RUTGERS
School of Health Professions

I. SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Energy demands during interactive video games and standard of care of individuals post-stoke
Principal Investigator: Judith Deutsch, PT, PhD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the Study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Dr. Judith Deutsch is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Judith Deutsch may be reached at 973-972-2373, 65 Bergen Street, Newark, NJ 07101

The study doctor Dr. Judith Deutsch or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: QED Science Center

Who might benefit financially from this research?

Research studies like this one are designed to determine whether rehabilitation based video games are beneficial and enjoyable for persons poststroke. Rutgers University owns a patent on some of the technology used in the video games being studied. Dr. Deutsch, the primary investigator in this study, is an inventor of the video games being studied. If these video games were to be commercialized Dr. Deutsch and Rutgers (who owns the patent) would receive a part of the profits from any sales of the video games.

Why is this study being done?

To observe enjoyment levels and exercise intensity when participants play interactive video games and standard of care for rehabilitation post-stroke.

Why have you been asked to take part in this study?

You are being asked to participate in this study because you are a person that has had a stroke and fit the inclusion requirements for this study.

Who may take part in this study? And who may not?

You may take part in this study if you are a person who has had a stroke more than 6 months ago and are between the ages of 19 and 80 years old. You also have to be able to walk 100 feet without physical assistance, but may use a device like a cane or walker and may use a brace. You also must be able to stand for 3 minutes.

You may not participate in the study if you:

1. Have a history of severe heart disease, heart attack, valve replacement or coronary artery bypass surgery, severe lung disease, uncontrolled diabetes, traumatic brain injury or neurological disorder other than stroke.
2. Are unable to follow directions.
3. Do not have adequate vision and hearing ability (either aided or unaided with glasses, contacts or hearing aids)
4. Are unable to sign a consent form.
5. Have an unstable medical condition or musculoskeletal disorder such as severe arthritis, knee surgery, hip surgery, or any other condition that the investigators determine would impair the ability to perform the required stepping for the games presented.
6. Any other medical condition contraindications to exercise.

How long will the study take and how many subjects will participate?

You will be one of 15 persons participating in this study. Participation will be a one-time visit and will last approximately 2 hours.

What will you be asked to do if you take part in this research study?

You will familiarize yourself with four physical therapy interventions. Once you are familiar with each activity, you will be asked to participate in each activity for 8.5 minutes. During the activities you will be wearing a mask on your nose and mouth and small backpack. The mask will be used to measure your breathing. After each activity, you will fill out a short survey about your experience with each activity. You will be videotaped during some of the activities.

What are the risks and/or discomforts you might experience if you take part in this study?

There are no major risks associated with participation in this research study. However, there is minimal risk that you may experience mild fatigue or loss of balance; but, a clinician will be standing by you at all times to guard you during each activity.

Are there any benefits for you if you choose to take part in this research study?

The benefits of taking part in this study may be:

Your input will contribute to building useful tools for rehabilitation for persons post-stroke However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

No there is no cost to you if you take part of this study.

Will you be paid to take part in this study?

You will receive $30.00 for taking part in this study according to this schedule

- $30.00 at the completion of the experimental session

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Questionnaire responses will be coded and only identified by number. All data will be stored in SSB 723 in a locked cabinet. The links to personal identifiers will be contained in a single file on the PIs password protected desktop. PHI will only be reported in aggregate.

What will happen if you are injured during this study?

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: mild fatigue or loss of balance. In addition, it is possible that during the course of this study, new adverse effects of playing interactive video games that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided

that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Judith Deutsch 65 Bergen Street Bldg SSB 723, Newark, NJ, 07101

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Judith Deutsch
Rehabilitation and Movement Science Department
973-972-2373

If you have any questions about your rights as a research subject, you can call:

IRB Director
973-972-3608 Newark
and
Human Subject Protection Program
973-972-1149

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- Name
- Age
- Diagnosis

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Judith Deutsch, 65 Bergen Street, SSB 723, Newark, NJ 07101

How long will my permission last?

Your permission for the use and sharing of your health information will last until:
There is no set date when your permission will end. Your health information may be studied for many years.

We are asking for your permission to allow us to **videotaping** as part of that research study. You do not have to agree to be recorded in order to participate in the main part of the study.

The recording(s) will be used for

analysis by the research team;

- ***possible use as a teaching tool to those who are not members of the research staff (i.e. for educational purposes);***

The recording(s) will include videotaping that will mask your identity.
The recording(s) will be stored on a password protected computer in files that do not have a link to your identity. They will be kept ***retained indefinitely.***

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered. I agree to take part in this research study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

Title: Exercise intensity during interactive video games and standard of care of individuals post-stroke
PI: Judith Deutsch, PT, PhD

RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY IRB
AUDIO/VIDEOTAPE ADDENDUM TO CONSENT FORM

You have already agreed to participate in a research study conducted by **Judith Deutsch PT PhD**. We are asking for your permission to allow us to ***both audio and videotape*** as part of that research study. You do not have to agree to be recorded in order to participate in the main part of the study.

The recording(s) will be used for

1. ***possible use as a teaching tool to those who are not members of the research staff or may be members of the research staff in the future***
2. ***presented at a scientific conference to describe the study***

The recording(s) will include ***not include any personal identifier. whether the subjects Videotaping will block a participants' identity by covering the face and whenever possible videotaping from the back and side.***

The recording(s) will be stored ***on a secure computer with no link to the participants' identity*** **and will be** ***retained indefinitely.***

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

AGREEMENT TO VIDEO and RECORD

1. Subject consent:

I have read the consent to videotape and record or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form have been answered. I agree to allow video taping and recording during the research study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the videotaping and recording aspects of study. All questions of the research subject or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____