UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject"): _____

2. What is the title of this research study (this "Research Study")?
Synergizing home health rehabilitation therapy to optimize patients' activities of daily living

3. Whom do you call if you have questions about this Research Study (the "Study Team")?
Principal Investigator: Dr. Chiung-ju (CJ) Liu, PhD, OTR/L; Phone: 352-273-6496
Co-investigators: Dr. Dorian Rose, PT, PhD, and Dr. Peihua Qiu, PhD

4. Who is paying for this Research Study?
The sponsor of this study is the National Institutes of Health.

5. In general, what do you need to know about this Research Study?
Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

5.a) In general, what is the purpose of the research? How long will you be involved?
The purpose of the research is to test a study activity program with skilled rehabilitation therapy in home health patients. The study activity program involves using different strategies to practice daily tasks, such as taking a sponge bath instead of a shower. The length of your involvement will be approximately 5 months, depending on the duration of your home health care therapy services.

5.b) What is involved with your participation, and what are the procedures to be followed in the research?
You will receive three in-home evaluation visits and a phone call follow-up from a UF (University of Florida) research staff member. You will perform simple tasks and/or answer questions to show how well you can do daily chores, move your body, and maintain balance in these evaluation visits or the phone call follow-up.

You will be randomly assigned (much like the flip of a coin) to receive either the study activity program or not. In either case, you will continue to receive rehabilitation therapy services from your home health agency. If you are assigned to receive the study activity program, a UF study therapy staff member will provide 6 home visits over 6 weeks. You will discuss and practice strategies to carry out self-care activities and daily chores with the UF study therapy staff member during each visit.

5.c) What are the likely risks or discomforts to you?
You may experience fatigue, mild joint pain or muscle soreness, or a risk of falls because of increased activity levels. You may feel uncomfortable answering some study questions. There is also a potential loss of privacy or confidentiality due to the data collection efforts of this study.

5.d) What are the likely benefits to you or to others from the research?
One possible benefit from extra therapy sessions is an increased ability to carry out daily tasks, which is essential to support your independence at home.

You may also feel a sense of satisfaction from assisting with the research. Moreover, the information learned from this study will benefit home health therapy staff and home health patients in the future.

5.e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?
The alternative treatments and procedures to the study activity program are skilled rehabilitation therapy services provided by your home health agency.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?
The skilled rehabilitation therapy services provided by your home health agency, which include physical therapy and/or occupational therapy, will be your normal clinical care.

7. What will be done only because you are in this Research Study?

If you decide to take part in this study, you will be randomly assigned (much like the flip of a coin) to receive study activity program to practice different ways of performing daily acitivites in six home visits in addition to your regular home health therapy. This is to test what effects the study activity program has compared with no study activity program. In either case, you will continue to receive services from your home health agency, which aim to support your independence at home. If the study activity program is not assigned to you, you will not be exposed to the risks of the study activity program, if there are any, nor will you be exposed to its risks, which are described below under "What are the possible discomforts and risks?" You will have a 50% chance of receiving the study activity program and a 50% chance of not receiving the study activity program.

A UF research staff member will first schedule an in-home evaluation visit with you to complete several tests. These tests will assess your ability to perform daily chores, take care of yourself, move your body, and keep your balance. Examples include preparing a peanut butter and jelly sandwich, picking up objects from a table, and walking for 3 meters. The UF research staff member will also ask questions to determine your pain level, mood, and how well you can remember things. The visit will last between 90 to 120 minutes.

If the study activity program is offered to you, you will receive the study program in the form of 6 home visits over 6 weeks (about one visit per week). During each study therapy home visit, a UF study therapy staff member will discuss and teach you strategies to accomplish self-care tasks and everyday chores. You will practice these strategies on the daily activities that you select with the study therapy staff member. Each study therapy visit will last about 60 minutes. In addition to these visits, you will continue to receive therapy services from your home health agency. The UF study therapy visits are independent from your home health agency's services. Your home health agency's therapy staff will develop a specialized care plan for you, which is independent of what you may have with the UF study therapy staff.

If the study activity program is not offered to you, you will continue to receive therapy services from your home health agency's staff, who will develop a specialized care plan for you.

When you complete the study activity program or the home health rehabilitation services, the UF research staff member will schedule a second in-home evaluation visit with you. During the second evaluation, you will repeat the same tests from the first in-home evaluation visit. You will also be asked to rate your satisfaction with the study activity program (if applicable). The visit will last between 90 to 120 minutes.

One month after the second visit, the UF research staff member will schedule the third in-home evaluation visit to repeat the study tests once again. The visit will last between 90 to 120 minutes.

Three months after the completion of the study program or the home health rehabilitation services, the UF research staff member will call you to follow up. On this call, the staff member will ask questions to check your ability to perform daily activities, and if you have any falls, hospitalizations, or emergency room visits since the previous in-home evaluation. The duration of the call is about 15 minutes or less.

Below summarizes the time requirement to each evaluation appointment:

- First in-home evaluation visit: 90 to 120 minutes
- Second in-home evaluation visit: 90 to 120 minutes
- Third in-home evaluation visit: 90 to 120 minutes
- Final phone call follow-up: 15 minutes

Additionally, the UF research staff will collect demographic information and medical information from your home health medical record. Health information to be collected is described in Question 8. The UF research staff will communicate with your rehabilitation home health care team if there are concerns about your safety or if there is a change in health status.

8. What identifiable health information will be collected about you and how will it be used?
The Research Team will collect: your demographic information, telephone number, home address, patient ID or health plan numbers, and home health medical records on the length of stay, discharge information, diagnosis, hospitalization risk, height and weight, living arrangements, health literacy, device use, self-care and mobility skills, and therapy visit length and content.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?
This health information may be shared with:

- The study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns, such as the Centers for Disease Control and federal, state and local health departments; and
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?
You will be in this study for up to 5 months. The duration includes your time with the Brooks Rehabilitation Home Health and/or the study program, the three in-home evaluation visits (at the beginning of the study, at the end of home health therapy services or the study program, and one

month after therapy services completion or study program completion), and a phone call follow-up three months after the therapy services completion or study program completion.

This Authorization to use and share your health information expires at the end of the study unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?
64 people.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

- You may feel uncomfortable answering some questions. If this happens, you can tell the UF research staff that you want to skip these questions.
- You may experience fatigue or mild muscle soreness or joint pain due to increased activity levels. If this happens, you can ask the UF research staff or UF study therapy staff for a break, to stop the visit, or reschedule the visit.
- There is a risk of falls due to increased activity levels. If you feel dizzy or unsteady, please tell the UF research staff or UF study therapy staff immediately. The UF research staff and study therapy staff will follow safety procedures during their visits to reduce your risk of falls.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

To help us protect your privacy, we have requested a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?
One benefit that is reasonable to expect is the increased ability to carry out daily tasks that support your independence at home. People who receive the study activity program may experience a greater benefit. You may also feel a sense of satisfaction from assisting with the research.

13b. How could others possibly benefit from this Research Study?
Knowledge gained from this Research Study will inform home health rehabilitation services researchers and providers of ways to support their patients' independence at home.

13c. How could the Research Team members benefit from this Research Study?
In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?
You can receive the rehabilitation therapy services provided by your home health agency.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?
You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research

Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?
You may be withdrawn from this Research Study without your consent for the following reasons:

- Your health status or physical condition is no longer adequate for the study procedure.
- The intervention is associated with adverse effects that call into question the safety of the study program.
- Any new information becomes available during the trial that necessitates stopping the trial.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?
There is no extra cost to take part in this Research Study.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

17. Will you be paid for taking part in this Research Study?
You will receive a $40 gift card within two weeks after each in-home evaluation visit. In other words, the maximum amount that you can receive is $120 if you complete all three in-home evaluation visits. You will NOT be paid for the 3-month phone call follow-up.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

18. What if you are injured while in this Research Study?
If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants,

nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact the Principal Investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while taking part in this study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

X_____ _____/_____/_____

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

X_____ _____/_____/_____

Signature of Person Consenting and Authorizing Date