SAMPLE SUBMISSION FOR APPROVAL TO USE HUMAN SUBJECTS

1. The purpose of this study is to evaluate the use of assistive technology, more specifically the use of a computer and a single switch, to enhance the communication and mobility of a child with Cerebral Palsy. A "switch" is simply an alternative to a computer mouse. It is larger than a mouse and easier to employ. It only needs to be touched and allows for easy control. The null hypothesis is that the use of assistive technology will not enhance the communication and mobility of a child with Cerebral Palsy.

   Two students will first use a computer without a switch and a pre-test will be given to assess their current computer skills (see attached pre/post test). Then a switch will be added and the children will use various computer programs (choice of Living Books, Jump*Start Toddler and Little People Farm), and the researcher will look at whether or not child A or B used the switch to activate the program and whether there was communication directly between the two children or through the computer. Upon completion of this study the children will be given a post-test (same as pre-test) to evaluate their computer skills.

2. The source of the subjects is the children in my special education preschool classroom. They range in age from 3-4 years old and are male. Their disabilities include Cerebral Palsy (spastic quadriplegia), speech language delays and cognitive delays. One child was chosen because he alone has Cerebral Palsy and the other child was chosen randomly from a hat, which contained the names of all the students in my class.

3. The students will be given a pre-test (as described above and attached). Then, the students will play with a computer using a single action switch that is attached to the computer for 20 minutes a day, 3 days per week (Monday, Wednesday and Friday) for a period of six weeks. The session will take place in the morning and occur at the same time each day. Data will be taken on each child separately by the principal investigator. The children will be known as Child A and Child B. The data will include information on whether or not they used the switch to activate the program and if communication occurred from either one of the children. Upon conclusion of this study, the children will be given a post-test (same as a pre-test).

4. This study poses no risk of physical harm to the children. The children's names will not be used and only the principal investigator will know their identity. The benefit to the children will be improving their computer skills and expansion of their communication skills while working in a small group setting. Stress should be limited in this study because the switch is a large single switch activator and just needs to be touched (pointing or precision movement is not required).

5. The study names will not be used, they will be known as Child A and Child B. The principal investigator will be the only person who knows their identities. The pre/post test and data sheets will be coded with Child A and Child B and will be stored in a binder in a locked filing cabinet in my classroom (only I have the key). Upon completion of this study, the paperwork will be stored in my home in a locked filing cabinet.

6. NA.

7. See attached Consent Form.

8. NA.

Lehman College
The City University of New York

CONSENT FORM

Investigator: xxxxxxx xxxxxxxxxxx

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Study Description

The purpose of this study is to evaluate the use of assistive technology (a computer and switch) to enhance the communications of one child with Cerebral palsy and one child without the disorder.

The children will be asked to play with computer programs (Living Books, Jump*Start Toddlers or Little People Farm) and to use a single switch to activate these programs and to communicate with each other about the computer programs. A pre/post test to assess will be given to assess computer skills and additional behavioral data will be taken by hand during these sessions.

This study will take about 20 minutes per day, 3 days a week, and 6 weeks to complete.

Your Rights, Privacy & Welfare

In order to ensure that your child's data will remain anonymous and confidential, his name will not be included on the data sheets. No one will see the data except for members of the research team. Your child will not be identified by name on any published report. This study poses no threat of physical harm to your child and when finished, it should strengthen their computer, mobility and communication skills.

You are free to withdraw your consent for your child and to discontinue their participation in this study at any time.

Your decision to allow your child to participate or refusal to participate will not in any way affect your child in any class or the services they receive in school.

If you have any questions or concerns about this study or your child's rights as a participant, please contact the principal investigator or the institutional contact person at the addresses and telephone numbers above.

I have read this consent form and I understand the procedure to be used in this study. I freely and voluntarily choose to allow my child to participate. I understand that I man discontinue my child's participation at any time without penalty.

Name (printed): _____

Signature: _____ Date: _____