

COLLEGE OF THE CANYONS RESEARCH SUBJECT ASSENT FORM

Protocol ID:	[Insert IRB Protocol ID]
Protocol Title:	[Insert Title of Research Study]
Principal Investigator:	[Insert Name of the Principal Investigator] [Insert Address] [Insert Phone Numbers]
Emergency Contact:	[Insert Emergency Contact] [Insert Phone Number/Pager, etc.]
Institutional Affiliation:	[Insert Institute Name and Address]
Sponsor (if applicable):	[Insert Sponsor Name] [Insert Sponsor Address]

- 1. My name is [identify yourself to the child by name].
- 2. We are asking you to take part in a research study because we are trying to learn more about [Outline what the study is about in language that is both appropriate to the child's maturity and age.]
- 3. If you agree to be in this [Describe what will take place from the child's point of view in language that is both appropriate to the child's maturity and age.]
- 4. EXAMPLE OF ALTERNATIVE TEXT:

If you decide that you want to be in this research study, this is what will happen to you: Dr. [Insert Dr.'s Name] will ask you some questions today and he/she will also ask your mom or dad some questions. ThenYou will be here for about [Select #] hour/s today.

You will come back to see Dr.[Insert Dr.'s Name] in [Select #] week/s and she/he will ask you and your parents some more questions. This visit will only be for [Select #] hour/s.

- 5. *RISKS:* [Describe any risks to the child that may result from participation in the research.]
- 6. BENEFITS: [Describe any benefits to the child from participation in the research.]

- 7. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.
- 8. If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop.

Alternative, simpler language:

You don't have to be in this research study if you don't want to. Nobody will be mad at you if you say no. Even if you say yes now and change your mind after you start doing this study, you can stop and no one will be mad.

- 9. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me *[Insert Your Telephone Number]* or ask me next time. *[If applicable, you may call me at any time to ask questions about your disease or treatment]*.
- 10. Signing your name at the bottom means that you agree to be in this study.[If the study is related to treatment insert the following: Your doctors will continue to treat you whether or not you participate.]

You and your parents will be given a copy of this form after you have signed it.

 \Box Yes, I will be in this research study \Box No, I don't want to do this

Date: _____

Printed Name of Study Participant

Signature of Study Participant

Date: _____

Printed Name of Person Administering Consent

Signature of Person Administering Consent

<u>Note to Investigator: Keep it simple. Tell what the words mean, do not use the bigger words at all. Use short</u> sentences in the common vernacular of kids. Grammar isn't as important as their understanding of what you mean. If you know a 7 year old, write the assent as if you were telling it to them. Do not assume they will understand medical concepts. Include only what will happen with the research, not with their normal therapy. But don't overwhelm them with details Keep it short and to the point. Use a large size font (at least- 12 point)