in the study?

Explain time commitment.

Example A. The study is for one year. You’ll come for two dentist check ups, which take about one hour each time. If you get cavities, you’ll come to another visit to get them filled. How long those visits take depends upon the number of cavities you have. It could take an hour each time.

Example B. You’ll be in the study for 9 months.

Example C. You’ll see the psychologist twice a week for one half hour. You’ll do this every week for five months.

Do I have other choices?

Example A. You can decide not to be in the study and use your regular toothbrush.

Example B. You can decide not to be in the study and get the regular cancer treatment without the new medicine.

Example C. If you don’t want to be in the study, you’ll still get the treatment that does not teach you to relax, and you will not answer the questions at the start and end of your treatment.

Will people know that I am in the study?

Describe confidentiality. Avoid using the word “secret”.

Example A. The people at the dentist’s office will know that you are in the study, but they won’t tell anyone else. If they talk about the study or write about it they won’t use your name.

Example B. Your regular doctor and people at the cancer treatment center will know that you are in the study. The doctors won’t use your name when they talk about the study or write about what they learned.

Example C. Only the psychologist and one person who helps the psychologist will see the questions that you answered. The psychologist won’t use your name when telling other people about the best way to help children like you.
Example of special risk statements to use if applicable:

If we learn that someone has abused (hurt) a child or an old person, we have to tell the police or other people who can make the abuse stop.

If we find that you have a disease that can be spread by having sex, like syphilis, clamidia, HIV or AIDS, we have to tell the Health Department and we have to tell your parents so that you can get medical treatment. (Note: if the study is not in the State of Florida, researchers should check applicable state law.)

If we find out that you committed a crime, we have to tell the police.

If we find out that your parents have committed a crime, we have to tell the police.

Is there anything else I should know about the study?

If there is additional information that needs to be disclosed, use this section.

Who can I ask questions?

If you have any questions you can ask _________. Remember, you should also talk with your parents or your guardian about this study.

Is it OK if I say “No, I don’t want to be in the study”?

You do not have to be a part of this study if you don’t want to. No one will be mad or upset.

If you change your mind, you can decide during the study to stop being in the study.

If applicable add: If you do stop during the study, we will keep the information that we got while you were in the study.

Do you understand and do you want to be in the study?

I understand. All my questions were answered.

- [ ] I want to be in the study.
- [ ] I don’t want to be in the study.

_____________________________________
Your name
Your signature                      Date

Signature of person explaining the study  Date