Evaluation of Safety, Tolerability and Immunological Responses to Lactobacillus Johnsonii N6.2 Supplementation in Adults With Diabetes Type 1

Informed Consent Form

NCT03961347

October 24, 2022

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

Evaluation of safety, tolerability and immunological responses to *Lactobacillus johnsonii* N6.2 supplementation in adults with Diabetes type 1.

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Michael Haller, MD	352-273-9264
Sub-Investigator: Laura Jacobsen, MD	352-294-8863
Other research staff: Study Coordinator	352-273-5580

For emergencies or after hours call 352-265-0111 and ask the operator to page Dr. Haller or Dr. Jacobsen.

4. Who is paying for this Research Study?

The sponsor of this study is National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research

subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to determine the effects of the **probiotic**, *Lactobacillus johnsonii* N6.2 on gastrointestinal health and measures of wellness in people with type 1 diabetes. We are looking to find out if this probiotic will modulate immune function, improve beta cell function, and lower A1c in people with type 1 diabetes. Probiotics are bacteria that are either the same as or very similar to the bacteria that are already in your body. You are being asked to be in this research study because you have type 1 diabetes (T1D), are between the ages of 18 and 45 years, and meet the inclusion and exclusion criteria. The total amount of time you will spend participating in this study is 52 weeks.

b) What is involved with your participation, and what are the procedures to be followed in the research?

This study is divided into 3 periods: baseline, study intervention (when you will receive either the study probiotic or placebo), and a washout period. You will be asked to take one capsule (study probiotic or placebo) daily for 24 weeks. You will undergo blood tests, stool collections and analyses, and mixed meal tolerance tests (MMTTs).

c) What are the likely risks or discomforts to you?

The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure. There are no known discomforts or risks associated with taking the probiotic. The MMTT may be uncomfortable for some individuals. There is a slight risk that information about you could be revealed inappropriately or accidentally.

d) What are the likely benefits to you or to others from the research?

Some healthy adults consuming *Lactobacillus johnsonii* N6.2. have shown improvement in digestive health, changes in immune function and overall well-being. Some individuals taking probiotics may experience improved immune function, and increased insulin production. There is a possibility that consuming *Lactobacillus johnsonii N6.2* may improve your beta cell function and lower your A1c.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

The alternative option to taking part in this study is doing nothing. Your consent is voluntary. You will continue with your normal clinical care.

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.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

Participation in this study or lack of participation will in no way affect your clinical care.

7. What will be done only because you are in this Research Study?

If you agree to this study, you will be expected to come to the UF Clinical Research Center (CRC) 4 times for study visits, complete study questionnaires, and have your blood and stool collected. The CRC visits will take place at screening, week 12, week 24 and week 48 of the study. After the screening visit, the study is divided into **3 periods**: the **baseline period**, the **intervention period** (when you will receive either the study probiotic or placebo), and the **washout period**.

Study Visits:

If you agree to be the study, you will be scheduled to come in for 4 CRC visits.

- **Screening visit:** At the screen visit, blood samples will be collected by a CRC nurse and sent to be analyzed. The blood samples will be collected for safety labs and immunological assays. The safety labs will include complete blood count test (CBC), comprehensive metabolic panel (CMP), and Hemoglobin A1C (HbA1C). If you are a female of child-bearing potential, a pregnancy test will also be administered. As part of this visit you will have a 2-hour Mixed Meal Tolerance Test (MMTT). Your height, weight, BMI calculated and vitals (blood pressure, heart rate, and temperature) will be measured and a physician will conduct a history and physical. Your vitals will be measured at each study visit. Demographic information will also be obtained at screening. If you already wear a continuous glucose monitoring (CGM) device or use an insulin pump we would like to collect this information, if you are willing to share it.
- **Weeks 12, 24, 48 visits:** At these visits, you will be asked to provide blood and stool samples. Blood samples will be collected during weeks 12 and 24 of the intervention period and during week 48 of the washout period. There will be 4 blood draws throughout the study. Additionally, a 2-hour MMTT will be performed at weeks 24 and 48. Pregnancy tests will also be done at these visits. If willing to share your data, your glucose and insulin pump output data will also be collected at weeks 12, 24, and 48 if you are already wearing a

CGM device or using an insulin pump. A physician will conduct a physical exam at your week 48 visit.

Study Periods:

1. Baseline period

After the screening visit and if you meet the study's inclusion/exclusion criteria, you will be scheduled to begin a 28-day baseline-period. During this period, you will complete a weekly questionnaire (paper or electronic). We will ask you questions regarding your gastrointestinal health (e.g. bowel movement frequency), questions regarding other symptoms, (i.e. constipation, diarrhea, stomach pain), and general wellness (if you took an antibiotic, visited a doctor, insulin usage, etc.). The weekly questionnaire includes the Gastrointestinal Symptom Response Scale (gastrointestinal symptoms and discomfort). You will also be asked to complete a Quality of Life Questionnaire (social activities and general health). At the end of the baseline period, you will be randomized to get the study probiotic or the placebo. Completing these questionnaires should take approximately 30-45 minutes.

You will be randomly assigned (much like the flip of a coin) to receive either the study probiotic or placebo. A placebo is a substance that looks like and is given in the same way as an experimental treatment but contains no medicine, for example a sugar pill. A placebo is used in research studies to show what effect an intervention has compared with taking nothing at all. If you are assigned to receive placebo, you will not receive the benefits of the probiotic, if there are any, nor will you be exposed to its risks, which are described below under "What are the possible discomforts and risks?" Studies have shown, however, that about 1 in 3 persons who take a placebo do improve, if only for a short time. You and study staff and other persons doing the study will not know whether you are receiving placebo or the probiotic, but that information is available if it is needed. You will have a 50% chance of receiving the probiotic and a 50% chance of receiving placebo.

2. Intervention period

You will receive in the mail a bottle with your study probiotic or placebo, and you will begin the study intervention. Participants will consume 1 study treatment capsule every morning with food daily for 24 weeks. The study probiotic or placebo bottle should be stored in your refrigerator.

At randomization, you will be asked to collect a stool sample at home and mail it to a study member or call the study phone for a pick-up service. You will be provided with a stool collection kit and very specific instructions and a return shipping box with prepaid shipping slips will be provided.

You will also be asked to collect and mail two stool samples at weeks 12 and 24. You will be asked to continue to complete the Weekly Gastrointestinal Symptom Response Scale Questionnaire and Weekly Quality of Life Questionnaire throughout the treatment period. In addition to completing questionnaires and taking the study treatment, you will be asked to complete two telephone

interviews about your food intake. In the event that internet access is not available for a portion of the study, paper copies of the questionnaires may be provided. For females, pregnancy tests will be conducted at home (kits will be provided) at weeks 0, 4, 8, 12, 16 and 20). Your glucose and insulin information will be collected at weeks 12 and 24.

3. **Washout period**

   During the washout period, you will not consume the capsules (study probiotic or placebo), but you will be asked to continue completing the Weekly Gastrointestinal Symptom Response Scale Questionnaire and Weekly Quality of Life Questionnaire until the end of the study. You will be asked to collect the final stool sample. Your glucose and insulin information will be collected at week 48. The washout period will be 24 weeks long.

Visit Procedures:

- **History and Physical examination**

  We will ask you questions about your health and perform a routine physical examination. This is to be sure that you do not have any health problems that would prevent you from being in the study.

- **Mixed Meal Tolerance Test (MMTT)**

  The study requires that you have 3 MMTTs to find out how much insulin your pancreas is making. The MMTTs will be done at the screening visit, week 24 visit, and week 48 visit.

  Before each MMTT, you will get special instructions about diet and insulin dosing. To make the blood sampling easier for the test, an intravenous needle and plastic tube (IV) will be placed in your vein. This IV will be kept in place for about 2 hours. Two blood samples will be taken ten minutes apart (approximately one teaspoonful of blood for each sample) will be taken through the IV. You will then be given a drink called Boost that is the “mixed meal”. This drink will raise your blood sugar and cause your body to produce insulin. After drinking the Boost, approximately one-half teaspoonful of blood will be taken through the IV at regular intervals. The total amount of blood taken for the MMTT will not be greater than 2 tablespoonfuls.

- **Blood Test**

  Safety labs blood samples will be taken from your vein to gather some information about your diabetes, your immune system, and your overall health. The volume of blood drawn at each visit will be less than 25 mL (1-2 tablespoonfuls) and will not exceed 550 mL (about 2 cups of blood) in any 8 week period.

  The samples collected for the immunological assay tests are an important part of this study. These assays will help us better understand how the probiotic *Lactobacillus johnsonii* N6.2 can help individuals with type 1 diabetes, how individuals respond to interventions, and get ideas about new treatments in the future.

- **Stool Test**

  Stool samples will be analyzed for survival of the probiotic bacteria and to investigate any changes that may occur in the gut bacteria. Four stool samples will be collected throughout the study.

- **Urine Pregnancy Test**

  If you are female, and are capable of childbearing, you will have a urine pregnancy test performed. If you are pregnant or become pregnant during the study, you will not be able to participate in the study. Eight pregnancy tests will be done throughout the study.

- **Phone calls**

  You will complete 8 total 24-hour diet recalls by telephone interview during the baseline, study treatment, and washout periods.

- **Continuous Glucose Monitor (CGM) and Insulin Pump Downloads**

  If you are already wearing a continuous glucose monitoring (CGM) device and are willing to share the data from it, your glucose data will be collected. If you are already using an insulin pump and are willing to share the data from it, your pump information will be collected.

Visit Schedule:

		BASELINE PERIOD	TREATMENT PERIOD					WASHOUT PERIOD	
	Screening Visit (2-3 hrs)	*28 days*	*Randomization (Start of Treatment)*	*Virtual/ phone call*	*Follow-up Visit (1-2 hrs)*	*Virtual/ phone call (30 min)*	*Follow-up Visit (End of Treatment) (2-3 hrs)*	*Virtual/ phone call (30 min)*	*Follow-up Visit (2-3 hrs)*
Week			**0**	**1-11**	**12**	**13-23**	**24**	**25-47**	**48**
Visit number	**1**				**2**		**3**		**4**
Dispense treatment capsules			X						
Questionnaires	X	X[c]	X	X[d]	X	X[e]	X	X[e]	X
Physical exam	X								X
Height	X								
Weight	X				X		X		X
Vitals	X				X		X		X
CBC	X				X		X		X
CMP	X				X		X		X
MMTT[b]	X						X		X
HbA1c	X				X		X		X
Stool collection			X		X		X		X
Immune phenotyping	X				X		X		X
Autoantibodies	X								
PBMC	X				X		X		X
Pregnancy test	X		X	X [a]	X	X [a]	X		X
Metabolites	X				X		X		X

[a] Pregnancy test done at home with kits at weeks 4, 8, 16, and 20.
[b] MMTT will be a 2 hour fasting blood test with samples collected at -10, 0, 15, 30, 60, 90 and 120 minutes.
[c] Three diet recall phone interviews
[d] One diet recall phone interview
[e] Two diet recall phone interview

Once this research study is completed, any information that could identify you **might** be removed from any source containing identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in **Question 3** of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect the following information from you:

- Demographic information (full name, address, age, email, etc.)
- Results of physical exam
- Results from blood test
- Your social security number for compensation purposes
- Telephone number
- Email address
- Fecal (stool) microbial information
- Pregnancy status
- Study questionnaire responses
- Medical history

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in **Question 3** above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in **Question 4** of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

The total amount of time you will spend participating in this study is approximately 52 weeks.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

Approximately 68 people will be enrolled (sign consent) in this research study. However, due to failure to meet inclusion/exclusion criteria and potential drop outs, we are expecting 52 people to complete this research study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

Known Risks:

There are no known discomforts or risks associated with the consumption of *Lactobacillus johnsonii* N6.2 or the placebo. While some bacterial species belonging to the genus *Lactobacillus* are currently available and sold on the market (i.e. *Lactobacillus acidophilus*, *Lactobacillus plantarum*, *Lactobacillus bulgaricus*, etc), the particular strain (*Lactobacillus johnsonii* N6.2) being used in this study is not currently on the market in the United States. However, this particular strain (N6.2) of *Lactobacillus johnsonii* has previously been studied in healthy individuals with no adverse effects.

Potential Risks:

It is very important that you tell your regular doctor or any other doctors or health care providers who treat you while you are in this study that you are in a research study.

- Food allergy symptoms, such as tingling or itching in the mouth, hives, swelling of the lips, tongue, or other body parts, abdominal or diarrhea, or lightheadedness, may be experiences within a few minutes to two hours after consuming supplements if you are allergic to any of the ingredients.
- High blood sugar (hyperglycemia) or low blood sugar (hypoglycemia) can

occur for various reasons in diabetics, and it is usually related to diet and insulin dosing. You should tell the study doctor about these events.

Intravenous Needle (IV) and Blood Drawing: While on the study you may have side effects from having your blood taken or IV placed. The risks of side effects from these procedures are very small. The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure.

Mixed Meal Tolerance Test (MMTT): The MMTT requires that you drink a product called BOOST which contains milk and soy ingredients. People with severe allergies to these could have a reaction. If you have a known allergy to either of these ingredients, please let us know. It is possible we may need to advise you not to participate in the trial. This drink will also raise your blood sugar.

Stool Samples: Some people may feel uncomfortable providing a stool sample and some people may feel uncomfortable answering questions about their stool habits.

Genetic Testing: Your blood may be tested for genetic factors and the information obtained may reveal genetic information about you. We will not provide the results of your genetic testing to you or anyone else except other researchers involved in this trial. Although we will try very hard to keep any information about your genetic testing private, there is a very small possibility that someone else could learn about your testing.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information can be obtained at: http://irb.ufl.edu/gina.html or call 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer.

Other Potential Discomforts:

Some people may feel uncomfortable when body weight is measured.

Female Subjects of Childbearing Potential: If you are a female able to get pregnant, a pregnancy test will be done as part of the qualification for the study. While there are no known risks, females will be asked to inform the study coordinator or PI if they become pregnant or believe they may be pregnant at any time throughout the study and while no adverse effects are anticipated, they will be withdrawn from the study. The PI/study coordinator will follow-up with any woman who becomes pregnant, at any time during the study for pregnancy outcomes.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in **Question 3** of this form or the person

reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Researchers will take appropriate steps to protect any information they collect about you. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. Although proper procedures and steps will be taken to protect all collected information, there is a slight risk that information could be revealed inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in **Question 3** in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

Some healthy adults showed an improvement in digestive health, and immune function, and overall well-being as a result of consuming *Lactobacillus johnsonii* N6.2. Some individuals taking probiotics may experience improved immune function, increased insulin production and a reduction in the levels of A1c.

13b. How could others possibly benefit from this Research Study?

Others may benefit in the future from the information we find in this study.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in **Question 3** of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

The Co-Investigator for this research study, Dr. Graciela Lorca invented the probiotic that is being evaluated for this research. Therefore, the researchers and the University of Florida could benefit financially from the results of this research study. If you would like more information, please ask Dr. Haller or the study coordinator.

13d. Will you be allowed to see the research information collected about you for this Research Study?

You may not be allowed to see the research information collected about you for this Research Study, including the research information in your medical record, until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected and placed in your medical record.

14. What other choices do you have if you do not want to be in this study?

This is a safety trial. There is no other study treatment or procedure.

Your participation is voluntary. You can therefore choose not to take part in this study. If you decide not to participate in this study, you will continue to receive your standard treatment(s) and clinical care for your type 1 diabetes.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in **Question 3** of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in **Question 3** of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in **Question 3**.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- The study is stopped.
- You become pregnant.
- It is determined that you are not eligible for the study.
- There are unanticipated circumstances
- The Principal Investigator feels that you have not followed instructions given to you.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

Study Drugs

Probiotic, *Lactobacillus johnsonii* N6.2 or placebo will be provided at no cost to you while you are participating in this study.

Study Services

The Sponsor will pay for or provide all study services/activities required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Michael J. Haller, MD at 352-273-9264 or 352-359-1799 (24 hours).

Items/Services Not Paid for by the Sponsor

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

17. Will you be paid for taking part in this Research Study?

You will receive a stipend of $20 for every completed study visit. You will receive a stipend of $15 for every completed stool collection. You will also receive $5 per week for completing the weekly questionnaires (52 weeks total). At the end of all the study visits you will receive an additional $100 for completing the study. In total, you may receive up to $500. You can expect payment for each completed visit within 5-7 working days from the visit.

You will receive a travel reimbursement at the state rate of 44.5¢ per mile not to exceed $100 per round trip for every study visit. You can expect payment for reimbursement of travel within 5-7 working days from your study visit.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

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18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date