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Research Subject Informed Consent Form

Title of Study:	Optimizing Exercise for the Treatment of Anxiety s20-01348
Principal Investigator:	Kristin Szuhany, PhD NYU Psychiatry Department 1 Park Avenue, 8th Floor New York, NY 10016 646-754-5161
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to learn more about the efficacy (how well something works) of two different exercise regimens for individuals with anxiety disorders (generalized anxiety disorder, social anxiety disorder, and/or panic disorder) who also have high anxiety sensitivity, which is fear or distress when experiencing internal physical sensations associated with anxiety (like shortness of breath, sweating, shaking, etc.).

Anxiety disorders are associated with impairments in quality of life and overall functioning and can increase risk for certain types of medical conditions (like heart disease or stroke). Past research suggests that exercise can be helpful to improve anxiety symptoms and reduce risk of medical problems. However, research also shows that it can be hard for people with anxiety to start and keep up with an exercise routine. In this study, we are interested in how different intensities of exercise can impact anxiety and quality of life and how different exercise regimens can impact exercise adherence.

DC 05/10/2021

This study is a randomized study. This means, like flipping a coin, you will be assigned to one of the treatment groups and receive either 1) low intensity exercise (e.g., walking, light stretching) or 2) a stepwise titration up to high intensity exercise. The second regimen starts off at low intensity exercise and slowly works up to high intensity exercise across the 8 weeks of the intervention. Once you are eligible for the study, there are no special requirements or criteria to be in either of the exercise groups. You will not be able to choose to which of the groups you are assigned. You will have a 1 in 2 chance of receiving either treatment.

We are asking you to take part in this study because you have reported feeling anxious and having high anxiety sensitivity and have expressed interest in participating in this exercise study to target your anxiety.

3. How long will I be in the study? How many other people will be in the study?

It will take you about 5-6 months (20-24 weeks) total to complete this study. You will come to the study center at NYU Langone Health (NYULH) for one or two screening visits to see if you can take part. If you are eligible to continue after the screening visit(s), you will take part in 3 in-person visits and 5 telephone visits over the course of 8 intervention weeks. After the intervention, there will be 2 in-person, follow-up assessments at 1-month post-intervention (Week 12) and 3-months post-intervention (Week 20). We estimate consenting and evaluating 122 participants to have 90 meet entry criteria and be randomized to participate in the study. The total duration of this study will be approximately 6 years. This study will be an outpatient study taking place at 1 Park Avenue.

In order to have the study intervention and assessments be as complete as possible, any visit may be conducted remotely via Webex if needed at the discretion of the research team, such as in the circumstance of weather, possible COVID-19 exposure, or as needed for independent evaluator visits. Webex will only be used if deemed necessary by the research team.

4. What will I be asked to do in the study?

If you decide to take part in this research study, you may be asked to undergo the following study procedures that are not part of your standard medical care. The 3 steps include:

- Step 1 is the screening evaluation phase. This evaluation will determine if you are eligible to take part in the study (1 – 2 visits). You will only be asked to take part in Steps 2 and 3 if you are eligible.
- Step 2 is the intervention phase which includes randomization (like a flip of a coin) to one of the study interventions, either low intensity exercise or titration to high intensity exercise. You will also fill out questionnaire measures, complete an auction task (explained later in this section) and heartbeat detection task, wear a Fitbit activity monitor, and answer questions about your mood before and after your exercise at home. Step 2 includes 3 in-person visits (Weeks 1, 4, 8) and 5 telephone calls (Weeks 2, 3, 5, 6, 7).
- Step 3 is the follow-up phase. This includes participation in 2 assessment follow-up visits as 1-month and 3-month post-intervention (Weeks 12 and 20, respectively). During these visits, you will fill out questionnaire measures and complete an auction task and a heartbeat detection task.

If you are taking medication prior to starting the study and have been on a stable dose of your medication for at least 8 weeks, you may continue to take your medication at that dosage. If your dosage changes throughout the study, please inform study personnel.

Over the course of the study, the study doctor may wish to contact your mental health doctor/counselor and/or primary care doctor in order to confirm information about any medications you may be taking, or for other safety reasons, particularly related to your ability to exercise.

Do you agree to let the study doctor contact your mental health doctor/counselor in order to confirm information about your current medications or other safety reasons?

☐ YES ☐ NO ☐ N/A(No mental health provider) Initials _____

If you checked "YES" in the box above, we will ask you to provide us the name and contact information of your mental health doctor/counselor, which we will document in your research record.

Do you agree to let the study doctor contact your primary care doctor in order to confirm information about your current medications, your ability to safely exercise or other safety reasons?

☐ YES ☐ NO ☐ N/A (No primary care provider) Initials _____

If you checked "YES" in the box above, we will ask you to provide us the name and contact information of your primary care doctor, which we will document in your research record.

Step 1: Screening Evaluation Phase

This visit will take about 3 hours. The following things will happen during your Screening Visit:

- A study doctor (a psychiatrist or psychologist) will explain the study to you. You will be able to ask any questions you may have regarding the study.
- The study doctor will ask about your past and present psychiatric symptoms, any past or present medical illnesses, your current exercise level, and any medications you have been taking (including over the counter medications).
- You will have an electrocardiogram (ECG). This test checks the electrical activity of your heart. We will place several small, sticky pads on your chest, arms, and legs. Each pad has a wire attached. The wires connect to a machine that makes a recording of your heart rhythm. This painless test takes about 15 minutes. We will also take your vitals.
- We will ask you to provide a urine sample for a urine drug test. We will test for the use of illegal drugs, such as marijuana and cocaine. If your urine shows you have taken any of these drugs, we will ask you to discuss your use with us to make sure that it is safe and appropriate for you to take part in this study. The results of the urine drug test will not become part of your hospital medical record. These test results will, however, remain part of your study record.
- If you are a woman and can become pregnant, you will have a urine pregnancy test. You cannot take part in this study if you are pregnant. If you are planning to become pregnant , you should not take part in this study.

DC 05/10/2021

- If at the end of this screen visit the study is appropriate for you, we will give you a form to take to your primary care doctor to confirm you are safe to exercise. If you do not have a primary care doctor, a study physician or nurse practitioner will evaluate you to ensure that exercise is appropriate for you.
- You may not have to repeat a subset of overlapping screening measures if you recently participated in the screening evaluation phase of the "Role of exercise in the consolidation of fear extinction learning in adults with high anxiety sensitivity" (s21-01657), Randomized placebo-controlled trial to determine the biological signature of cannabidiol as a treatment for social anxiety disorder" (s22-00568), or "Elucidating neural mechanisms and sex differences in response to mindfulness based stress reduction in generalized anxiety disorder" (s21-00454) studies within the past 6 months. Dr. Szuhany (principal investigator on the current study) is the principal investigator on s21-01657 and a co-investigator on s22-00568 and s21-00454.

Any person will have the opportunity to be screened either in person or virtually. If the screen is conducted virtually – the procedures will be broken down into 2 visits. Virtual procedures may include e- consenting and discussing your past and present psychiatric symptoms, any past or present medical illnesses, your current exercise level, and any medications you have been taking (including over the counter medications). The in-person portion of the visit will include the ECG, urine test, vitals and medical clearance if needed.

If you are not eligible for this study, we will tell you why. We may tell you about another study that you may qualify to take part in or we will offer to provide you with a treatment referral.

Step 2: Intervention and Assessment

- You will be randomized (like a flip of a coin) to participate in one of two study interventions: 1) low intensity exercise or 2) titration to high intensity exercise. The study intervention will be delivered over 8 weeks.
- You will complete 3 visits (Week 1, Week 4, Week 8) in person at One Park Avenue with a study clinician. During these visits, you will be given instructions on how to complete the exercise intervention. These visits will also include completion of questionnaire measures of mood and exercise as well as the auction task and heartbeat detection task. These visits will last approximately 1 ½ -2 hours each.
- You will complete 5 brief telephone check-ins (Weeks 2, 3, 5, 6, 7). These will include asking questions about your exercise and assigning a new goal for exercise (and possibly new exercise intensity level for those in the titration condition) for the week. These phone calls will last about 15-30 minutes.
- You will be asked to wear a Fitbit (activity tracker worn like a wristwatch) and upload your data to Fitabase using an app for the 8 weeks of the intervention.
- During the study, you will be asked to fill out a brief set of questions about your mood immediately before and immediately after you exercise at home on your phone or computer or on paper if you prefer.
- After the intervention phase is over (completion of Week 8 visit), the clinician will also discuss referrals with you, if needed.
- Some participants (about 15 per group) will be chosen for a qualitative interview about their experiences in the study, which will occur at Week 8 and the 3-month follow-up.

Step 3: Follow-up assessments

- You will continue to wear a Fitbit and upload your data to Fitabase using an app.
- You will continue to fill our a brief set of questions about your mood immediately before and immediately after you exercise at home on your phone or computer or on paper if you prefer.
- During the follow-up visits in person at One Park Avenue, you will complete questionnaires of mood and exercise and the auction and heartbeat detection tasks. These visits will last approximately 1 ½-2 hours each.
- The clinician will also discuss referrals with you, if needed.

Procedures

Exercise Interventions

Titration to High Intensity Exercise: If you are randomized to this condition, you will first start exercising at a low intensity level (usually walking at a slow pace). After about 1-2 weeks, if this feels comfortable to you and has been helpful, you will work with the study clinician to go up to a moderate intensity (usually brisk walking). After another 1-2 weeks, the study clinician will check in to see if this was comfortable and helpful. If so, you will participate in high intensity exercise. High intensity exercise usually involves quick bursts of high energy/intensity exercise completed for a total of 10 to 30 minutes. For each week, you and the study clinician will work together to set exercise goals aiming for a total of 75 minutes of exercise per week. You will be provided with instructions and examples for each intensity level of exercise. You will meet in person at Week 1, Week 4, and Week 8 of the study. In between, you will have brief phone sessions (Weeks 2, 3, 5, 6, 7).

Low Intensity Exercise: If you are randomized to this condition, you will exercise at a low intensity level (usually walking at a slow pace) for the duration of the 8 weeks of the intervention. For each week, you and the study clinician will work together to set exercise goals aiming for a total of 75 minutes of exercise per week. You will be provided with instructions and examples of low intensity exercise. You will meet in person at Week 1, Week 4, and Week 8 of the study. In between, you will hae brief phone sessions (Weeks 2, 3, 5, 6, 7).

Fitbit and Fitabase

A Fitbit is an activity monitoring device that is connected to Fitabase. The PI, Dr. Szuhany, will set up a study project within the Fitabase system for generating unique identifiers, which will connect your device to the Fitabase system. With your consent for this study, the Fitabase system that the PI can access will access data collected as part of the study (e.g., steps, activity intensity, sleep). All your information will be de-identified. Fitabase stores information in the cloud, with access granted to approved study staff. Once your participation in the study is over, the PI will download all your data and the authorization to your data will be removed.

Ecological Momentary Assessments (EMA)

When you are completing exercise at home, you will be asked to fill out brief measures of your mood, motivation, energy, anxiety, and enjoyment both immediately before and immediately after you exercise. These measures can be completed on your phone or computer or on paper if you prefer. These measures will help the study clinician know how exercise is affecting your mood.

Questionnaires (approximately 30-40 minutes)

You will be asked to fill out self-report questionnaires that ask about your exercise and about psychiatric symptoms you may be experiencing, like anxiety, sadness, and stress. You will also fill out questionnaires asking about your quality of life and how much anxiety has bothered you. Clinicians will also ask you questions about psychiatric symptoms you may be experiencing as well as whether you have had thoughts or plans of harming yourself or ending your life.

Auction Task (completed at NYU for approximately 15 minutes)

You will be given an extra $10 and will be asked to make bids on how much you would be willing to pay to avoid exercising for certain time frames (e.g., 1min, 10min) at certain intensity levels (low, moderate, high). If you win the auction, you will pay your bid, but will not have to exercise. If you lose the auction, you can keep the $10, but will have to complete the exercise.

Heartbeat Detection Task (completed at NYU for approximately 10 minutes)

You will be asked to count you heartbeats while being monitored on an EKG, which will assess your actual amount of heartbeats.

Audio/Video Recording
For study integrity, we will audio-record some sessions with the study clinician and assessors, which will bereviewed by the principal investigator or another approved study team member. For videoconference calls, we will train participants to use the system securely, for example to be aware of their surroundings, others who might be able to overhear, and to use only in locations where there is a reasonable expectation of privacy.

While we will make every effort to ensure confidentiality by the use of study codes and secure servers for audio storage, and transfer, it is possible someone could without permission gain access to study related audio recordings during the time they are being used or stored for study integrity review.

Participation in other studies

In order to minimize risk and to assure your health and safety, it is important for us to assess whether you are participating in other research studies. We will ask you to inform us of the research studies in which you have participated *in the past year that involve medication, investigational drugs, or psychotherapy*. We will include the dates of participation, principal investigator name, and brief information about the study in your research record. By signing the consent form, you are also agreeing that we may contact the study staff of research studies you are currently participating in so that we can coordinate the studies if necessary and assure your safety.

OPTIONAL: Contacting You in the Future:

We may wish to contact you in the future about related research studies, to obtain additional information, or if necessary, obtain additional questionnaire measures. Is it okay to contact you in the future? If you agree to be contacted, you may refuse to provide additional information at any time.

Do you agree to be contacted in the future?

_____YES, it's OK to contact me in the future
(initials)

_____NO, don't contact me in the future
(initials)

Any identifiable private information and/or specimen collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

Risk of Study

Exercise Intervention
There are small, but potential risks associated with the exercise interventions. Possible risks associated with increasing physical activity in general include, but are not limited to, injuries to the muscles, ligaments, tendons, and joints of the body. Other risks associated with exercise include, but are not

limited to, abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or death. Risks may be more likely at high intensity (due to potential impact on joints), though many exercise options will be provided. However, the level of exercise recommended by this study is in line with recommendations by the American College of Sports Medicine. Additionally, you will need approval from a doctor (either your own primary care doctor or the study doctor/nurse practitioner) stating you are at low to moderate risk for physical activity before engaging in this study. If you notice any significant symptoms, please contact your doctor immediately.

Questionnaires/Tasks
Some participants may find certain questions distressing. Participants may withdraw or refuse to complete assessments. At study end, referrals will be provided.

Risks Associated with Use of the Fitbit
Possible risks include discomfort wearing the Fitbit.

Electrocardiogram (ECG)
The ECG test is a recording of the electrical activity of your heart and an ECG harmless. The sticky pads (electrodes) that are placed on your chest can sometimes cause discomfort such as redness or itching. We may need to shave your chest before we attach these pads. Irritation from shaving also may occur.

Risks of Breach of Confidentiality of Study Information
Although every effort is being made to assure your confidentiality including the use of study codes instead of names and secure servers for study information, it is possible someone could, without permission, gain access to study-related information. If your study information were to become generally known, this knowledge of your study information could potentially impact you. It may cause feelings of discomfort or embarrassment. As ecological momentary assessment data will be collected via a HIPAA compliant application (REDCap) over your phone or computer, there is a chance of a risk of breach of confidentiality; however, all precautions will be taken to reduce this risk. Similarly, Fitabase, where physical activity data is stored, is a comprehensive data management platform that implements robust industry standards to maintain secure databases and keep data private.

If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm. Please see Sections “How will you protect my confidentiality” and “HIPAA Authorization” for more detail about how your information will be protected.

6. Can I be in the study if I am pregnant or breastfeeding?

Participation in this study requires that you can be randomized to participate in either low intensity exercise of the titration to high intensity exercise. Because exercise recommendations may change with pregnancy and consultation with a primary care provider is recommended, pregnant women will not be able to participate in this study. Breastfeeding does not exclude you from participating.

If you are currently pregnant, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you are able to become pregnant, you will be required to use a medically accepted method of birth control while you participate in the study:

DC 05/10/2021

- Hormonal methods like birth control pills, patches, vaginal rings or implants,
- Barrier methods such as condoms or a diaphragm used with spermicide (a foam, cream or gel that kills sperm),
- Intrauterine device (IUD),
- Abstinence (no sex).

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons. The principal investigator may ask you to provide information about the outcome of your pregnancy and the health of your baby.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

You may or may not benefit from taking part in this research study. There is no guarantee that your symptoms may improve. You may benefit from screening procedures that include a careful examination of your mental health. If the study is a good fit for you, you may also benefit from the exercise intervention and the ongoing close mental health evaluation during the course of the study. It is possible that your anxiety symptoms will improve during this study. It is also possible that your physical health will improve during this study. However, we cannot guarantee any benefits from participation. Other individuals with may benefit in the future from what we learn in this study about exercise as an intervention for anxiety.

9. What other choices do I have if I do not participate?

You do not have to take part in this research study to be treated for anxiety. Standard of care treatments for anxiety at NYU can involve:

- Psychotherapy, such as cognitive behavioral therapy
- Medications, including antidepressant medications and anti-anxiety medications

Exercise interventions are also available outside of this study. You may discuss alternatives with your personal physician.

10. Will I be paid for being in this study?

You will be paid $25 for the Week 1 and Week 4 in-person study visits and $30 for the Week 8, 1-month follow-up, and 3-month follow-up visits for a total of up to $140. You will also be provided with $10 for the auction task on Week 1, Week 4, Week 8, 1-month follow-up, and 3-month follow-up. Depending on the results of the task, you could keep anywhere from $0-10 on each of these

occasions. Participants will also be provided with a Fitbit, which they can keep following participation in the study. If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for each completed in-person visit.

In addition, we are able to reimburse you up to $5.80 in transportation reimbursement per visit. In order to be reimbursed for these travel costs, you must provide a receipt for transportation tickets (train/bus).

As is required by the laws that apply to NYU Langone, in order for you to receive a payment, you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise the study PI, Kristin Szuhany.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

11. Will I have to pay for anything?

There are no costs associated with your participation in the research study as study funds will cover the costs of the intervention, study evaluations, and study visits.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

12. What happens if I am injured from being in the study?

For medical emergencies, contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator’s name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for

the injury, but you may also be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans for the NYU School of Medicine or NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

Early Withdrawal:
If during the study treatment phase you or your study doctor thinks you should not continue to take part, the study doctor will stop your treatment and evaluations and make an appropriate treatment referral taking into consideration your needs and preferences.

If you are hospitalized or become physically ill during the study, we will ask for your permission to access your medical records and/or consult with your PCP (primary care physician). We would do this in order to obtain your diagnosis, results of your lab tests, and the treatment you receive. If we have concerns about your physical and emotional health, we will share these concerns with your PCP.

14. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

DC 05/10/2021

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may

be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, diaries and other assessments.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institutes of Health
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Data & Safety Monitoring Board

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be

reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date/Time

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date/Time

DC 05/10/2021