Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

☒ Rhode Island Hospital	☐ The Miriam Hospital
☐ Bradley Hospital	☐ Newport Hospital
	☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

0012-18
Committee #

Name of Study Volunteer

Effects of Dehydroepiandrosterone in Pulmonary Hypertension (DIPH)

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

You are being asked to participate in this study because you have been diagnosed with pulmonary arterial hypertension (PAH) and you are receiving drug therapy for PAH. The purpose of this study is to determine if a naturally occurring hormone called dehydroepiandrosterone (DHEA) can reduce the negative effects PAH has on the right side of the heart. Previous studies of DHEA levels in the blood have shown that DHEA levels are significantly lower in people with PAH versus people who do not have PAH and that these lower levels are linked to right heart failure. A small study of DHEA treatment in COPD patients with pulmonary hypertension showed some benefit. Treatment with DHEA may therefore be beneficial for right heart function in PAH patients.

Your body naturally produces DHEA in the adrenal gland. In turn, DHEA helps produce other hormones, including testosterone and estrogen. Many PAH researchers believe there is a link between sex hormones and PAH. Natural DHEA levels peak in early adulthood and then slowly fall as you age. A synthetic version of DHEA is available as a supplement for oral use, as a tablet. It is available for sale at many local retailers and on-line, but the purity of those supplements may not always be tested or guaranteed by the manufacturer. The DHEA that will be used in this study will be supplied by a manufacturer that employs good manufacturing practices (GMP) and will be independently tested for purity to assure the tablets contain the correct amount of DHEA.

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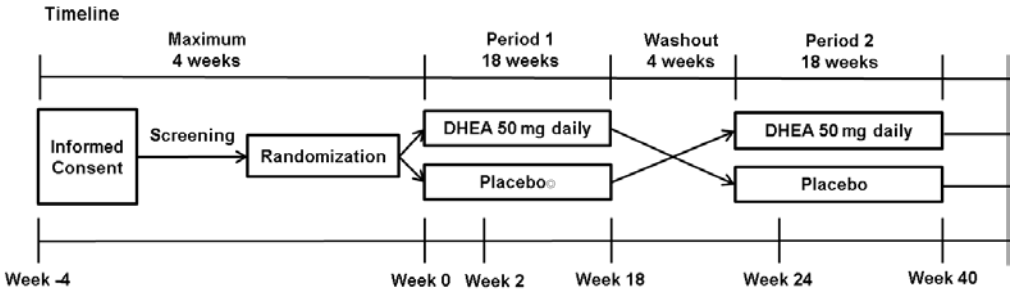
We expect to enroll 26 subjects, 13 women and 13 men, into this study at Rhode Island Hospital. The study is sponsored by the National Institutes of Health (NIH).

2. Explanation of Procedures:

If you agree to take part in this study, you will first read and sign this consent form before any study procedures begin. This study has been designed to be a randomized cross-over trial. This means there will be 2 treatment periods in the study. "Randomized" means that you will be randomly assigned (like flipping a coin) to receive either DHEA 50 mg daily or placebo (an inactive substance) in the first treatment period of the study. "Cross-over" means that you will receive in the second treatment period whatever treatment you didn't receive in the first treatment period. For example, if you were randomized to receive placebo in the first treatment period when you cross-over to the second treatment period you will receive active DHEA. This means that every patient enrolled in this study will receive both active DHEA and placebo during this study. While research subjects can end their participation in a study at any time, because of the design of this trial, it is very important that you are sure you can commit to participate in the entire study.

This study is also designed to be "blinded." Blinded means that neither you, the study doctor nor any of the research staff know what group you have been assigned. Only the pharmacists preparing the drug supply will know what each patient is receiving during the 2 treatment periods. In the case of an emergency, the study doctor can find out what group you have been assigned. You will be given 2 study drug supplies during the study. The first will be labeled as study drug "A." The second will be labeled study drug "B." All patients will start on Study Drug A and then crossover to Study Drug B.

The specific procedures for this study will be explained in more detail later on in this form. Study staff will schedule the visits with you and call you to remind you of study visits the day before. As an overview, this study will include the following phases over a maximum of 46 weeks:



- **Informed Consent and Screening (week -4)** Through the course of normal clinical care or review of your medical record, the study investigator has identified you as potentially eligible for this study. Should you agree to participate, a screening visit will be scheduled in order to make a final determination of eligibility. This visit may be able to take place after a routine clinical visit or may be scheduled for a separate time. The visit will likely occur at the Pulmonary Hypertension Center in East Providence where you normally see your PAH doctor. However, based on your convenience, it could potentially also occur at Rhode Island Hospital. Blood samples and information regarding your medical history and medication use will be collected. Your active participation time for this visit will last about 30 minutes.

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- **Baseline (week 0):** During this phase, a final review of your medical records will be performed to ensure you are still eligible to take part in this study. After successful completion of the screening visit, you will be scheduled to come in for a study visit within 4 weeks of signing this consent where you will have blood samples taken, a physical exam, a review of your current medications, answer 2 questionnaires, have a 6-minute walk test (6MWT) and a cardiac magnetic resonance imaging (MRI) performed. You will then be randomized to either receive DHEA or placebo in the first treatment period. You will be given an 18-week supply of Study Drug 1 (DHEA or placebo). Instructions on how to take the study drug is explained later in this consent form. This visit will occur at the main campus of Rhode Island Hospital at 593 Eddy Street in Providence. Your active participation time for this visit will last about 3-4 hours.

- **Treatment period 1 (weeks 1-18):** This phase will last 18 weeks and will consist of 2 visits: one at 2 weeks and one at 18 weeks after you were randomized and received your Study Drug A supply. At both of these visits you will have blood samples taken, a physical exam, review of your current medications and adverse events (if any), answer 2 questionnaires, and have a 6-minute walk test (6MWT) performed. Your adherence to taking the study drug as instructed will also be assessed.

    - **At the 18-week visit only**: You will have another cardiac MRI. **At the 18-week visit you must return any leftover Study Drug 1 and empty bottles you may have.** You will be given your Study Drug 2 supply (DHEA or placebo) at this visit with instructions on when to start taking it.

  Both the 2-week visit and 18-week visit will occur at the main campus of Rhode Island Hospital at 593 Eddy Street in Providence. Your active participation time at the 2-week visit will last about 2 hours. Your active participation time at the 18-week visit will last about 3-4 hours.

- **Washout (weeks 19-22): During this phase you will stop taking all study drug for 4 weeks.** If you did not return any leftover Study Drug 1, do not take it during this phase of the study. You should also not take any of the Study Drug 2 you were given at the 18-week visit until the date the study staff told you to take it. The study staff will call you and remind you on what date you should start taking Study Drug 2. There is no in-person study visit during this phase of the study.

- **Treatment Period 2 (weeks 23-39):** This phase will last 18 weeks. Two weeks after you start taking Study Drug 2 you will be scheduled to come in for a study visit where you will have blood samples taken, a physical exam, review of your current medications and adverse events (if any), answer 2 questionnaires, and have a 6-minute walk test (6MWT) performed. Your adherence to taking the study drug as instructed will also be assessed. This visit will occur at the main campus of Rhode Island Hospital at 593 Eddy Street in Providence. Your active participation time for this visit will last about 2 hours.

- **End of Treatment (EOT) (week 40):** After 18 weeks of treatment on Study Drug 2, you will be scheduled for your final in-person study visit where you will have blood samples taken, a physical exam, review your current medications, answer 2 questionnaires, have a 6-minute walk test (6MWT) and another cardiac magnetic resonance imaging (MRI)

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performed. We will review your current medications and adverse events (if any). Your adherence to taking the study drug as instructed will also be assessed. **You must bring any leftover Study Drug 2 and/or empty bottles you may have.** We will collect them from you at this visit. This visit will occur at the main campus of Rhode Island Hospital at 593 Eddy Street in Providence. Your active participation time for this visit will last about 3-4 hours.

- **End of Study (EOS) (week 42):** This is a phone call visit that will occur 2 weeks after you ended Study Drug 2 treatment. A study staff member will call you to see how you are doing and if you have had any new adverse events since stopping the study drug treatment. This visit will mark the end your participation in the study. Your active participation time for this visit will last about 10 minutes.

- **Unscheduled Visit (US) (as needed/if necessary):** If you have abnormal lab values at a study visit that a study physician is concerned about, you may be asked to come in for an unscheduled visit in order to retest the labs in question.

At the baseline visit, you will be given a study reference card with all the contact information of study staff members and all the dates of your visits. Brief instructions on how to take the study drug will also be on this card. Keep this card in a convenient place as a quick reference. You can always refer back to this consent form for information as well or you can call a study staff member if you have any questions.

How to take the study drug: The study drug will come in tablet form. The placebo will be made to look similar to the active DHEA so that you will not know which treatment you are on.

Treatment Period 1: You will take 1 capsule once per day of Study Drug 1.

Washout: You will *not* take any study drug.

Treatment Period 2: You will take 1 capsule once per day of Study Drug 2.

During the entire study period you **must not** take any commercially available DHEA supplements or other products containing DHEA. There are many DHEA supplements (that are clearly labeled) and vitamin supplements that contain DHEA (that are not always clearly labeled as containing DHEA) available to buy over the counter at stores and on-line. Before starting any new supplements or vitamins please contact the study doctor or staff to check if the supplement contains DHEA. There are a number of medications that may interact with DHEA. The study team will review your current medications to ensure you are not taking any of them. If you start a new medication make sure you inform the study doctor or staff to ensure there is no possible interaction with DHEA. For each of the two treatment periods you will be given a study drug dosing diary in which you will record each day whether you took your dose of study medication or not. You will return the diaries at your week 18 visit and week 40 visit.

Study Procedures:

- **Blood Samples:** At each visit described above (including the screening visit) you will have blood samples drawn by venipuncture (needle in a vein). This is a total of 6 blood draws.

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Your blood will be tested for hormone levels, complete blood count, standard chemistries like sodium, potassium, chloride, etc., insulin, cholesterol and other biomarkers (chemical substances in the blood). Each blood sample will be 50mL, a little over 3 tablespoons. A total of 300mL or about 1.25 cups of blood will be drawn over the screening and 40-week treatment period of the study. If an unscheduled visit is necessary, additional blood will be collected. The specific amount will vary based on which laboratory tests are required but will not exceed 20 ml or about 1.5 tablespoons. Some of the collected blood in the scheduled visits will be stored for future, unknown testing. Storing samples like this is called "specimen banking". Please refer below to the section "Specimen Banking" for a full explanation of what this means. **Pregnancy testing:** If you are female and of child-bearing age we will draw your blood for a pregnancy test at the screening visit and again at the week 18 visit. You cannot take part in this study if you are pregnant. If you learn you are pregnant at any time during the study, you must notify the study team immediately.

- **6-Minute Walk Test (6WMT):** At each of the 5 treatment period study visits between week 0 and week 40, you will have a 6MWT. A 6MWT is a test where the distance you are able to walk in 6 minutes and how short of breath you get in doing so is measured. You will have your blood pressure, heart rate and oxygen level taken before and after the 6MWT. Your heart rate and oxygen level will be monitored during the test.

- **Questionnaires:** You will complete 2 questionnaires at each of the 5 treatment period study visits. You will complete these questionnaires using an electronic tablet. The study staff will show you how to use the tablet.

- **Cardiac Magnetic Resonance Imaging (MRI):** You will have a cardiac MRI at the baseline visit, at the week-18 visit and the end of treatment (EOT) visit. A cardiac MRI is a test that uses a combination of a large magnet, radio waves, and a computer to produce detailed images of the heart. These images will be analyzed using software purchased just for use in this study. Imaging takes place inside of a large tube-like structure, open on both ends. You must lie perfectly still for quality images. Due to the loud noise of the MRI machine, earplugs will be provided. A member of the study staff will complete an MRI screening form with you before each MRI to make sure you have no contraindications to having an MRI. Study visits that require a cardiac MRI must be done at Rhode Island Hospital because that is where the MRI machines and software are located.

Specimen Banking:

As part of the blood draw to measure various chemical substances in the blood (as explained above) we will also store some blood (in the form of plasma and serum) for future, unknown testing. Storing samples like this is called "specimen banking." Having your blood stored for future testing is a required part of the study. If you do not want your blood samples banked for future testing then you cannot participate in this study. Along with the specimens, portions of your personal health information collected as part of the Main Study will also be stored. Your Specimen and personal health information may be stored and analyzed at Lifespan; or, they may be shared with researchers at other institutions or companies that may store them and use them for their own research. It is very unlikely that any future research performed using your Specimen would benefit you directly. However, the research may provide important medical knowledge that in the future could help other patients with your medical condition or other medical problems.

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At this time, we do not know what future research studies may be done using your Specimen. Such research studies may include genetic tests that would analyze your DNA, RNA or other gene products, like proteins and metabolites. These genetic tests may be done by Lifespan, or they may be done by other researchers with whom your Specimen and data have been shared. Because any genetic testing of your Specimen would be for research purposes, the results would have no clear implications for your health or medical condition, or that of your family members. Any testing results would not be made available to you or to any insurance company, your employer, your family, or any physician who treats you in the future.

There is a very remote possibility that your Specimen and some associated data may become part of a process or product that ultimately has commercial value. For instance, the Specimen could be used to establish a cell line (a group of cells that are able to reproduce, sometimes indefinitely) that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

Your Specimen will be stored for an indefinite period of time, until it is no longer usable. The Specimen may also be used to create a cell line, which would also be stored for an indefinite period of time. If you decide at some time in the future that you no longer wish your stored Specimen to be used in future studies, you have the right to request that the Specimen be withdrawn from the specimen bank. However, withdrawal cannot be guaranteed and may be impossible. For example, it is possible that the Specimen might no longer be identifiable as belonging to you, or it may have been used up, or it may already have been shared with other institutions or companies for their own research. To request withdrawal of your Specimen, please write to: ***Dr. Corey Ventetuolo, Rhode Island Hospital, 593 Eddy St., Providence, RI 02903.***

Compensation: At the screening, week 2, and week 24 visits you will be paid $75 and at the 3 visits that include having an MRI you will be paid $100 for a total of $525 if you complete the entire study. You will be paid in the form of a Visa® (or similar) gift card. If you prefer, you can alternatively be paid by a cash voucher which can be brought to the Rhode Island Hospital cashier's office to receive your payment in cash. You must present the cashier with a valid form of ID, like a driver's license, in order to receive cash. A member of the study staff can assist you with this process.

Costs for participating in this study

Some of the services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include the study drug, study clinic visits, study blood tests, 6MWT, and cardiac MRI. Those services will be paid for by the study and will not be billed to you or your health insurance company.

Other services you will receive during this research study are considered "routine clinical services" that you would have received even if you were not in the research study. Examples are your other PH medications and all other tests, treatments, bloodwork, doctor office visits and any other medical care you require to treat your medical condition(s). These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Contact Information: If you have any questions or concerns about this study you may contact:

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Corey Ventetuolo, MD	**Principal Investigator**	**(401)-444-3565**
Amy Palmisciano, RN	**Study Coordinator**	**(401)-444-2733**

If you are having a study related problem after normal business hours or on a weekend/holiday you may **call 401-419-2868.** The person on call will contact the study staff and a study staff member will call you back.

3. Discomforts and Risks

There may be risks to taking part in this study. Below are the known risks of DHEA and the study procedures. There may be other risks that are unknown at this time.

- **DHEA**: DHEA has been given to over 1200 patients in clinical trials without severe adverse effects. Known side effects of DHEA include: hirsutism (excessive body hair growth), alopecia (hair loss) and acne (skin pimples). In previous studies (of patients without PAH) these side effects were mild, short-lived and well tolerated. Stomatitis (swelling of the lips and mouth) was reported in patients in a study where DHEA or placebo was given. This was a study of patients that did not have PAH and all patients were on immune suppressing medications. The patients receiving DHEA in that study had a lower rate of stomatitis than the group receiving placebo. In a small study of COPD patients with pulmonary hypertension, no adverse events occurred with DHEA treatment.

  Other side effects may include slight changes in blood cholesterol, insulin and triglyceride levels. Those blood tests will be monitored during study participation. Additional side effects that may occur are skin rash, breast tenderness or enlargement (in both men and women), oily skin, irregular or abnormal menstruation (periods) (women only), and lower blood pressure. There is also a possible risk of benign prostatic hyperplasia (BPH - an enlargement of the prostate) as DHEA has been shown to increase a hormone that may prompt BPH.

  Because DHEA has not been tested in patients with PAH there may be side effects that are not known at this time.

- **6MWT:** During a 6MWT you may become short of breath or may have leg cramps or fatigue. You can rest during the test at any time and you may also end the test at any time if your breathing becomes too uncomfortable. Your oxygen level and heart rate will be monitored during the 6MWT and the test will be stopped if your oxygen level goes too low or your heart rate goes too high.
- **Venipuncture:** The risks of having blood drawn can include bruising and bleeding at the needle stick site. In extremely rare instances infection can also occur. You may become dizzy, light headed or faint. Please let the study staff know if you have had any of these symptoms in the past when having blood drawn.
- **Cardiac MRI:** An MRI does not expose you to any radiation and this study will not require the injection of any kind of contrast (dye) in the veins. Because of the structure of the MRI machine you may get a feeling of claustrophobia (fear of small spaces) which may cause anxiety while inside the MRI machine. Please inform the research staff if you have ever experienced claustrophobia while having an MRI. Depending on the severity of your previous claustrophobia, a mild anti-anxiety medication may be prescribed to you to take before the

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MRI. The study will cover the cost of this medication. A screening form will be completed before each MRI to ensure you have no metal or implanted devices in your body. If you are on medications that require a pump for your PAH (Veletri, epoprostenol, Remodulin, treprostinil), the Pulmonary Hypertension Center will make arrangements and assist with the MRI process so that you may still participate. If you have any contraindications to having an MRI you will not be able to take part in this study.

If we discover any potential new conditions or abnormal lab results through the study testing that may require medical attention we will inform you and your doctor(s).

4. Benefits

This study is not aimed at treating your PAH. You may or may not benefit from being in this study. Your PAH may get better, it may get worse or it may stay the same. However, in general, the information learned in this study will add to the body of knowledge of what doctors and researchers know about pulmonary hypertension and right heart failure. This knowledge may help patients with pulmonary hypertension in the future and may lead to the study of new treatments including DHEA.

5. Alternative Therapies

This is not a treatment study. You do not have to take part in this study in order to get treatment for your PAH. Your doctor can discuss with you all the other available medications used to treat PAH. You will not be taken off any of your current PAH medications while in this study and your PAH medications can be adjusted if needed.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 40 weeks. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____

Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study please tell the head researcher, Dr. Corey Ventetuolo, 401-444-3565.

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7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor: National Institutes of Health
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;

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- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

You will not be allowed to see or copy the information described in this form as long as the research study is open. You may see and copy the information when the study is completed.

Additionally, 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.

GINA STATEMENT

This study involves 'genetic testing' as defined by the Genetic Information Nondiscrimination Act of 2008 (GINA). GINA generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. There are some limitations to GINA's protections (it does not apply to all insurers or employers, nor does it apply to all genetic information, such as information related to a genetic disease that you already have). In addition to GINA's protections regarding the ultimate use to which your genetic information is put, Lifespan's privacy policies generally protect the privacy of such information and restrict its release outside of Lifespan, unless you specifically authorize its disclosure or unless disclosure without your authorization is permitted under applicable privacy laws.

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For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on 1/8/2020.
DO NOT sign this document after this expiration date.

The Researcher is required to provide a copy of this consent to you.

_____ _____ _____
Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

_____ _____
Signature of witness (required if consent is presented orally or at the request of the IRB) Date

_____ _____
Signature of Translator Date

_____ _____ _____
Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

_____

_____