

## **Consent and Authorization Document** *for Minimal Risk Research*

### **BACKGROUND**

You are being asked to take part in our research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

### **Why are we conducting this research?**

Stroke can have a large impact on a person's life as well as on the life of his or her family. Unfortunately, changes in mood, such as feeling down, sad, or having difficulty enjoying things can be a common experience for persons who have had a stroke. Similarly, changes in mood can also affect the person's spouse/partner, who is providing support (caregiving). We are creating an intervention for couples who are coping with these effects of stroke and have difficulties with changes in mood or have trouble enjoying things they used to enjoy. We have developed this intervention for couples to complete together. We will look at things like mood, well-being, and participating in valued activities during the intervention and after the intervention.

### **STUDY PROCEDURE**

If you and your spouse decide to participate in the study, you will be randomly assigned to either start the intervention right away or be waitlisted. We will ask you to come in for three (3) in-person sessions at the University of Utah. The first session will take approximately 4 hours. During this time, you will be asked to fill out some surveys about how stroke has affected you, your mood, and your relationships. You and your spouse will also participate in a discussion task and a problem-solving task together, and we will assess your participation in valued activities. We will be videotaping you during these tasks. You will then be trained in the intervention activities you and your spouse will complete at home. You will complete these activities for 8 weeks, both on your own and with your spouse. We will call you to check in every week and to remind you to complete and send in a weekly check-in sheet.

At the end of the 8 weeks, you will return for another in-person session. This second session will last approximately 3 hours. You will fill out surveys and give us feedback about the intervention. We will also have you complete the same tasks with your spouse as during your first session. Finally, we will ask you and your spouse to return for another in-person session in 3 months to fill out a survey and provide us with some more feedback. This last session will last approximately 2 hours. Both feedback interviews (at 8 weeks and 3 months) will be recorded.



## RISKS

The risks of this study are minimal. You may feel upset thinking about or talking about personal information related to your experience with stroke. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and s/he will tell you about resources available to help.

## BENEFITS

We cannot promise any direct benefit for taking part in this study. However, possible benefits include increased feelings of well-being or decrease in symptoms like sadness or apathy. We hope that the information we get from this study may help develop a greater understanding of coping after stroke in stroke survivors and their spouses in the future.

## PERSON TO CONTACT

If you have any questions, complaints, or concerns about this study, or if you feel you have been harmed as a result of participation, you can contact Alexandra Terrill, Department of Occupational and Recreational Therapies, University of Utah, at (801) 581-5951.

**Institutional Review Board:** Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu).

**Participant Advocate:** You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at [participant.advocate@hsc.utah.edu](mailto:participant.advocate@hsc.utah.edu).

## VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. This will not affect your relationship with the investigator or clinic staff.

## COSTS AND COMPENSATION TO PARTICIPANTS

There are no direct costs related to participating in the study. You will not be charged for any assessments or treatment you receive as part of the study.

If you choose to participate in the study, you will be compensated for your time. For your 3 in-person visits, you and your partner/spouse will receive a total amount of \$90: \$30 at your first visit, \$30 at your second visit, and \$30 at your third visit. You will also receive \$5 for each completed weekly check-in sheet (total up to \$40). If you are waitlisted, you will receive an additional \$20 for completing an initial waitlist survey at the beginning of the study.



Since you will be paid for participating in this study, it is necessary for us to collect your Social Security Number. You will provide this information for a Federal W-9 Form that is filed with our Accounts Payable department. Accounts Payable will have limited access to the study information (e.g. the name of the study) for payment purposes. The amount you receive for taking part in this study will be turned into the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study; however, we will not be able to pay you as outlined in this consent form.

### **AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION**

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like your name, address and telephone number, and date of birth
- Related medical information about you like current medications or therapies, and medical diagnoses
- All tests that will be done in the study, including study assessments, your answers on interview questions, and videotapes of you and your spouse during the interaction tasks.

### **How we will protect and share your information:**

- Your data will be kept confidential. Your audio-tape and information will be identified by a specific identification number. Digital audio recordings, data and records will be stored in a locked filing cabinet or on a password protected computer located in the researcher's work space. Only the researcher and members of her study team will have access to this information. The data will only be used for medical and scientific purposes, including publications and presentations. You will not be identified by name in any publications or presentations produced from this research. Your data will be identified only by an identification number on both hard copy and computerized records for data management. This number will be linked to a master list for identification. This master list will be stored on a secured computer server within the University of Utah which will be available only to the Principal Investigator and her research group. In order to protect your confidentiality, no names will be used on any of the data collection sheets or data spread sheets.
- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected on a secure University of Utah College of Health server. We may need

to disclose information if required by law.

*We will do everything we can to keep your information private but we cannot guarantee this.* Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

- Members of the research team;
  - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights.
- If we share your information with groups outside of University of Utah Health Sciences Center, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.
  - If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health Sciences Center.

### **What if I decide to Not Participate after I sign the Consent and Authorization Form?**

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

**CONSENT:**

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

**I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

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Participant's Name

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

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Participant's Name

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Participant's Signature

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Date

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Name of Person Obtaining Authorization and Consent

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Signature of Person Obtaining Authorization and Consent

\_\_\_\_\_  
Date

