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Oct 12, 2017
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Response to inflammatory challenge in major depressive disorder

Protocol #2016-002-03

NCT03142919

Laureate Institute for Brain Research, Inc., Tulsa, OK, United States

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	Response to inflammatory challenge in major depressive disorder

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Response to inflammatory challenge in major depressive disorder
PROTOCOL NO.:	2016-002-02 WIRB® Protocol #20161841
SPONSOR:	Laureate Institute for Brain Research
INVESTIGATOR:	Jonathan Savitz, PhD 6655 S Yale Ave Tulsa, Oklahoma 74136 United States
STUDY-RELATED PHONE NUMBER(S):	Jonathan Savitz, PhD 918-502-5155 918-481-4000 (24 hours)

This consent form describes a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision about participating in the study.

This consent form may contain words that you do not understand. Please ask the Principal Investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Why Have You Been Asked To Participate In This Study?

You are being asked to take part in this study because:

- You are in good health

or

- You are in good health and have been diagnosed in the past with depression.

Why Is This Study Being Done?

This project seeks to understand how the immune system is altered in depression and how these changes in immunity may affect brain activity and symptoms of depression. To do this we will use an investigational bacterial toxin that can initiate chemical reactions that are similar to those seen in individuals with mild sickness symptoms, such

as a slight increase in body temperature, muscle aches, or tiredness. It is a safe way of investigating the body's response to inflammation and how these changes may alter cognitive, emotional, or neural function. It has been given hundreds of times to healthy volunteers without any serious side effects.

What Drugs and Devices Are Involved In This Study?

Lipopolysaccharide (LPS) is a component of the cell wall of bacteria such as *e. coli*. Our immune systems recognize this sugar molecule and begin an inflammatory response to fight what "it thinks" is an infection. You will not be receiving live bacteria but rather these sugar molecules that activate/stimulate the immune system into launching an inflammatory response. You have a 50% chance of receiving LPS and a 50% chance of receiving saline (purified water) which will not cause any immune response.

The Magnetic Resonance Imaging (MRI - use of a magnetic field to produce an image) scanner is used to look at brain function and anatomy. The LIBR is using the MRI scanner in a research (experimental) mode. U.S. Food and Drug Administration (FDA) approval has not been obtained for the particular ways that information about inter-personal interaction from the MRI may be used in this research; however, the MRI scanner will not be used for purposes outside its intended application. It is considered to be a non-significant risk investigational device.

A physiological recording system will also be used to monitor heart rate and breathing.

How Many Subjects Will Take Part In The Study?

About 100-120 subjects will take part in this study at the Laureate Institute for Brain Research (LIBR).

What Is Involved In The Study?

The study involves:

- Questionnaires
- Laboratory tests
- Electrocardiogram (EKG)
- Physical Exam
- LPS injection or placebo (saline)
- An IV
- Blood draws
- Saliva sampling
- Cognitive tests
- MRI scanning
- Physical Measurements
- Urine tests
- Meals and/or snacks
- Post Study Visits

Visit Schedule Summary:

Visit 1

Visit 1 will take 5-6 hours to complete. You will be consented to the study, have your blood drawn, receive a physical exam and an electrocardiogram (EKG), complete an hour-long MRI scan, and complete some questionnaires.

The blood draw at this visit will include testing for Hepatitis C and HIV. State/Provincial law requires positive test results for certain communicable diseases, including HIV, hepatitis, sexually transmitted infections, and tuberculosis, to be reported to a local health agency. Some of the tests for this study must be reported when positive. The study doctor can discuss this with you.

Visit 2

Timeline	LPS or Saline	EKG	Vital Signs	Urine Screen & Breathalyzer	Mood Ratings	MRI	Cognitive Testing	Blood Draw	Physical Symptoms Scale	Lunch or Snack	MD Discharge Assessment
8:30 AM											
9:00 AM											
9:30 AM											
10:00 AM											
10:30 AM											
11:00 AM											
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4:00 PM											
4:30 PM											
5:00 PM											

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ALL TIMES ARE APPROXIMATE

Post Study Visits

There is a post study visit 1 day (visit 3) and at 1 week (visit 4) after your study visit 2. Each visit will last approximately 30 minutes. You will be asked questions about physical symptoms, depressive symptoms, and sleep quality. You will complete various questionnaires to obtain this information. There is a blood draw at each of these visits. If you are unable to come in for the visits, we will contact you by phone at the same intervals. The questions will be the same, but there will be no blood draws.

Questionnaires

These tests and questionnaires about your health, mood, and personality will measure your mental and physical states.

Laboratory Tests

You will have blood tests. A trained nurse will take a small amount of blood from a vein in your arm. Blood will be collected using sterile techniques by a person experienced in drawing blood. Blood will be drawn through a needle in your arm during Visit 1. Visit 2 has up to five blood draws so a peripheral intravenous (IVP) line will be placed in both arms. This is a small flexible catheter in the vein that blood can be taken from and the injection can be given. You will not be charged for any of these tests. We may give you up to 500 ml of normal saline in your IVP to help hydrate you. The blood will be used for the measurement of various immune markers, metabolic panels, and for genetic analysis.

Visit	# Blood Tubes	# ml of Blood*	# TBSP of blood *
Study visit 1	7	46	3
Study visit 2	25	220	15
Study visit 3	5	44	3
Study visit 4	5	44	3
Total for All	47	380	26
		*approximately	*approximately

Lipopolysaccharide (LPS) Injection

You will be given an intravenous injection of a low dose LPS or a placebo of normal saline by a Registered Nurse. Whether you receive LPS or a placebo is decided randomly (by chance). Half the participants will receive LPS and half will receive saline. However, neither you nor your study doctor will know when you will receive the LPS or saline.

MRI Scanning

You will be asked to participate in the MRI scanning. For your safety, you will be given a brief pre-screening form to complete. It will tell us if you have any metal inside your body. The pre-screening form may identify some unanticipated medical findings that prevent you from participating in the MRI scan. If so, these findings will remain as confidential as possible, and will be discussed with you by a researcher involved in this study. Female participants will have an over-the-counter urine pregnancy test immediately before the scanning session. You will not be allowed to participate in the study if the pregnancy test reads positive.

Prior to your scan, you will be taught some tasks for use in the scanner. This will take about 5 minutes. The tasks will be decision making tasks and you will have the opportunity to be paid up to $30 during these tasks. See section below entitled **"Will I be Paid for Participating in this Study?"** for further information.

The MRI scanner rapidly takes pictures of your brain without exposure to radiation. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you will lie on a table that can slide in and out of the cylinder. You will be asked to lie still during scanning by remaining as relaxed as possible. While in the scanner you will hear loud knocking noises, and you will be fitted with earplugs to muffle the sound. You will be able to communicate with the MRI staff at all times during your scan, and you may ask to be moved out of the machine at any time. We may also monitor your heart rate and respiration using a device on your finger and a rubber belt that fits loosely around your chest using the built-in scanner equipment.

The study will use anatomical MRI and functional Magnetic Resonance Imaging (fMRI). During the fMRI, the MRI scanner measures changes in blood oxygen levels in different neuroanatomical regions while you perform mental tasks. This procedure involves *no* injections or radiation and will provide us with information about which neuroanatomical areas become more active (that is, receive more blood oxygen) while you are performing the tasks.

There will be two brain-scanning sessions (one at visit 1 and one at visit 2). The time in the scanner will be approximately 1 hour for each scan.

Physical Measurements

Your weight, height, blood pressure, pulse, Electrocardiogram (EKG), breathalyzer, and other like measurements will be obtained for research purposes.

Urine Tests

If you are a female of childbearing years, you will receive an over the counter urine pregnancy test during the screening visit and prior to the LPS/saline administration.

Meals and/or Snacks

During Visit 2, you will be provided with meals and or snacks as needed.

Saliva Sample

You may be asked to provide a saliva sample by spitting into a tube. This saliva sample will be used to obtain information about regulation of the activity of genes involved in immune function.

How Long Will You Be In The Study?

There are 4 study visits. We expect you will be in this study for up to 2 weeks.

There may be circumstances under which your participation in the study may be stopped by the investigator without your consent. Functional MRI is dependent upon measuring very small changes in blood flow in the brain. Therefore, there may be times in which the information collected will be unusable due either to a scanner malfunction or from you moving your head too much. Under these circumstances your participation may be stopped without your consent.

You **may stop participating in this study at any time. You may also refuse to be contacted again in the future about participating in the study again.**

What Are The Risks Of The Study?

Questionnaires

There is no medical risk associated with the questionnaires. You may experience temporary discomfort, including anxiety and sadness, when recalling particularly negative memories. Members of the research staff are trained to help you if you have an unusually strong reaction to these memories. You can also stop the procedure at any time. Also, if you show a strong reaction, such as extreme sadness, to any part of the study, researchers will stop the procedure and help you relax before leaving the LIBR.

Blood Collection

For the blood collections, you may have some discomfort and bruising at the site of needle entry. There is a very small risk of fainting or infection in the area of the needle insertion.

LPS injection

Although we will be administering very low doses of LPS, you may experience some side effects, such as a slight increase in body temperature, decreased or increased

heart rate, decreased blood pressure, nausea, shivering, headache, muscle pain or a slight increase in depressive symptoms. In very rare cases (~1%), there is a possibility of vomiting or diarrhea.

Some significant changes in heart rate/blood pressure and body temperature have been found to occur following endotoxin administration, although such abnormalities are only found at doses that are 4-fold greater than the highest dose used in this study. There also is one recorded case of asystole (a state of no electrical activity from the heart, potentially leading to cardiac arrest) in a participant who was thought to be dehydrated and who received more than double the dose of endotoxin that you will be receiving in this study.

Throughout the infusion protocol and for several hours following infusion, you will be carefully monitored with repeated vital signs and behavioral observations. If you do show any of the symptoms listed here, they will be most prominent for two to three hours after the endotoxin dose and then lessen considerably by six hours after the dose is given. If any symptoms are particularly distressing, they can be relieved by aspirin or ibuprofen. Furthermore, if any symptoms do develop, they should disappear by the following day. If you do show a clinically significant increase in physical symptoms or depressive symptoms, the study physician (Martin Paulus, M.D. or Yoon-Hee Cha, M.D. or Sahib Khalsa, M.D.) will be called and will evaluate you to determine the severity of your symptoms. If there are significant symptoms, the study physician will continue to monitor you until the symptoms are resolved and will not discharge you from LIBR until symptoms have returned to normal.

There is a risk that you may become more depressed some time after the study completion. Therefore, we will follow-up with 2 in-person visits, one day and one week after visit 2. The study physician will be available for you to contact if you continue to experience a worsening of depressive symptoms after the study is completed.

Common risks and complications (more than 5%; 1/20 individuals):

- Physical symptoms (chills, body aches, headache, and nausea) that usually lasts less than 6 hours
- Increased temperature (increase of <2 degrees; ~100° F)
- Increased heart rate

Very rare risks and complications (less than 1%; less than 1 person in 100)

- Significant reduction in blood pressure
- Vomiting
- Diarrhea

An MD and RN will be available during the study visit to monitor you for any problems.

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Frequently Asked Questions about LPS

Question: *Is the e. coli bacteria that will be used in the study alive?*

Answer: No. When we expose you to e. coli, we are actually exposing you to a part of the cell wall of the e. coli bacteria. The cell wall of the bacteria stimulates your immune system to send out immune agents to clear it from your system. So, you will only be exposed to a specific part of the bacteria that has been isolated and that is known to induce an immune response by your body.

Question: *How can this study be safe when I keep hearing that e. coli can make you very sick?*

Answer: There are several things that make this study safe. First, when you get e. coli from food (which is what can make people sick), you are getting the whole bacteria into your gut and bloodstream. When we expose you to e. coli here, we are exposing you to only a part of the e. coli bacteria – the cell wall. Moreover, the e. coli that we use in this study is the same kind of e. coli that is found naturally in your gut, whereas the kind of e. coli that you can be exposed to from food can be one of several different types of e. coli that your body may not be as familiar with. Second, we will be giving you a very low dose of LPS that is tightly controlled and is known to elicit very few sickness symptoms. This type of e. coli has been used in many different studies to better understand the immune system and over 3000 people have been exposed to it with no negative consequences. When you are exposed to e. coli in your food, you are being exposed to it in much larger doses that are obviously not controlled.

Question: *How long will the e. coli be in my system?*

Answer: The cell wall of the e. coli will actually be completely degraded and destroyed within 15 minutes of it entering your body. All of the possible symptoms that occur in response to e. coli exposure (aches, fatigue, nausea) are the result of the immune system sending out signals to your brain to engage in certain behaviors to recover from this foreign agent. We are interested in these symptoms that occur in response to exposure to e. coli.

Question: *What if I have a bad reaction to the e. coli?*

Answer: If you find that the symptoms that occur in response to e. coli exposure are too distressing or uncomfortable, we can resolve many of these symptoms by having you take aspirin or ibuprofen. This should reduce fever and any aches, pains, or chills that accompany e. coli exposure. In addition, you will have the attention of the nurses and doctors on staff there, who can provide full medical services to you to help resolve any unwanted or distressing symptoms.

Question: *How long will it take for my body to go back to normal?*

Answer: As mentioned previously, the e. coli will be completely out of your system within about 15 minutes. The symptoms that you may experience in response to the e. coli, however, will last longer. Symptoms such as fatigue, aches, nausea, and chills will peak at around 2 hours after e. coli exposure. After this time, they should continue to decrease. For most individuals, all symptoms will be gone within 6 hours after exposure to e. coli.

Brain MRI

People are at risk for injury from the MRI magnet if they have any of the following metal implants or fragments:

- pacemakers or other implanted electronic devices
- brain stimulators
- dental implants
- aneurysm clips (metal clips on the wall of a large artery)
- metallic prostheses (including metal pins and rods, heart valves, and cochlear implants)
- permanent eyeliner
- implanted delivery pump
- shrapnel fragments

Welders and metal workers are also at risk for injury because they may be unaware of small metal fragments in the eye.

You will be screened for these implants or metal fragments before the study, and if you have any of them, you will not receive an MRI scan and cannot be in the study. Tell the study doctor if you are uncertain whether you have any metal objects in your body. In addition, all magnetic objects (for example, watches, coins, jewelry, and credit cards) must be removed before entering the MRI scanner room.

Because of potential risk to an unborn baby, women who are pregnant are excluded from having an MRI and cannot be in the study.

You will be asked to complete an MRI screening form and to sign a separate MRI consent form for each MRI scan.

There are no known long-term risks or consequences of MRI scans. However, you may become uncomfortable because you will be lying in a small space. Some people are bothered by the loud thumping noises made by the scanner. You will wear earplugs to reduce the noise and increase your comfort during scanning. LIBR study staff will

closely and continuously monitor you throughout the scanning procedure. You will be removed from the scanner immediately if you request to be removed.

Physical Measurements

There are no known risks in taking your physical measurements.

Saliva Samples

There are no significant risks with the saliva collection.

Genetic Testing

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does not protect you or your family against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Also, GINA does not prohibit discrimination of individuals with a genetic disorder that has been diagnosed. However, in order to do everything possible to keep this from happening, the results of this test along with information that could identify you (as described in the next paragraph) will only be shared with the study staff. This means that the genetic information we obtain will not be made available to you, your family members, your private physician, your employer, your insurance company or any other party as allowed by law.

Delaying Treatment

You may participate in this study if you are currently unmedicated or if you are currently receiving anti-depressant treatment. You will not be asked to discontinue any medications you have previously been taking for the purposes of this study. It is very important that you inform the principal investigator or his assistant of your recent medication use. You should also check with the study doctor or his assistant before taking any over-the-counter or prescribed medications while you are in the study. We

request this communication in order to be certain that you do not take any medication that might interfere with the study measurements, interpretation of the findings, or may cause side effects. It is also important that you do not make major changes to your routine before or during the study – e.g. start an exercise program.

If you are unmedicated, in order to avoid long delays in treatment for conditions that might require you to take medications, you will be provided an opportunity to participate in the study within two weeks of the signing of this consent form. You should not participate in this study if it will be difficult for you to delay treatment longer than two weeks. To reduce the risks associated with delaying treatment, during this drug-free period, you may contact the study doctor. The study doctor will put you in touch with a healthcare professional with which you can consult.

If you are unmedicated, the risks of delaying treatment may include a worsening of your symptoms of depression and the development of suicidal thoughts. There is the possibility of hospitalization or a stop in your participation by the principal investigator in the study if it becomes clear that continued participation is not in your best medical interest. To reduce the risks associated with delaying treatment, during this drug-free period of two weeks, you will be monitored by a health care professional.

Pregnancy Risks

If you are a woman of child-bearing years, you must not be pregnant while participating in this study. There may be other risks from study participation that currently are unknown.

You Should NOT Participate in the Study if:

- You are pregnant or suspect that you may be pregnant
- You have heart disease, kidney disease or another chronic medical illness.
- You have a chronic infectious illness or an autoimmune disease
- You have had a recent infection (e.g. cold or flu) or were vaccinated in the last 2 weeks
- You are feeling suicidal
- You are currently using hormone-containing medications (except contraceptives)
- You are currently taking pain medications
- You are currently taking medications for your heart
- You are claustrophobic

Are There Benefits To Taking Part In The Study?

There is no direct medical benefit anticipated for you in this study. Your participation should help us better understand how depression and stress affect the immune system.

What Are The Costs Of Participating In The Study?

Neither you nor your health insurance will be charged for any of the study tests, procedures, or activities. If you need to be hospitalized, voluntarily or involuntarily, Laureate Institute for Brain Research does not intend to provide payment for this, and you or your insurance provider will be billed for these costs.

Will You Be Paid For Participating In This Study?

Visit 1	Approximate Time in Hours	Compensation	Incentive Earned
Consent	0.5		
Blood draw, Physiological measures & EKG	0.5	$25	
Interviews & behavioral evaluations	2	$20	
MRI scan	1	$50	
Incentive Tasks in scanner	0		up to $30
Total for Visit 1	4	$95	up to $125
Visit 2			
Blood draw x5, Physiological measures & EKG x2	1	$25	
IV placement x2	0.5	$50	
Interviews & behavioral evaluations x5	4	$40	
LPS or Placebo injection	2	$100	
Lunch & Rest provided	1	$0	
MRI scan	1	$50	
Incentive Tasks in scanner			up to $30
Total for Visit 2	9.5	$265	up to $295
Visits 3 and 4 (x2)			
Blood draw	0.5	$25	
Interviews & behavioral evaluations	0.5	$20	
Total per Visit		$45	
Total for visits 3 and 4		$90	

You will be paid through a ClinCard (similar to a debit card) that may be used approximately 1 business day after the visit.

What Other Options Are There?

This study is for research purposes only, so your other option is not to participate in the study.

Confidentiality

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

THE INFORMATION AUTHORIZED FOR RELEASE MAY INCLUDE RECORDS WHICH MAY INDICATE THE PRESENCE OF A COMMUNICABLE OR NONCOMMUNICABLE DISEASE.

This information is made confidential by law and can be released only with your permission except by order of the court or health department in certain limited cases of persons who have risk of exposure of the diseases. Information from this study may be submitted to governmental agencies in other countries where the study medication may be considered for approval. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed.

Who may use and give out information about you?

The study doctor and the study staff.

Who might get this information?

The sponsor of this research. “Sponsor” means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission and may no longer be protected.

If you have any questions or concerns about your privacy rights, you should contact the LIBR Privacy Officer at 918-502-5155 or via email at privacy@laureateinstitute.org.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study is finished.

What If You Are Injured While Participating In This Study?

If you get hurt or sick while participating in this study, emergency medical treatment is available from the Saint Francis Hospital and/or the Laureate Psychiatric Clinic and Hospital. If you get sick after the study is completed, call 911 in an emergency. Be sure to tell the emergency staff and other healthcare providers of your participation in this study. Contact the Principal Investigator of this study, Jonathan Savitz, PhD, as soon as possible at 918-502-5155 or 918-481-4000 (24 hours) if you think you have a research-related injury or illness.

You or your health insurance provider will be billed to cover the cost of the medical or emergency services provided. Some insurance carriers may not provide coverage for injuries received while participating in a research study. You are encouraged to contact your insurance carrier to determine whether coverage is available. Otherwise, you may have unexpected expenses as a result of your participation in this study. No funds have been set aside by the Laureate Institute for Brain Research to compensate you if you are hurt or get sick. However, you still have the right to bring a law suit if you think you were harmed and deserve compensation.

You do not give up any of your legal rights by signing this consent form.

Who Will Provide Funding For The Study?

Funding for this research study will be provided by the Laureate Institute for Brain Research and through a grant from the National Institute of General Medical Sciences.

What Are Your Rights As A Participant?

Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Can The Researchers Remove Me From This Study?

The investigator may withdraw you from this research activity (without your consent) if certain circumstances arise. For example, you may be withdrawn from this study if the investigator feels that your continued participation places you at unnecessary risk or harm or you become ineligible (because of illness) to continue or because of non-adherence to protocol instructions. You may have to drop out, even if you would like to continue. The investigators will make a decision and let you know if it is possible for you to continue. The decision will be made to protect your health and safety.

What If There Are New Findings?

We will provide you with any significant new findings developed during the research study that may affect your health, welfare, or willingness to continue your participation in this study. You may be asked to sign a new consent form if this occurs.

Whom Should You Call If You Have Questions Or Problems?

Your contact person for this study is Jonathan Savitz, PhD. He can be reached during business hours at 918-502-5155 or through his cell phone # 918-508-9942 (for urgent enquiries).

If you have questions about your participation in this study, concerns, or complaints about the study, or have a research-related injury, contact the study doctor, Jonathan Savitz, PhD, at 918-502-5155 or 918-481-4000 (24 hours). For emergencies call 911.

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will be given a signed and dated copy of this consent form.

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.

Signature

I have read the information in this consent form. I have been given an opportunity to ask questions. All my questions about the study and my participation in it have been answered.

I Agree To Participate In This Study

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

_____

PRINTED NAME OF PARTICIPANT

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Consent Signature

PARTICIPANT SIGNATURE (18 years and older)	Date
SIGNATURE OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION	Date

☐ The subject passed the LPS Consent Test with a score of 85% or more.

☐ The subject did not pass the LPS Consent Test.

PRINTED NAME OF PERSON CONDUCTING THE INFORMED CONSENT DISCUSSION	Date