INFORMED CONSENT FORM

Study Title: Exercise Training Effects on Cognition and Brain Function in Multiple Sclerosis: A Systematically-Developed Randomized Controlled Trial

NCT Number: NCT03677440

Document Date: 5/1/2023

KESSLER FOUNDATION

INSTITUTIONAL REVIEW BOARD

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: Exercise Training Effects on Cognition and Brain Function in Multiple Sclerosis: A Systematically-Developed Randomized Controlled Trial

RESEARCH STUDY #: R-1110-20

I, _____, am being asked to consent to participate in a research study led by Dr. Brian Sandroff. Other persons who work with him as study staff may be asked to help him. 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 doctor 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?	The purpose of this research study is to compare the effects of two different 12-week long exercise programs (treadmill walking or stretching-and-toning) on cognitive (thinking) performance in persons with multiple sclerosis (MS). As a participant, I will complete one of these 12-week long exercise programs. This is important because exercise has been identified as a possible way to improve thinking performance in people with MS. There will be 72 participants enrolled at Kessler Foundation.
How long does the study last?	This study will take me 40 separate visits to Kessler Foundation over the course of 3 months. The first visit will last about 3 hours in total, the second visit will last 2 hours in total, visits 3-38 will each last 1 hour (36 total hours), visit 39 will last about 3 hours in total, and visit 40 will last about 2 hours in total.
What will happen during this research study?	While I am part of this study, I will be asked to complete paper and pencil tests of thinking performance, an exercise test that will exhaust me, and an MRI of my brain. I will then complete either a 12-week treadmill walking exercise program or a 12-week stretching-and-

	toning exercise program (both taking place at Kessler Foundation 3 days per week for 1 hour per visit). Both exercise programs will be supervised by trained exercise leaders; the program I complete will be determined at random (like the flip of a coin). After the 12 week period, I will then complete paper and pencil tests of thinking performance, an exercise test to exhaustion, and an MRI of my brain.
What risks are associated with participating in this study?	With the completion of the exercise test and exercise training visits, there are always risks of death, heart attack, arrhythmia (heart beating too fast, too slow, or irregularly), difficulty breathing, and complications that require hospitalization. All lab personnel in attendance are trained in CPR (cardio pulmonary resuscitation), AED (a device to restart the heart), and First Aid. I may experience some discomfort, fatigue, sprains, cramps, and muscle soreness after the completion of the maximal exercise test and exercise training visits. Those responses can be temporary for a few hours afterwards. There is a small risk of falling and injury when performing walking exercise on a treadmill. To minimize this risk, I will be encouraged to hold on to the handrails on the treadmill, as well as having a gait belt around my waist, and a research assistant within arm's reach to quickly assist if I lose my balance. There are risks of injury from the MRI magnet based on having metal in the body. To minimize these risks, I will be screened for these conditions before having any scan, and if I have any, I will not receive an MRI scan.

	There are some risks of tiredness and mild frustration during the thinking task, and a small risk associated with the completion of questionnaires (such as embarrassment or anxiety) in responding to some questions.
What are the benefits of participating in this research study?	I may receive no personal benefit from taking part in this study. However, the beneficial effects of exercise training on general health are very well known. Further, this study may help researchers better understand the effects of exercise in persons with MS. The results of this research may also lead to more effective ways to treat individuals with MS.
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?

The purpose of this research study is to compare the effects of two different 12-week long exercise programs (treadmill walking or stretching-and-toning) on cognitive (thinking) performance in persons with multiple sclerosis (MS). As a participant, I will complete one of these 12-week long exercise programs. This is important because exercise has been identified as a possible way to improve thinking performance in people with MS.

WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?

While I am a part of this study, I will be asked to do the following during 40 separate visits to Kessler Foundation over the course of 3 months:

The first visit will last about 3 hours in total and will occur at Kessler Foundation, located at 120 Eagle Rock Ave, Suite 100, East Hanover, NJ 07936.

- On the first visit, I will first take a paper-and-pencil thinking test of how quickly I can match shapes with single-digit numbers.
    - Depending on my score on this test, I may be ineligible to participate in this study.
        - If this is the case, I will be paid $50 in the form of a check for my time.

- If I am eligible to participate based on that test, I will then undergo a brief examination, where a researcher will measure my reflexes, how well I can feel a light touch, my muscle strength, vision, and ask me some questions concerning my bladder/bowel function and thinking ability.

- I will then complete a brief questionnaire on whether or not it would be safe for me to undergo an MRI scan.
    - If it is unsafe for me to undergo an MRI scan, I will be ineligible to participate in this study, but I will be paid $50 in the form of a check for my time.

- I will then have my blood pressure measured when I am seated comfortably in a chair using an automated blood pressure cuff in order to ensure my safety in participating in the study.
    - If my blood pressure is too high (i.e., greater than 200/110), I will be ineligible to participate in this study, but I will be paid $50 for my time.

- If my blood pressure is below 200/110 at rest, I will then complete several computerized and paper-and-pencil thinking tasks that will take approximately 45 minutes.

- I will then undergo a six-minute long walking test which will be performed indoors, on a flat surface with no obstacles.
    - I will be asked to walk laps around a circle of cones and continue for 6 minutes.
    - I will be allowed to stop and rest during the test; however, the clock will not stop.
    - For my safety, study staff will stay close to me during walking trials.

- Then, I will complete a short walking test measuring how fast I can walk over a 25-foot distance, followed by a seated test of flexibility, and then several more paper-and-pencil thinking tasks that will take approximately 15 more minutes.

- After a brief rest period, I will then complete a maximal exercise test to determine my aerobic fitness level.
    - This test will involve fitting me with a mouthpiece to monitor my breathing and a heart rate monitor to assess my heart rate during exercise.
    - The test will require me to walk on a motor-driven treadmill at zero incline (flat), and after a 3-minute warm-up, the incline will continually increase until I can no longer continue to exercise.
    - The test should take approximately 10-15 minutes.
    - For my safety, two researchers will be present within an arm's reach at all times during this test.

- The researcher will end the exercise session early if I begin to feel uncomfortable.

Two (2) days later, I will visit the Rocco Ortenzio Neuroimaging Center at Kessler Foundation (1199 Pleasant Valley Way, West Orange, NJ 07052) to complete more tests of my thinking ability, some questionnaires about my physical and mental well-being, and an MRI/fMRI scan. This visit will last approximately 2 hours.

- First, I will complete several paper-and-pencil thinking tests that will take approximately 30 minutes. This will be followed by several questionnaires about my symptoms, quality of life, and the impact of MS on my daily life that will take another 30 minutes.

- I will then undertake an MRI scan.
  - Magnetic resonance imaging (MRI) uses a strong magnetic field and radio waves to take pictures of the brain.
    - fMRI allows the researchers to see what parts of the brain are used when I perform certain thinking tasks.
    - The MRI scanner is a metal cylinder surrounded by a strong magnetic field.
  - During the MRI, I will lie on a table that can slide in and out of the cylinder.
    - A device called a "coil" will be placed over my head.
    - Before the scan, I will be told about the thinking tasks that I will do during the scan and I may have the opportunity to practice.
    - There is a computer screen that I will be able to see when I am inside the scanner.
    - The screen will show me the thinking task that I will do in the scanner.
      - This task involves deciding whether two groups of letters are either the same or different as quickly as possible.
  - I will be in the scanner for about 60 minutes.
  - During the scan, I will undertake the thinking task.
    - I will respond by pressing a button on a button box that will be attached to my hand with a Velcro strap.
  - I may be asked to do this task, or I may be asked to lie still for up to 10 minutes at a time.
  - While in the scanner, I will hear loud knocking noises and I will be fitted with earplugs or earmuffs to muffle the sound. I will be able to communicate with the MRI staff at all times during my scan and I may ask to be moved out of the machine at any time.
  - It is very important for the experiment that I do not move my head or body inside the scanner.

        - Padding, a vacuum bag, or expanding foam will be placed around my head to help keep it in position.

- For the next 12 weeks (i.e., 3 months), I will then be randomly picked (like the flip of a coin) by a computer to participate in one of two exercise groups.
    - One group will complete an in-person treadmill walking exercise program, and the other group will complete an in-person stretching-and-toning exercise program
        - Both programs are based on activity guidelines for people with MS and will be led by trained exercise leaders.

    - I will have a 50/50 chance of being placed in either group.

- No matter which group I am assigned to, I will be asked to complete 36 exercise training visits (treadmill walking or stretching-and-toning) that will take place at the main Kessler Foundation facility located at 1199 Pleasant Valley Way, West Orange, NJ 07052.

- These visits will take place 3 days per week for 12 weeks and will each last approximately 1 hour in total.

- These will be individual visits led by a trained exercise leader and will initially consist of 15 minutes of actual exercise and progress up to 40 minutes of actual exercise.
    - Each visit will begin and end with a 5-to-10 minute warm-up/cool-down period.

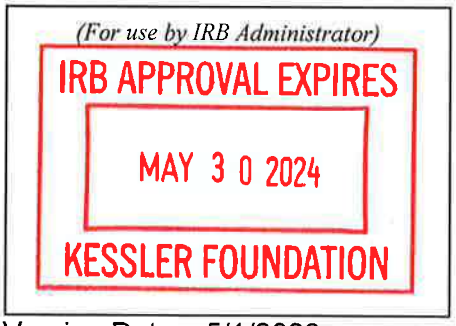
- During the initial visit, I will learn how to safely perform the exercises.
    - I will be given a log book to monitor and record my progress.

- For each visit, I will also be given individualized feedback and changes will be made to my program if needed.

- During 6 of these visits (i.e., once every two weeks), after I am finished with the actual exercises, I will be invited to participate in a 30-minute discussion led by my exercise leader on ways to enhance my experience with exercising.
    - After these informational sessions, I will be given motivational newsletters summarizing the content of what was discussed.

- At the end of my 12-week training program, I will return to the Kessler Foundation location in East Hanover, NJ for a follow-up visit.
    - This visit will last 3 hours where I will repeat the tests I completed during my initial visit.

- Two (2) days later, I will return to the Rocco Ortenzio Neuroimaging Center at Kessler Foundation in West Orange, NJ for a final follow-up visit.



- This visit will also last 2 hours where I will repeat the tests I completed during your second overall visit, and will also involve another MRI scan.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 72 people with MS between the ages of 18-65 will take part in this study.

WHO QUALIFIES TO PARTICIPATE IN THIS STUDY?

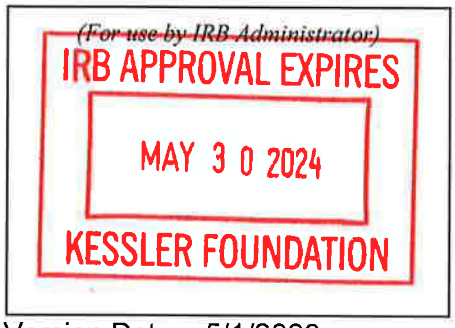
Persons with a clinically definite diagnosis of MS who:

- Are between the ages of 18-65
- Are on a stable dose of medication for MS for at least 6 months
- Can walk at least 500 meters (about 500 yards) without using an assistive device like a cane or walker
- Have problems with thinking performance
- Are relapse-free for at least 30 days
- Have corrected vision better than 20/80
- Do not have known/diagnosed heart disease including uncontrolled high blood pressure, diabetes, or kidney disease.
  - Individuals with known/diagnosed heart disease, diabetes, or kidney disease who do not have symptoms will be included only with a physician's approval.
- Engage in less than 2.5 hours of moderate-to-vigorous physical activity per week
- Demonstrate relatively normal blood pressure at rest

WHAT MIGHT MAKE ME INELIGIBLE FOR THIS STUDY?

If any of the items listed below are true for me, I will tell the researcher. To ensure my privacy, I do not have to say which item or items apply to me. If I choose to tell the investigator which items are true for me, the information will not be shared with anyone.

- I have taken steroids for my MS in the last 30 days
- I have a history of major depressive disorder, schizophrenia, bipolar disorder I or II, or substance-abuse disorders.
- I am regularly taking medications that can affect my thinking, such as antipsychotics or benzodiazepines. Study staff will review my medications to determine if I am taking any that would make me ineligible for this study.
- I am unable to make everyday decisions on my own.
- I am currently receiving cognitive rehabilitation or participating in regular brain fitness activities



- I have metal (e.g., non-MRI compatible aneurysm clips, metal shards in the body or eyes, or recently placed surgical hardware) or electronic devices (e.g., pacemaker, cochlear implant) within the body.
- I have been told by my physician that it is unsafe for me to have an MRI scan as part of my medical care.
- I am pregnant.

Because of the potential risk to the fetus of MRI scans, pregnant women will not be enrolled in this study.

WHAT RISKS ARE ASSOCIATED WITH PARTICIPATING IN THIS STUDY?

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

Exercise:

- With the completion of the exercise test and exercise training visits, there are always risks of death, heart attack, arrhythmia (heart beating too fast, too slow, or irregularly), difficulty breathing, and complications that require hospitalization.

- All lab personnel in attendance are trained in CPR (cardio pulmonary resuscitation), AED (a device to restart the heart), and First Aid.

- Importantly, it is still possible that I will experience some fatigue, sprains, cramps, and muscle soreness after the completion of the exercise test and exercise training visits. Those responses can be temporary (i.e., for a few hours afterwards).

- Any possible symptoms associated with an increase in body temperature will be reduced by controlling the room temperature with air conditioning and using multiple fans.

- There is a small risk of falling, injury, head trauma, and death when performing walking exercise on a treadmill. To minimize this risk, I will be encouraged to hold on to the handrails on the treadmill, as well as having a gait belt (i.e., a belt with handles on it where spotters can provide physical support in case of a slip) around my waist, and a research assistant within arm's reach to quickly assist if I lose my balance.

- During the exercise test, there may be some discomfort when wearing the mouthpiece.

MRI:

- People are at risk for injury from the MRI magnet if they have:
  - Pacemakers or other implanted electrical devices
  - Brain stimulators
  - Particular types of dental implants
  - Aneurysm clips (metal clips on the wall of a large artery)

  - Metallic prostheses (including metal pins and rods, heart valves, and internal hearing aids [cochlear implants])
  - Permanent eyeliner
  - Implanted delivery pumps
  - Shrapnel fragments
  - Welders and metal workers are also at risk for injury because of possible small metal fragments in the eye of which they may be unaware.

- I will be screened for these conditions before having any scan, and if I have any, I will not receive an MRI scan.

- If I have a question about any metal objects being present in my body, I should inform the study personnel.

- In addition, all magnetic objects (for example, watches, coins, jewelry, hair clips and credit cards) must be removed before entering the MRI scanning room.

- People with fear of confined spaces may become anxious during an MRI.

- Those with back problems may have back pain or discomfort from lying in the scanner.

- Some may experience dizziness or paresthesia (tingling or numbness).

- The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss.
  - Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, I should let the study personnel know right away.

  - I will notify the investigators if I have hearing or ear problems.

- I will be asked to complete an MRI screening form for each MRI scan I have. There are no known long-term risks of MRI scans.

- If I am unsure if I am pregnant, I will talk with the research assistant before signing this form. The researchers advise that all women take a urine pregnancy test if there is any uncertainty. I will be given this test for free here at Kessler for me to take in private. However, it is my decision. I do not have to take the pregnancy test if I am sure that I am not pregnant.

- I will indicate here if there is any chance that I could be pregnant:
  Yes [ ] No [ ] Not Sure [ ]

_____
Signature

(For use by IRB Administrator)

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- If I become pregnant during the course of the study, I will notify the principal investigator of this fact as soon as possible since the risks to the fetus or me are unknown.

Thinking tasks:

- I may also feel tired or experience mild frustration during the tasks designed to measure my thinking ability. This is because the tasks are often difficult. I will be allowed to take short breaks as necessary.

Walking tests:

- There is also a small risk of falling or injury during the six-minute or 25-foot walking test. For my safety, study staff will stay close to me during the walking trials.

- There is also a risk of dizziness or fatigue. I will be permitted to take breaks as needed to minimize these effects.

- All study procedures and testing will be performed under supervision of qualified personnel.

Questionnaires:

- There is a small risk associated with the completion of questionnaires such as embarrassment or anxiety in responding to some questions.

I will be assigned to 1 of 2 exercise groups by chance. The one I am assigned to may prove to be less effective or slightly more fatiguing than the other exercise group.

There also may be risks and discomforts that cannot be foreseen.

WHAT WILL HAPPEN IF THE RESEARCHERS LEARN NEW INFORMATION ABOUT THE STUDY?

During the course of the study, I will be told about any new findings that might affect my willingness to remain in the study.

Incidental Findings

Because the purpose of the MRI scan is not to diagnose or identify medical problems I may have, neither Kessler Foundation, its researchers, staff or employees are responsible for identifying any medical conditions I may have.

While my scan is being done for research purposes only, and not part of my health care, it is possible that the research staff may see something in the MRI scan that could be a sign of a health problem. If that happens, the scans will be sent to a Rutgers radiologist to see if a health problem may be present.

When scans are sent to Rutgers, my name and birthdate will be provided to the radiologist and my privacy will be protected by Kessler and Rutgers policies that cover protected health information.

If the radiologist feels follow-up with a physician is needed, a Kessler physician will coordinate with the Rutgers radiologist and communicate the findings to me so I may follow-up with my physician as I choose. Copies of the scans can be sent to my physician at my request.

I understand that if I enroll in this study, my MRI scan may be sent for review to a Rutgers radiologist as described above.

_____
Signature

_____
Date

Courtesy Copy for my Physician

☐ I would like Kessler Foundation to provide a copy of my MRI scan results to my physician. My physician's contact information is:

Please Print:

_____
Physician Name

_____
Physician Address

_____
Physician Telephone Number

☐ I do not want Kessler Foundation to provide a copy of my MRI scan results to my physician.

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

The researchers would like to use information about my health as well as information that identifies me. This information is referred to as "Protected Health Information" and 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.

If I participate in this research study, information that will be used and/or released may include the following:

- Information from my medical records, such as my diagnoses, medications or other treatments I am receiving, laboratory test results, images (such as x-rays or other scans), reported symptoms, ability to function, and other observations made by health professionals as part of my medical care.
- Questionnaires about how I am feeling physically or emotionally
- Results of tests of my physical or mental function
- Results of laboratory tests or physical examinations given for purposes of the research study
- Other observations made by researchers during the course of the research study

Protected Health Information such as my name, address, date of birth, etc., that is stored electronically 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, etc., are kept in locked cabinets that only members of the research team can access.

Sharing Protected Health Information

My health information 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. 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 (National Institute of Child Health and Human Development; National Institutes of Health) 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 Drs. Brian Sandroff, Glenn Wylie, John DeLuca
- The Finance Dept. of the Kessler Foundation, who will prepare subject payments for participation in the study
- Other organizations: DHHS (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 the study doctor's office 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.

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 used for research. However, researchers may continue to use the information that was provided 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.

Brian M. Sandroff, Ph.D.
Kessler Foundation
1199 Pleasant Valley Way
West Orange, NJ 07052
Phone: 973.965.6649
Email: bsandroff@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 will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify me. At most, the Web site will include a summary of the results. I can search this Web site at any time by using NCT number 03677440 as the search term.

WILL IT COST ANYTHING TO PARTICIPATE IN THIS STUDY?

There will be no cost to me for taking part in this study. All tests, exams, and exercise related to this study will be provided to me at no cost during the 3-month study period. However, attending visits can involve some transportation costs (i.e., the cost of gas). But, parking will be free for each of the 40 visits I attend.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

I will receive up to $380 for taking part in this study according to the following schedule:

$100 after the baseline evaluation and MRI scan (i.e., the first 2 study visits); up to $180 at the conclusion of the 3-month exercise program (i.e., $5 for attending each exercise visit [up to 36 visits]; and $100 after completion of the follow-up evaluation and MRI scan.

Please ask the study staff about the method of payment that will be used for this study (e.g., check). The payment is prorated per visit in the event that I stop participating in the study or the investigator terminates the study.

Note: If I receive $600 or more in a calendar year from Kessler Foundation for participation in research, I will have to provide my social security number to Kessler Foundation before I can be paid due to United States tax laws. I have the option to provide my social security number to the research team now, or wait until it is required for payment and provide it at that time. As described above, many actions will be taken to ensure that the confidentiality of my social security number is protected.

WHAT WILL HAPPEN IF I AM INJURED IN THIS STUDY?

If I take part in this study, I will be exposed to certain risks of physical injury. I may request assistance from the Principal Investigator to arrange medical treatment for any physical injury that occurs as a direct result of my taking part in this study. I understand that I will be responsible for any costs associated with treatment for any physical injury that occurs while I am in this study. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of my medical treatment. I will be responsible for any part of the treatment cost not paid by my insurance or managed care provider. No financial payment will be offered to me in the event of physical injuries that happened as a direct result of my taking part in this study.

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.

I may be removed from the study without my consent if the sponsor ends the study or if the Principal Investigator decides it is not in the best interest of my health.

WHO CAN I CONTACT FOR MORE INFORMATION?

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

Brian M. Sandroff, Ph.D.
Senior Research Scientist
Kessler Foundation
1199 Pleasant Valley Way
West Orange, NJ 07052
Phone: 973.964.6649
Email: bsandroff@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. The researchers may use or share my information in future research in a way that does NOT identify me without additional informed consent from me. In this situation, the researchers who are using my information do not have access to my name or other identifying information and would not know that I am the person who provided the information. If researchers wish to use or share information that can identify me, they will be required to obtain my informed consent, in writing, for the use or sharing of my information or samples in future research.

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.

Participant Name:_____Signature:_____

Date:_____

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 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.

Witness Name:_____

Signature: _____

Date:_____