Title of Study: HAPTIC SIMULATION DESIGN FOR MOTOR REHABILITATION AND FINE MOTOR SKILL TRAINING

Principal Investigator: David Kaber
Faculty Sponsor (if applicable): N/A

General Information
You are being asked to take part in a research study. Your participation in this study is voluntary. You have the right to be a part of this study, to choose not to participate or to stop participating at any time. The purpose of research studies is to gain a better understanding of how virtual reality simulations (VR) may help develop motor control skills. You are not guaranteed any personal benefits from being in this study. Research studies like this may also pose risks to those that participate. In this consent form you will find specific details about the research in which you are being asked to participate. If you do not understand something in this form it is your right to ask for clarification or more information. A copy of this consent form will be provided to you. If at any time you have questions about your participation, do not hesitate to contact David Kaber at 919-515-3086.

Purpose of this study
The purpose of this study is to learn more about using virtual reality simulations (VR) to improve impaired motor functions and new fine motor skills. The VR simulation to be used in this study involves a visual display on a desktop monitor with a 3-dimensional perspective (see below image). Your control of events in the VR simulation will be through a hand-held stylus (similar to a joystick; see below image) that provides force-feedback (when a virtual cursor contacts a virtual object). The tasks to be performed in this study involve simulated drawing and shape manipulation and sorting. Your performance on motor control tests and while using the VR system is expected to provide insights into VR design features and approaches to best develop motor skills.

Procedure
If you agree to participate in this study, you will be asked to:
1. Read and sign this consent form once you understand the research and agree to participate
2. Fill out a background survey;
3. Attend a preliminary visit at Duke University Medical Center (approximately 1 hr.) where you will be asked to:
   (a) complete preliminary neuro-psychological testing on attention, memory, cognitive, and motor functioning;
(b) complete baseline motor performance tests while functional Magnetic Resonance Imaging (fMRI) is used to examine your brain blood-flow responses;
(c) complete some standardized motor-performance tests

4. After this visit at DUMC, you will be asked to go to a lab at NC State University for three different experimental sessions to use the VR system. These visits will last 1 to 2 hrs. each, and will involve training and testing on the VR systems in several trials. During these experiment sessions you will use a VR system under varying test conditions. The experiment sessions will be conducted s follows:
(d) Session 1 will include the background survey, motor-performance tests and workload survey described in parts 2 and 3 (above). You will then be asked to complete approximately 1 hour of training and testing on the VR system for a total of approximately 2 hours;
(e) Session 2 will be scheduled following Session 1 and will include approximately 1 hour of training and testing on the VR system;
(f) Session 3 will be scheduled following Session 2 and will include approximately 1 hour of training and testing on the VR system;
(g) Session 4 will be scheduled following Session 3 and will include approximately 1 hour of training and testing on the VR system followed by additional motor-performance tests and a follow-up workload survey. The total time for Session 4 will be approximately 2 hours.

5. Again after the fourth visit to use the VR system, you will be asked to return to DUMC for a second and final time to repeat the preliminary tests (about 1 hr.). Again, you may elect to participate in any number of sessions or none.

Risks
There should be no risk to you from the fMRI activities, unless you are pregnant. fMRI imaging uses a powerful magnet to take pictures of internal body structures. Although the strong magnetic field is not harmful in itself, medical devices that contain metal may malfunction or cause problems during an MRI exam. Current medical guidelines recommend that pregnant women undergo MRI only when essential and that pregnant women should not participate in research studies involving MRI. On this basis, if you are currently pregnant, you may not participate in this study. If you are not certain of whether you may be pregnant, you may not participate in this study. If you are a female volunteer and are NOT currently pregnant, please initial here. _____

Other risks from this research include: (1) general fatigue due to attending to the VR displays during the test trials; and (2) anxiety while completing the drawing and simulated surgical tasks with the computer systems. Rest periods will be arranged between trials. There is no time limit for your drawing and other task performance.

Benefits
There are no direct benefits to you from this research. While we hope to learn more about how to help people regain motor skills, it’s unlikely that participating in this study will improve your motor skills. Knowledge gained from this study will help researchers understand how VR systems and designs can help rehabilitation in people with motor skills impairment.

Eligibility
You must be 18 years or older on the date of the first session to participate in this research study.

Confidentiality
The information in the study records will be kept confidential. Data will be stored securely in the Cognitive Ergonomics Lab in the NC State Department of Industrial and Systems Engineering and in the Brain Imaging and Analysis Center at Duke University Medical Center. The data will only be made available to the persons conducting the study. No reference will be made to you in oral or written reports of the study, which could link you to the research. A background survey will collect identifying information such as your name. Other data will include your gender, age, etc. and will be used for demographic statistics. A code number will be matched to your name and a master list of codes for all subjects will be kept separately from all other survey and response data collected as part of the experiment. This code list and all other data will be destroyed at the close of the study.

Compensation
For participating in this study you will be paid $15 per hour for testing and training at NCSU (6 hours total) and $25 per hour for testing at Duke University Medical Center (2 hours total). If you complete the study, your total
compensation will be up to $140 ($90 for participation at NCSU and $50 for participation at DUMC). If you withdraw from a session prior to its completion, you will receive compensation at a rate of $5 per hour for any time that you provided to NCSU and $25 per hour for any time that you provided to DUMC, and your participation in the full study will be terminated.

**Contact**
If you have questions at any time about the study or the procedures, you may contact the researcher, Dave Kaber, at 448 Daniels Hall, NC State University main campus, or 919-515-3086. If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact Deb Paxton, Regulatory Compliance Administrator, Box 7514, NCSU Campus (919/515-4514).

**Consent to Participate**
‘I have read and understand the above information. I have received a copy of this form. I agree to participate in this study with the understanding that I may withdraw at any time.’

Subject's signature_______________________________________ Date _________________

Investigator's signature__________________________________ Date _________________