

Research Registry Information Sheet

Sponsor: Brooks Rehabilitation: Clinical Research Center

Protocol Title: Brooks Active Research Registry

Investigator: Floris Singletary, M.S., CCC-SLP, Research Manager Brooks Clinical Research Center

You are being asked to be in a research registry that will collect, store and screen information about you and your personal health related information for determining your eligibility to participate in a clinical trial and contact you at a later date.

Your participation will involve answering questions about yourself as related to current and future research interests in the context of your overall health status or existing medical conditions and will take about 15 minutes to complete. Your participation will help us to better identify potential research participants and plan for future research trials. The following information may be collected, used, and disclosed to authorized research personnel to determine your potential eligibility for research participation:

- Name
- Address
- Email Address
- Telephone number
- Date of Birth
- Alternate Contact Information
- Pertinent Medical History as related to your admission, diagnosis or current disability
- Work status
- Level of education
- Primary Language
- Current and past medications or therapies
- Functional levels of activity
- Activities of daily living before and after the onset of your current disability.

IF REVIEW OF MEDICAL RECORDS IS REQUIRED A SEPARATE AUTHORIZATION TO RELEASE AND REVIEW MEDICAL RECORDS WILL BE SENT TO YOU. SUCH AUTHORIZATION WOULD ALLOW US TO REVIEW THE INFORMATION LISTED BELOW TO DETERMINE YOUR ELIGIBILITY TO BE FURTHER SCREENED OR YOUR ELIGIBILITY TO PARTICIPATE IN A CURRENT OR FUTURE CLINICAL TRIAL:

- Information from a physical examination
- Information from therapy assessment and discharge summaries to specific rehabilitation related services
- Results from x-rays or other imaging studies that may more accurately describe your current medical diagnosis.

Researchers will take appropriate steps to protect any information they collect about you. However, there is always the risk that information about you could be revealed inappropriately or accidentally. Any information collected about you will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

You will be told about any new information that might change your decision to be in this study. You may not receive a direct benefit if you agree to participate. However, people in the future may benefit from the information obtained from this research. Your alternative is to not participate in this study and your participation in any other services offered through this organization will not be affected in any way. Your participation in the Brooks Active Research Registry does not enroll you in any other research project and you will have to give your consent to be further screened or contacted for any additional research participation. There is no cost to participating in this registry.

Contact Floris Singletary at 904-345-8973 for questions about the research or if you think you have been harmed as a result of joining this research. Contact the Western Institutional Review Board (WIRB) if you have questions about your rights as a research subject: 1-800-562-4789. WIRB is a group of people who perform independent review of research.

The information about you that will be collected for this research will be entered into a secure, password protected web-based data base with access granted only to designated research personnel of the Brooks Clinical Research Center and may be shared with research personnel that may be screening your data for potential participation in a research study for which you may qualify based on your health status. This information is shared so the potential to participate in research can be conducted and properly monitored.

This permission will not end unless you cancel it. You may cancel it by sending written notice to the investigator, Floris Singletary, Brooks Clinical Research Center Manager, 3901 University Blvd. South, Suite 101, Jacksonville, FL 32216.

Your decision to be in this study is voluntary. You will not be penalized or lose benefits if you decide not to participate or if you decide to stop participating.

Your part in this study may be stopped at any time by the study investigator or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to changes made in the registry plan;
- if the registry project is discontinued.

We plan to enroll a minimum 500 participants per year in this registry.

A copy of this study information and consent will be mailed to your preferred address.