I. SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: **Home based rehabilitation for upper extremity**

Rutgers School of Health Professions - Department of Rehabilitation and Movement Sciences
and
New Jersey Institute of Technology - Department of Biomedical Engineering
Contact Telephone: 973 972-8529

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. Gerard Fluet, DPT, PhD, Dr. Sergei Adamovich and Dr. Alma S. Merians will be conducting this research study and will have overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Fluet may be reached at
Department of Rehabilitation and Movement Sciences
Rutgers University
65 Bergen Street
Newark, NJ 07107
973-972-8529

fluetge@shp.rutgers.edu

The study doctor, Dr. Fluet 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.

Who might benefit financially from this research?

At this current time there are no financial gains from this study. The study members have no conflicts of interest to declare.

Why is this study being done?

The primary goal of this study is to test the benefits of long-term, home based training for the hand and arm.

Who may take part in this study?

1) Healthy persons between the ages of 20 and 90
2) Persons at least six weeks post stroke between the ages of 20 and 90
3) Persons with difficulty moving their weak shoulder, elbow, wrist, and hand

Who may not take part in this study?

1) Persons with severe arm weakness making them unable to move their arm enough to interact with objects on a table while they are seated.
2) Persons with severe increased in muscle tone of their weak arm
3) Persons with difficulty following instructions or paying attention to a quiet motor activity for at least ten minutes,
4) Persons with visual problems that make it impossible for them to work in a 24 inch wide space without moving their head.

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

You will be tested pre and post the study as well as at 1 month after ending the study and again 6 months after ending the study. You will be asked to do hand and arm exercises in your home for between three and twelve months. We will enroll a total of 60 people.

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

Everyone will undergo a series of clinical and computer based tests at our lab at Rutgers Newark before and after the study as well as at 1 and 6 months after the end of the study. This testing takes approximately 3 hours and transportation back and forth will be provided at no cost to you if needed. After initial testing, you may be be assigned to one of three groups. Each of the three

groups will be taught to perform one of three different home exercise programs presented on a computer screen. After this, your study therapist and an assistant will meet with you in your home, to make sure you can perform your exercise program using your own computer safely and independently. Everyone will be asked to do their exercise program for 1 hour per day/ 5 days per week for 3 to 12 months. Your study therapist or another study team member will check in with you periodically to make sure you can perform your exercise program without any difficulties. You will have a message system that you can use to send messages to your study therapist if you have difficulty using the system or performing your exercises. .

After the one month follow-up test session, a member of the research team will call and ask you about your experiences during the research study.

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

There is less than minimal risk involved. The exercises are non-invasive and pose no obvious risk. You may experience occasional fatigue in your hand or arm.

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: You may have better use of your weak hand and arm.

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?

You do not have to participate in this study. There are other treatments available. Your choice is not to take part in this study and to participate in currently existing therapies.

The following alternative treatments are available if you choose not to take part in this study: Home exercise program provided by your own physical therapist.

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?

There will be no cost to you to participate in this study.

Will you be paid to take part in this study?

You will not be paid for the testing and training during the 3 to 12 month study however you will be paid $100 for the testing at 1 month and $100 for the testing at 6 months after the training has ended.

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. Confidentiality of your research records will be strictly maintained except as required by law. Your name will be removed from all of your data and the data will be tagged with a coded ID number. After the experiment, the data collected will be analyzed on a computer by an experienced researcher. The link between your name and your ID will be kept in one secure and separate file cabinet in the investigator's cabinet. Your name will not be used in any publication that may result from this study. All of your records will be kept in a locked cabinet only accessible to the investigator. You records will be identified by code number rather than by your name. The codified information about you will be maintained only by Drs. Merians, Adamovich, and Fluet and this information will not be shared with anyone not directly involved on the project. When the data is published, only codified information will be used.

The information obtained during this research will be kept confidential to the extent permitted by law. However, this Research Record and your personal Medical Record (if any and if relevant to the study) may be reviewed by government agencies (such as the Food and Drug Administration or the Department of Health and Human Services), the agency or company sponsoring this research, and individuals who are involved in, or authorized to monitor or audit, the research if required by applicable laws or regulations.

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if you are injured during this study?
This study poses less than minimal risk. 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. Fluet.

Dr. Fluet may be reached at:

Department of Rehabilitation and Movement Sciences
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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:

Gerard G Fluet DPT, PhD
Assistant Professor
Department of Rehabilitation and Movement Sciences
Rutgers University
65 Bergen Street
Newark, NJ 07107
973-972-8529

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

Carlotta Rodriguez
(973)-972-3608
or
Human Subject Protection Program
973-972-1149 - Newark

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.

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: _____