Vanderbilt University Institutional Review Board
Proposal for Research Using Human Participants
Assent Document for Research Study
Assent Document for Stages 2 and 3

PI XXXXXXXXXX Version Date: XXXXXX
Title of Study: XXXXXXXXXX
Institution/Hospital: Vanderbilt University Medical Center

This assent document applies to children, 13 - 17 years old who have Down syndrome.

Name of participant _____ Age ____

Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form.

1. Why are you doing this research?
You have a condition called Down syndrome. Some people with Down syndrome have a hard time sleeping. We hope this study will help us know why.

2. What will I do and how long will it take?
If you decide that you want to be in this study, your parents will answer questions about how you sleep and how you act during the daytime.

If it is OK with you, we will have you come to the Vanderbilt Kennedy Center and XXXXXXXXXX will weigh and measure you and ask you and your parents about your medical health. This will take approximately 30 minutes. XXXXXXXXXX or XXXXXXXXXX will give you a test called the K-BIT. This test is a group of questions that looks at how your brain works in 4 different ways. It will take you about 20 minutes to take this test.

After you finish the K-BIT, you may be asked to participate in 2 sleep studies on 2 different days. If you want to, you will be asked to wear a special watch on your wrist for 7 days. This watch can record the times when you are awake and asleep.

At the end of that week, we would like you and your parent to sleep overnight at the hospital for two nights in a row. The room where you will stay looks like a motel room. While you are in the hospital, a sleep technician will paste sponges to your head. These sponges will measure what your brain and muscles do while you are asleep. These sponges will be covered with a cap.

You will also have a soft tube taped under your nose. This will measure the air that comes out of your nose when you breathe. You will also have tape on your face, chin, shoulders, and legs. These tapes will measure what your muscles do while you are asleep. You will also have a soft belt around your chest. This will measure how much your chest moves while you are asleep.

This will last as long as you sleep those nights. The sleep technician will be in a nearby room, watching you sleep and making sure that you are comfortable. You will be able to leave with your parents in the morning.

A video camera will record you as you sleep.

3. Do I have to be in this research study and can I stop if I want to?
You do not have to be in this study. if you say you want to stop, we will listen and you can stop. You can tell your parents if you want to stop. You can tell XXXXXXXXXX or the sleep technician if you want to stop.

4. Could it make me sick [or sicker]?
This study cannot make you sick.

5. Will anyone know that l am in this research study?
No one will know that you are in this study unless you or your parents tell them.

6. How will this research help me or other people?
If you have troubles with your sleep, we can help you know this so you can get help to sleep better. We think that people with Down syndrome may learn and behave better if their sleep is more restful. You may learn to sleep better because of this study.

7. Can I do something else instead of this research?
You can talk about your sleep with your parents or your doctor.

8. Who do 1 talk to if I have questions?
If you have any questions, you can ask your mom or dad.

Your parents will always be with you.
You do not have to participate in this study.
If participating in this study is OK with you, please sign below:

_____ _____
Date Signature of patient/volunteer

Consent obtained by: _____
Signature Printed Name and Title

Child gave permission but could not sign. _____
Signature Printed Name and Title

YOU DO NOT HAVE TO BE IN THIS STUDY.