KESSLER FOUNDATION

INSTITUTIONAL REVIEW BOARD

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: Early Intervention to Promote Return to Work for People with Spinal Cord Injury or Brain Injury

RESEARCH STUDY #: L-1171-21

I, _____, am being asked to consent to participate in a research study led by an Executive Committee that includes Drs. John O'Neill, Trevor Dyson-Hudson, Nancy Chiaravalloti, and Steven Kirshblum at Kessler and Dr. David Mann at Mathematica. Other persons who work with them as study staff may be asked to help them. I understand that taking part in this study is completely voluntary; I do not have to be part of this study unless I choose to be. I am free to leave the study at any time if I change my mind. All research studies carried out at Kessler Foundation are covered by the rules of both the Federal Government and Kessler Foundation.

The Information provided may contain words I do not understand. I will ask the study leader or the study staff to explain any words or procedures I do not understand.

The table below contains a brief summary of key information about this research study. Additional information can be found throughout this document.

Study Summary	
Why is this research being done?	This study will compare two programs designed to help people with spinal cord injury and brain injury pursue employment.
How long does the study last?	The study will be ongoing through September 30, 2026. However, my active participation in study-related activities will last only about 12 months from the time I enroll.
What will happen during this research study?	While I am part of this study, I will be randomly assigned (like the flip of a coin) to participate in one of two programs. Both programs involve services designed to help me reach my employment goals but are coordinated differently. In one program, services are coordinated by a counselor employed by the New Jersey State Division of Vocational Rehabilitation Services, a state-based agency that assists people with disabilities who are interested in pursuing employment. In the other program, services are coordinated by a facilitator who is employed by the rehabilitation hospital at which I am receiving care. I also will be asked to complete a survey about my spinal cord injury or brain injury, physical and emotional

	health/well-being, employment status, education, earnings, and participation in community activities. I will be asked to complete a follow-up survey 12 months after enrolling in the study. Information about my earnings, benefits, and services received will be collected from state and federal databases. My Social Security number and other information that identifies me will be used to ensure information is collected accurately from these databases and to enable me to access services for which I am eligible.
What risks are associated with participating in this study?	There are no physical or medical risks associated with this study. As with all studies that involve collection of private information, there is a small risk of a breach in confidentiality by Kessler Foundation or Mathematica, but there are extensive procedures in place to prevent this from happening. I will be informed immediately of any specific threat to my privacy. It is also possible that I may be uncomfortable responding to some questions about my status. I may choose not to answer any question that makes me uncomfortable.
What are the benefits of participating in this research study?	The benefits of participating in this study may be a greater likelihood of employment after my injury because of the assistance I received. However, I may receive no personal benefit from taking part in this study. The information obtained from this study may also help other people with spinal cord injury or brain injury by enabling the researchers to identify which programs and services are most helpful in enabling people with these conditions to return to work.
What other options are available to me if I choose not to participate in this study?	Participation in this study is completely voluntary. If I choose not to participate in this study, there will be no effect on my medical care, employment status, or access to benefits to which I am otherwise entitled.

The following sections offer more detail about the study.

WHY IS THIS RESEARCH BEING DONE?

For many people with spinal cord injury or brain injury, seeking employment after injury is an important goal. There are services available to help people with disabilities. However, the best ways to coordinate and deliver these services are not yet known. This project will compare two ways of coordinating and delivering services that are designed to help people with spinal cord injury or brain injury obtain employment.

Researchers at Kessler Foundation and Mathematica will work with staff at organizations that provide rehabilitation or employment-related services (Kessler Institute for Rehabilitation and the New Jersey Division of Vocational Rehabilitation Services and service providers with whom they work) as well as the organizations that store and manage data related to employment, earnings, and benefits I receive (New Jersey Division of Department of Labor).

WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?

While I am a part of this study, I will be asked to do the following:

Enrollment Survey

At the beginning of the study, I will complete a survey about my personal characteristics (such as age and race/ethnicity), my spinal cord injury or brain injury, my work history, education, earnings, thoughts and feelings about employment after injury, and physical and emotional health/well-being. This survey will be completed during an in-person interview while I am in the hospital or a phone interview after I am discharged. My medical records will also be reviewed to gather information about my injury that is needed for the study.

At the time that I enroll in the study, I will also be asked to provide my Social Security number and other information that identifies me (referred to as Personally Identifiable Information or PII). This information is needed to access services for which I am eligible and to accurately collect information about me from state and federal databases. As will be discussed further below, many procedures are in place to ensure my information is kept secure.

Program Participation

I will be randomly assigned (like a coin flip) to participate in one of two programs being examined in this study. Both programs involve services designed to help me reach my employment goals but are coordinated differently.

- Program 1: In this program, services are coordinated by a counselor employed by the New Jersey State Division of Vocational Rehabilitation Services (NJDVRS), a state-based agency that assists people with disabilities who are interested in pursuing employment. While I am in inpatient rehabilitation or soon after my discharge, a member of the research team will assist me in completing the necessary documentation to apply for services from this agency. Services for which I am eligible will be provided directly through NJDVRS.

- Program 2: In this program, services are coordinated by a facilitator who is employed by Kessler Institute for Rehabilitation and works cooperatively with NJDVRS. The facilitator will begin working with me during inpatient rehabilitation, or soon after discharge, depending on when I enroll in the study. Some services for which I am eligible will be provided through NJDVRS and others will be provided to me by the facilitator.

Both Program 1 and Program 2 provide services that consider my condition, needs, and goals. Services I may receive include:

- Education on programs designed to help people with spinal cord injury or brain injury pursue employment
- Advice and guidance from professional counselors who have special training in helping people with disabilities pursue employment
- Help completing applications for services
- Assistance communicating with my employer about my needs and ways to accommodate them
- Referrals to and services from other health care or technology providers

Follow-Up Survey

I will be asked to complete a survey about 12 months after enrolling in the study. The survey will ask me to describe employment, benefits I have received, satisfaction with services, well-being, and other outcomes related to my pursuit of employment.

Database Information Collection

Information about my earnings, benefits, and services received will be collected from state and federal program databases. My Social Security Number and other information that identifies me will be used to ensure that the correct information is collected. The study team will take care to obtain this information from me in a way that cannot be overheard and will store this form in a locked location that can only be accessed by members of the study team. If I have questions or concerns about collecting this information, I am encouraged to share these with the study team, who will make sure they are addressed to my satisfaction before I consent to participate.

WHAT RISKS ARE ASSOCIATED WITH PARTICIPATING IN THIS STUDY?

The study described above may involve the following risks and/or discomforts:

There are no physical or medical risks associated with this study. As with all studies that involve collection of private information, there is the risk of a breach in confidentiality by Kessler Foundation or Mathematica, but there are extensive procedures in place to prevent this from happening. These include collecting this information in private settings (to prevent what I share from being overheard or seen) and storing this information in secure databases that can only be accessed by authorized personnel. I will be informed immediately of any specific threat to my privacy.

Some study questions are about my financial status and physical and emotional health and functioning. It is possible I may be uncomfortable as I respond to questions about these topics. I may take breaks while completing the surveys and may decline to answer questions that make me feel uncomfortable.

WHAT WILL BE DONE TO PROTECT INFORMATION ABOUT ME?

Every effort will be made to maintain the privacy of my study records.

Protected Health Information and Personally Identifiable Information

The researchers would like to use information about my health ("Protected Health Information") as well as information that identifies me ("Personally Identifiable Information"). My Protected Health Information is given special protections under The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996. The researchers must obtain my approval to use Protected Health Information and Personally Identifiable Information.

If I participate in this research study, health information that will be used may include the following:

- Information from my medical records, such as my diagnoses, treatments I am receiving, reported symptoms, ability to function, and other observations made by health professionals as part of my medical care.
- Surveys about my work history, services and benefits received, earnings, participation in the community, and how I am feeling physically or emotionally
- Other observations made by researchers during the course of the research study

If I participate in this research study, Personally Identifiable Information that will be used may include the following:

- My name, phone number, email, address, etc. so that the researchers can contact me as needed during the study.
- My Social Security number, sex, and date of birth (which is needed to determine if I qualify for certain services and to accurately collect information about my earnings, benefits, and services received).
- Earnings and vocational rehabilitation program information from the state of New Jersey.

Protected Health Information and Personally Identifiable Information such as my name, address, date of birth, Social Security number, etc., that is stored electronically by Kessler Foundation is kept in a separate system called the Subject Information Management System (SIMS). SIMS is managed using a database called REDCap. REDCap meets the requirements of laws that protect health information. Access to study data in REDCap will be restricted to members of the study team only. Data are secured by requiring multiple types of login information to reach the study database. REDCap/SIMS also tracks access to and changes made to any records. Kessler Foundation does not permit Protected Health Information to be kept electronically in documents that are not protected in this way in order to ensure my privacy and the confidentiality of my information. Hard copy documents that contain my name, phone number, address, date of birth, Social Security number, etc., are kept in locked cabinets that only members of the research team can access.

Mathematica also takes many actions to safeguard Protected Health Information and Personally Identifiable Information. These actions comply with federal laws that protect this information. These actions include (but are not limited to) staff training and signed confidentiality agreements, use of appropriate technology, strict control of access to records, use of encryption (a way of preventing unauthorized viewing of information) while information is being shared, and secure methods of disposing data when it is no longer needed.

Sharing Protected Health Information and Personally Identifiable Information

My health information and information that identifies me may be shared with people and researchers at this institution and associates of the sponsor(s), university, clinic or hospital who help with the research or provide employment-related services to me. The researchers may share this information with other people or organizations who are in charge of the research, others who are helping the research study to be done, those who pay for the research, or those who make sure that the research is done properly.

The study team may share a copy of this approval form and records that identify me with the following people or organizations:

- The Institutional Review Board - a committee that reviews research studies for the protection of the people who participate in research.
- Auditors from Kessler Foundation, the sponsor (Social Security Administration), or government agencies responsible for the conduct of research to make sure the researchers are following regulations, policies, and study plans.
- Members of the study team, including Dr. John O'Neill, Dr. Trevor Dyson-Hudson, Dr. Steven Kirshblum, Dr. Denise Fyffe, Dr. Jay Verkuilen, Dr. Jeanne Zanca, Dr. David Mann, Ms. Tessa Huffman, Dr. Anna Hill, Ms. Stacie Feldman, and Ms. Sarah Croake. Changes in this list of personnel may occur over the years during which the study is taking place.
- Other organizations:
    - The New Jersey Division of Vocational Rehabilitation Services
    - The New Jersey Department of Labor
    - Mathematica, a research organization that is evaluating the programs being examined in this study
    - The U.S. Department of Health and Human Services, the government agency that oversees and funds research involving human beings.

I have the right to look at my study information at Kessler Foundation and to ask (in writing) for corrections of any of my information that is wrong.

If the findings from the study are published, I will not be identified by name. My identity will remain private unless its release is required by law.

Information shared with the Social Security Administration by Kessler Foundation will not be used to determine current or future benefits.

Removing Approval

I can change my mind at any time and remove my approval to allow my information to be used in the research. If this happens, I must remove my approval in writing. Beginning on the date I remove my approval, no new information will be collected about me if I revoke permission for those activities. However, researchers may continue to use any information that was collected before I withdrew my approval.

If after signing this form, I want to remove my approval, I can contact the person(s) below. He/she will make sure the written request to remove my approval is processed correctly.

John O'Neill, Ph.D.
Director, Employment and Disability Research
Kessler Foundation
120 Eagle Rock Rd., Suite 100
East Hanover, NJ 07936-3147
Tel. (973) 324-8387; Fax. (973) 324-8373
joneill@kesslerfoundation.org

Approval Expiration

This approval has no expiration date. However, as stated above, I can change my mind and remove my approval at any time.

Questions should be directed to the research staff person who is reviewing this form with me. I can also call the Kessler Foundation Privacy Board – *John DeLuca, Ph.D., ABPP at (973) 324-3572.*

WHERE ELSE CAN I FIND INFORMATION ABOUT THIS STUDY?

A description of this clinical trial is available on http://www.ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT05508802). This website will not include information that can identify me. At most, the website will include a summary of the results. I can search this Web site at any time.

WILL IT COST ANYTHING TO PARTICIPATE IN THIS STUDY?

There will be no cost to me for my taking part in this study. However, some of the services I may be offered may have costs associated with them. These costs may be paid by a combination of insurance, my own funds, or other sources. The cost for these services is the same as would be the case if I were not participating in this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

I will receive a $25 gift card in appreciation of my completing the one-year follow-up survey.

CAN I CHANGE MY MIND ABOUT PARTICIPATING IN THIS STUDY?

I understand that taking part in this study is my choice, and I may refuse to take part, or may stop taking part in the study at any time without penalty or loss of benefits to which I am otherwise entitled. I also understand the investigator has the right to withdraw me from the study at any time.

If I choose to withdraw from the study, researchers will ask if I want to revoke permission to access my information in state or federal databases. Researchers will also ask whether I still want to participate in the one-year follow up survey. The study team will retain access to any data collected about me before my withdraw from the demonstration.

WHO CAN I CONTACT FOR MORE INFORMATION?

If I have any questions about my treatment or the research procedures, I can contact:

Trevor Dyson-Hudson, M.D.
Director, Center for Spinal Cord Injury Research
Kessler Foundation
1199 Pleasant Valley Way
West Orange, NJ 07052
Tel. (973) 324-3576; Fax.(973) 243-6984
tdysonhudson@kesslerfoundation.org

John O'Neill, Ph.D.
Director, Employment and Disability Research
Kessler Foundation
120 Eagle Rock Rd., Suite 100
East Hanover, NJ 07936-3147
Tel. (973) 324-8387; Fax. (973) 324-8373
Joneill@kesslerfoundation.org

If I have concerns only regarding my **rights as someone taking part in a research study**, I may contact Donna Servidio, IRB Manager, at 1-800-648-0296, extension 6972.

I will receive a copy of this consent form if I agree to take part in this research study.

WILL INFORMATION ABOUT ME BE USED FOR OTHER RESEARCH STUDIES IN THE FUTURE?

The information collected in this research study may be useful in future research studies.

In some future studies, the researchers may want to use my information in a way that identifies me. This means that the researchers would have access to my name, contact

information, Social Security number, medical record number, or other identifying information, and would know that I am the person who provided the information. If, in the future, researchers wish to use information that can identify me, they will be required to obtain my specific permission, in writing, for the use of my information.

In other cases, researchers may want to use my information in a way that does NOT identify me. In this situation, the researchers do not have access to my name (or other identifying information) and would not know that I am the person who provided the information. In this section, I am being asked whether it is acceptable to me for researchers to use information that does not identify me without asking for my specific permission at the time of the future research study.

[ ] **Yes**, I agree to allow information collected in this study that does not identify me to be used in future research without my specific permission.

Participant Signature: _____

[ ] **No**, I do not agree to allow information collected in this study that does not identify me to be used in future research without my specific permission.

Participant Signature: _____

CONSENT TO DISCLOSE SOCIAL SECURITY ADMINISTRATION RECORDS

As part of my agreement to participate in this research study, I authorize the Social Security Administration (SSA) to release the following information to Kessler Foundation for purposes of this research study:

- The diagnoses/impairments used to determine my eligibility for benefits,
- My applications for benefits and eligibility,
- How long I have been enrolled in benefit programs,
- Benefit amounts I received,
- Employment supports I received, and
- Employment milestones I reached.

Information released by the Social Security Administration under this consent will be released to Kessler Foundation at the following address:

Kessler Foundation
Center for Employment and Disability Research
120 Eagle Rock Ave., Suite 100
East Hanover, NJ 07936-3147

The end date of my consent to allow SSA to release information to Kessler Foundation for purposes of this research study is January 1, 2029.

SIGNATURE OF PARTICIPANT

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study and authorize the release of my information to the Social Security Administration as described above.

Participant Name:_____Signature:_____
_____

Date of Signature:_____

Date of Birth: _____

Social Security number: _____

SIGNATURE OF WITNESS*

I was present when the researcher(s) described the study to the participant (or his/her parent or legal guardian) and I am a witness to the fact that the participant (or his/her parent or legal guardian) consented to participation in this study and to the authorization to release his/her information to the Social Security Administration as described above.

Witness Name:_____Signature: _____
_____

Date:_____

*If the Signature of Participant section was completed with a mark (X) rather than a full signature, please have two witnesses complete the section on the following page in lieu of the witness section above. Please print the signee's name next to the mark (X) on the signature line above.

Witness 1:

Witness Name: _____Signature: _____
_____

Date: _____

Street Address:_____

City, State, Zip: _____

Witness 2:

Witness Name: _____Signature: _____
_____

Date: _____

Street Address:_____

City, State, Zip: _____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL

To the best of my knowledge, the participant, _____, (or his /her parent/legal guardian) has understood the entire content of the above consent form, and comprehends the study and its risks as well. The participant's questions and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator Name:_____Signature:_____
_____

Date:_____

SIGNATURE OF READER/TRANSLATOR IF THE PARTICIPANT DOES NOT READ ENGLISH WELL

The person who has signed above, _____, does not read English well. I read English well and am fluent in *(name of the language)* _____, a language this person (his/her parent/legal guardian) understands well. I have translated for him/her (his/her parent/legal guardian) the entire content of this form. To the best of my knowledge, he/she (his/her parent/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and that these questions have been answered.
Reader/

Translator Name:_____Signature:_____
_____

Privacy Act Statement
Collection and Use of Personal Information

Section 1110 of the Social Security Act, as amended, allows the Social Security Administration (SSA) to collect this information, which SSA will use to evaluate the Interventional Cooperative Agreement Program (ICAP)/Vocational Resource Facilitation Demonstration (VRFD). Providing this information is voluntary; not providing all or part of the information will not affect any SSA benefit. As law permits, SSA may use and share the information you submit, including with other Federal agencies, contractors, cooperative agreement awardees, and others, as outlined in the routine uses within System of Records Notices 60-0089, 60-0218, and 60-0320, available at www.ssa.gov/privacy. The information you submit may also be used in computer matching programs for Federal benefit programs or to recoup debts under these programs.

See Revised Paper Reduction Act Statement

~~**Paperwork Reduction Act Statement**~~

~~This information collection meets the requirements of 44 U.S.C. § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer the survey questions unless we display a valid Office of Management and Budget (OMB) control number. The OMB control number for this collection is 0960-0829; expiration date 5/31/2026. We estimate that it will take about 30 minutes to read the instructions and answer the survey questions. You may send comments about our time estimate to: Social Security Administration, 6401 Security Blvd, Baltimore, MD 21235-6401~~