Official Title: Gerofit Exercise Intervention for Older Adults with Sickle Cell Disease (SICKLE-FIT Study)

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study

SICKLE-FIT: Gerofit Exercise Intervention for Older Adults with Sickle Cell Disease

CONCISE SUMMARY

This purpose of this research study is to see how easy or hard it is to complete a virtual personalized exercise training program for older adults with sickle cell disease by Zoom and confirm its safety. We will also ask questions about why you exercise. You will have functional assessments using the Sickle Cell Disease Functional Assessment (SCD-FA) to measure your strength, endurance, and various areas of your health. One assessment will be before the exercise program, one will be immediately after the program, then 3 month after, 6 months after, and then annually. This study will help us to develop good exercise programs for adults with sickle cell disease with the goal of improving heath.
The study will include adults with sickle cell disease age 40 and older.

We will use the Gerofit exercise program that has been shown to improve physical abilities, mental health, and allow older adults to live longer. The program will be done through video (you will exercise in a safe area at home) with 5-8 participants in each group and will last up to 12 weeks. You will start with 10-15 minutes of low- to moderate-intensity exercise (meaning an intensity level where you can still speak while exercising) and this will gradually increase each week at your own pace. You will work up to exercising for 60 minutes. Each exercise session will be up to 90 minutes, which includes up to 60 minutes of exercising and 15-30 minutes of safety/health check-ins and talking. Exercise sessions will be virtual (video calls) 3 days a week. We will do some exercise testing in clinic to track your progress and collect urine and blood. After each visit in clinic, we will measure your physical activity with a wearable step monitor worn on your wrist. At the end of the study we will ask your group questions to get a better understanding of how to improve the exercise program. If you are benefiting from the SickleFit exercise program, you will have the option to continue exercising.

The benefits of this study are that you may learn useful information about your strengths and weaknesses based on the physical and cognitive testing. The exercising may improve your fitness. The possible risks of this study is a small chance of physical injury/fall or sickle cell pain crisis during the exercise sessions, physical testing, or within 24 hours of exercise sessions due to overexertion. We will provide frequent breaks and our exercise coach will give you advice on how to reduce the risk of injury. To ensure safety, we will monitor you on the Zoom video while you exercise and check in frequently throughout the workout by asking you to rate how hard the work out is. We will ask you to lighten the workout or rest if you are having pain or discomfort.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have sickle cell disease. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this

consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Charity Oyedeji, MD and John Strouse, MD, PhD will conduct the study and it is funded by the Duke Center for REsearch to AdvanCe Healthcare (REACH) Equity and the National Institute of Health. The sponsor of this study, the National Institute of Health, will pay Duke University to perform this research, and these funds may pay part of Dr. Charity Oyedeji's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Charity Oyedeji and Dr. John Strouse will be your doctors for the study and will be in contact with your regular health care provider while you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to see if a personalized exercise training program can be completed in adults with sickle cell disease. We will also have focus groups and individual interviews to ask about how to improve the exercise program.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Up to 50 people will take part in this study at Duke University Medical Center.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures:

- Virtual exercise sessions by video call
- Physical exam and medical history
- Vital signs
- Exercise tests
- Blood and Urine tests

Gerofit Exercise Program
Each participant will get a written exercise program that is customized to their health status based on the Sickle Cell Disease Functional Assessment (SCD-FA). Our exercise instructor is trained in common complications of sickle cell disease.

All exercise sessions will be virtual in a group setting. Before starting each exercise session, the exercise instructor will check in with you to ask if problems, such as pain crises, have occurred. This is to decide

if you are safe to exercise that day. You will start with 10-15 minutes of low- to moderate-intensity exercise and this will gradually increase each week. You will work up to exercising for 60 minutes. This is based on the American College of Sports Medicine guidelines for exercise in adults with chronic conditions.

Group 1: The first group of 3-5 participants and the sickle cell exercise coach will exercise for up to 8 weeks with the Durham Veteran Affairs Gerofit Exercise Program. We will join by video call and exercise with the veterans.

Groups 2-4: All other groups will exercise in a 12-week virtual or hybrid in-person exercise program. These groups will only include adults with sickle cell disease and the sickle cell exercise study team.

If you are benefiting from the exercise program, you will have the option to continue exercising in the SickleFit program after completing the 12-week feasibility evaluation. This will be at the discretion of the study team as long as you have no significant safety concerns and continue to benefit from the exercise program. You can continue exercising in the Sickle-Fit exercise program for up to 10 years.

Session will be up to 90 minutes (no more than 60 minutes of exercise) for 3 days a week and includes:

- 15-30 min of safety/health check-ins before and after exercising and talking about exercise
- Cardio exercise
- Strength training
- Balance training
- Warm-up and cool-down exercises (stretching and mindfulness breathing)

Rating of perceived exertion (RPE)

We will ask you to rate your exercise throughout the session using the **rating of perceived exertion (RPE). It is a scale from 0 (easy) to 10 (very hard)**. Initial exercise sessions will start with easy and short exercise and will gradually increase the intensity and duration to reach recommended exercise levels for each person at their pace.

The instructor will be familiar with your functional assessment and will modify the exercise program for your strengths and weaknesses. Options for doing exercise from sitting or standing will be included at each session

We will ask you to reflect on your experience exercising throughout the program to help make the program better.

Equipment Participants will need:

- A non-rolling chair (we can provide a sturdy folding chair).
- We will provide you with resistance bands and other equipment for strength training.

- We will provide tablet computers and Wi-Fi for participants who do not have internet access or a computer.

Functional Assessment

To track your progress, we will have you **come to clinic in-person** to test your physical function, mental health, record your medical problems, and ask about your social support. We will test you in clinic 4 times during the study: At the start of the study, immediately after the 12-week exercise program ends, 3 months later, 6 months later, then annually. If you choose to remain in the study, we will monitor changes in your physical function with an annual assessment for up to 10 years. If you stop exercising in the program we will also track your physical function with your annual Sickle Cell Disease Functional Assessment. You will have a functional assessment and wear an activity monitoring watch for one week after each testing visit. Each session will take about 1 hour to complete. Refreshments and parking passes will be provided when you come to clinic for in-person assessments.

The functional assessment includes:

- Functional Status: we will ask you about what you are able to do on a daily basis, number of falls, and how you do with more intense daily activities
- Questions about what medical issues you have
- Questions about anxiety and depression
- Questions about your family and friend support system
- Questions about social activities
- Question about your nutrition, weight, and recent weight loss
- We will ask you the number of medications you take
- We will assess your memory and brain function using a short test called the Mini-Cog

We will test your physical function by:

1. *Usual Gait Speed:* We will time you walking at your usual walking pace
2. *Timed Up and Go*- We will measure the number of seconds it takes you to stand up from a standard chair, walk 10 ft, turn back to the chair, and sit down again
3. *6 minute walk:* We will measure the distance you can walk as fast and as safely as possible for 6 minutes and will walk behind you through entire time to ensure that you don't fall.
4. *Seated Grip strength:* We will measure your grip strength using a device while you are seated
5. *30 second Chair stand test:* We will measure the number of times you can stand up and sit back down with arms across your chest in 30 seconds.
6. *Functional Movement Screen* – We will assess how your body moves
7. *Core Strength and Balance Assessment* – We will test the strength of your core (abdomen/back/pelvis). Additionally, we will test you balance, such as the ability to stand on one leg.

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All tests will be performed by trained professionals in the Duke Adult Sickle Cell Clinic and you will have frequent breaks. We will not push you beyond your limits and will watch you to make sure you are safe and do not fall. We will monitor you very closely throughout the study.

Water will be provided during the assessment and you will be encouraged to remain hydrated 24 hours after the exam to minimize the risk of a sickle cell pain crisis.

Activity Monitoring
We will have you wear an activity monitor (like a wrist watch) for one week to measure your physical activity after each study visit

Sample Collections
We will collect your blood and urine samples at the beginning of the study, at each functional assessment and at the end of the study and freeze the samples so that that they can be tested at a later time. We will analyze your samples to determine if markers related to physical function and frailty improve in response to exercise.

Your blood samples will be collected by taking blood from a vein in your arm or hand with a needle.

Maintaining confidentiality is important to us. All samples will be kept and stored in a secure place in a lab in the Duke Division off Hematology. Your sample will be identified by an ID number, which means that your name will not be on the sample. However, this study ID can be linked to your age, gender, and ethnic background. Besides protecting your confidentiality, we will discard your samples in case you change your mind. Your sample will be kept for at least 10 years. After that time, the sample will be destroyed by methods in accordance with laboratory or institution procedures.

Optimization of the Exercise Program
Participants will be interviewed in focus groups and/or individually to help us improve the exercise program. The interviews will be by video, by phone, or in person, depending on your or your group's preference. The questions will help us to understand any barriers to exercising. We will record the focus groups and interviews and write down what you say for further study. Your quotes from the interview will not include your name or other identifiers. We will use the results of the exercise program, assessments, and focus groups/interviews to change, remove, or add exercises to the program. This is to make it more useful and easier for participants. The revised versions of the exercise program will be used for the next group of adults with sickle cell disease. We will ask you questions after each study visit to see if the program is acceptable to you and if knowing your results changes your health. We may need to change the exercise program during the course of the study.

The Gerofit personalized exercise program is experimental in people with sickle cell disease, but has been completed by hundreds of older adults. Participation is voluntary. Refusal to join the study will involve no penalty or loss of benefits to which you are otherwise entitled.

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If you want to stop being in this study you need to tell Dr. Oyedeji and/or Dr. Strouse and you must return the activity monitor and tablet computer.

If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

Communication

If you choose to participate in the study, we will communicate with you via your preferred method, which may be by email, phone or text message. We will also respond to any messages you send us using responses in the following categories:

- Scheduling questions for functional assessments and exercise sessions
- General study-related questions
- Evidence-based advice on exercises in the SickleFit Program
- Advice on managing soreness and pain based on the participant's established safety/care plan

Please be aware that email is not a secure form of communication.

Please note that SMS text messages are not secure, there is a possibility the mobile carrier, or others may have access to the SMS text messages you exchange with the study team. There is a potential risk to confidentiality by sending and receiving SMS text messages. In addition, there is also a chance that your identifiable information may be seen by others outside of the research team. You may also be sent a survey link via email from a secure database called REDCap to complete your study-related surveys.

Exercise Sessions Video Recording

Participants may be video recorded during the online exercise sessions to help us improve the exercise program. The video recording may take place while the group of participants are exercising in person or while exercising online via Zoom. The recordings will be used for educational purposes. Based on participant feedback, recorded exercise sessions will be made available to participants in this study so they may exercise at their leisure outside of the scheduled exercise sessions. During the focus groups and interviews we will ask for your feedback on whether having access to the recorded videos are helpful.

The study team will also review the recorded exercise sessions to improve the program. recordings of the exercise sessions will be made available to participants via email from a secure database called REDCap. If you agree to be recorded during the exercise sessions, you will be asked to sign a Video Release HIPAA Form and will be provided a copy of the sign form. If you would like to participate in the exercise study but would not like to be recorded during the sessions, please initial next to the "Opt-Out" option at the end of the consent form.

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Data collected from this study will be sent to an external biostatistician/Richard Faldowski PhD for statistical analysis. This data transfer is protected under the confidentiality agreement.

HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for up to 10 years.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Results of this research important to your health will be communicated with you. If we detect any serious physical, cognitive, or laboratory abnormalities we will inform you and your physician so that these can be appropriately addressed.

WHAT ARE THE RISKS OF THE STUDY?
There is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Risk Related to Exercising:
There are risks associated with this study since you will be exercising and doing physical assessments. There is a potential risk of physical injury and falls during the exercising due to overexertion. According to the American College of Sports Medicine, the most common risks associated with exercise are **musculoskeletal injuries**. Injuries are usually related to the type and intensity of exercise. Walking and moderate intensity exercises (the ones done in the Gerofit exercise program) have a very low risk of causing injury. If an injury does occur, the most common sites of injury are the lower extremities (knees, feet, and ankles). In this study, the intensity, duration, and type of exercises will be customized to each person's health status to minimize musculoskeletal injury.

Sudden cardiac death is a rare risk of exercise in older adults and individuals with chronic diseases; however, this typically occurs during vigorous exercise and in patients with unstable heart conditions. Exercises in Gerofit are moderate intensity. No falls or adverse events have been associated with the virtual Gerofit program since exercises are personalized to each person's health status, there is a safety protocol in place, and individuals with unstable heart conditions do not participate in Gerofit.

Risk of sickle cell related events:

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There is a risk of vaso-occlusive events triggered by exercise such as pain. Previous research on exercise in adults with sickle cell disease showed that moderate intensity exercise was safe.

Adverse events will be classified in the following categories:

Minor adverse events are defined as having a vaso-occlusive pain crisis or injury that can be successfully treated at home. You can return to exercise when you feel you are able to tolerate exercising again.

Major (severe) adverse events are pain crises or injuries that cannot be managed at home and that require you to be seen in the emergency room, sickle cell day hospital, or hospital. If your pain is too severe to be managed at home, you will be asked to come to the sickle cell center for evaluation and treatment in the Duke Sickle Cell Day Hospital or ED depending on the severity of the pain crisis and time of day. You will be able to return to exercise one week after intense crises resolved.

Major life-threatening events are life-threating complications such as acute chest syndrome, organ failure, or stroke. If this happens you will no longer continue in the exercise program. If you have a non-sickle cell related hospital admission, the research team will evaluate these on a case-by-case basis.

To assist in tracking adverse events and pain levels, a pain journal will be provided. Instructions for filling out the pain journal will be discussed at your Safety Orientation Zoom meeting prior to beginning the exercise program.

Risks of Drawing Blood:
Risks associated with drawing blood include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

SAFETY FEATURES

To maximize safety and minimize risk of injury during or within 24 hours of each exercise session:

- During exercise, you will report your rate of perceived exertion (RPE) on a scale of 1 (easy) to 10 (hard) and will be given guidance on how to safely adjust the intensity of exercising as needed. The exercise instructors will let you know what to expect including soreness versus pain; they will remind you to tell us if you have pain so that changes can be made as needed.
- The amount (duration, intensity) of exercise is unique to each person. You will start the program by doing 10-15 minutes of low- to moderate-intensity exercise (being able to still talk while exercising) and will gradually increase over the course of 12 weeks based on your tolerance level (RPE, muscle soreness outside of class) and improved capacity (aerobic endurance, strength, balance).
- Every session we will 1) inquire about health concerns, 2) monitor all participants in real time using the gallery view on Zoom, 3) instruct participants with balance issues to hold on to a non-rolling chair, and 4) warm-up and cool-down/stretch
- Research staff will have emergency contact information for each participant.

- If major or life-threatening adverse events happen during or within 24-hours of exercise activities, participants will know to immediately call research staff in the Duke Sickle Cell Clinic or page if it is after hours.
- We will avoid overexerting participants, encourage wearing proper shoes, exercises are done in a safe area of the home with space with no trip/fall hazards, and we monitor each person for proper exercise form and safety to avoid injuries.

Twillio

We may use Twillio, a messaging program recommended by Duke, to send you SMS text messages to discuss study related information. Your name and phone number will be entered into REDcap for this purpose. There is a chance Twillio may see and use your name and phone number. Also, as SMS text messages are not secure, there is a possibility that mobile carriers, Twillio or others may have access to the SMS text messages you exchange with the study team. In addition, there is also a chance that your identifiable information may be seen by others outside of the research team. There is a potential risk to confidentiality through use of Twillio and by sending and receiving SMS text messages.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. You may see improvements in your function and confidence and motivation to exercise. You may notice improvements in your strength, endurance, flexibility, and balance. You may learn useful information about your relative strengths and weaknesses based on the physical assessment provided by the study. We hope that in the future the information learned from this study will benefit other people with sickle cell disease.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. Additionally, all data transferred to Richard Faldaowski/external biostatisticians will be stored electronically on a secure computer or in an encrypted REDCap database. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of this study, you will be asked to have certain tests and/or procedures performed. Some of these tests and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your medical record.

Certificate of Confidentiality

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The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Retention of Records
The electronic study results will be retained in your research record forever. Any electronic research information in your medical record will also be kept indefinitely.

This information may be further disclosed by the sponsor of this study, the National Institute of Health. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law

designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

There are no additional costs to participate in this study. You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Oyedeji or Dr. Strouse**.** At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

We will monitor your DUHS patient care charges to make sure that costs related to the study are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

There will be no additional cost to you if you choose to continue exercising in the Sickle-Fit program.

WHAT ABOUT COMPENSATION?

You will be compensated $40 for each in-person functional assessment visit for your expenses related to your participation (parking, gas, and time). We will also provide parking passes and compensation for the number of miles you travel to come to in-person study visits at the current approved government rate, up to $50 per study visit. Compensation will be prorated if you withdraw from the study. For completion of the exercise program you will be allowed to keep the tablet computer. There will not be monetary compensation for virtual exercise sessions. If you complete the focus group or individual interviews, you will receive an additional $25. You will receive compensation for the completed portions, up to $185 + cost for mileage over the course of the study.

Payment for participation in research is considered taxable income and Duke University is required in many cases to report this information to the Internal Revenue Service (IRS).

Duke University requires that you provide your name, mailing address, and social security number for this tax reporting purpose before payment can be issued. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

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Research subject payments to a non-employee of Duke University adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

Participant compensation made to a Duke University employee at any time during the calendar year will result in a 1099 (Miscellaneous Income) form being issued to the employee and a copy sent to the IRS regardless of the total amount paid.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Charity Oyedeji or Dr. John Strouse at (919) 684-0628 during regular business hours and page Dr. Charity Oyedeji or Dr. John Strouse through the Duke operator at 919-684-8111 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Oyedeji or Dr. Strouse in writing and let them know that you are withdrawing from the study. The mailing address is 40 Duke Medicine Circle, Clinic 2N, Durham, NC 27710. You will be asked to return the activity monitor by mail or in person.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include changes in funding or concerns about safety. If this occurs, you will be notified and your study doctor will discuss other options with you.

For withdrawal of samples

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If you agree to allow your blood and urine to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact Dr. Strouse or Oyedeji in writing and let them know you are withdrawing your permission for your identifiable blood and urine to be used for future research. The mailing address is 40 Duke Medicine Circle, Clinic 2N, Durham, NC 27710. At that time, we will ask you to indicate in writing if you want the unused identifiable blood/urine samples destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research. Your blood samples and data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

A description of this clinical trial will be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Charity Oyedeji or Dr. John Strouse at (919) 684-0628 during regular business hours and page Dr. Charity Oyedeji or Dr. John Strouse through Duke operator at 919-684-8111 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form"

Participants are given the option for telephone verbal consent, which is indicated below.

_____ Initials **I give permission** to be quoted for publications.

_____ Initials **I give permission** for you to contact me for future studies.

_____ Initials **Opt-In: I give permission** to be video recorded during the exercise sessions for educational purposes

_____ Initials **Opt-Out: I do not give permission** to be video recorded during the exercise sessions for educational purposes

_____ _____ _____
Signature of Participant Date Time
or Indicate if Telephone Consent was Obtained

_____ _____ _____
Signature of Person Obtaining Consent Date Time