IRB APPROVED
AS MODIFIED
Apr 07, 2020

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

TITLE:	Biological Sample Collection Protocol
PROTOCOL NO.:	BT001 WIRB® Protocol #20141589
SPONSOR:	Bloodworks Northwest
INVESTIGATOR:	David M. Lin, MD, MHA 921 Terry Ave Seattle, WA 98104 United States
STUDY-RELATED PHONE NUMBER(S):	David M. Lin, MD, MHA, Principal Investigator 206-689-6117 206-689-6616 206-689-6525 (24 hours) *Ask for Apheresis MD On Call

This consent form may include words that you do not understand. Please ask the research program coordinator, nurse, or phlebotomist 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, friends, personal physician or others before making your decision.

Background and Purpose of Research

You are invited to participate in a Biological Sample Collection Program (the "Program") being conducted at Bloodworks Northwest ("Bloodworks"). The Principal Investigator of the Program is Dr. David Lin who is a Medical Director at Bloodworks. The biological samples collected for the Program is intended for research and/or clinical use. The purpose of the Program is to provide a human biological specimen ("biospecimen") repository of blood samples, as well as a registry of volunteers willing to participate in current and future Programs.

- Biospecimens can be blood, cells, clippings of hair or nail, tissues from biopsies, body fluids, etc.
- A repository is a bank or collection of biospecimen samples which may be used for research and/or clinical purposes.
- A registry is a voluntary database of individuals, with their contact and other demographic information, who are willing to consider participation in projects by donating a biospecimen sample.

Researchers are hoping to learn more about cancer, heart disease, diabetes, and many other diseases and health conditions. Many research projects are aimed at finding better ways to prevent, diagnose or treat those conditions. Human biospecimens, from people with and without those conditions, are needed for such research. Your biospecimens can be used for research purposes by Bloodworks Northwest and/or clients ("Client Investigators") of Bloodworks, to help understand health and disease, and to discover and develop methods and develop new technologies for diagnosis, medicines, and treatments. The research may involve the use of advanced biochemical analyses, such as RNA transcript profiling, proteomic methods, and/or genotyping (analysis of DNA, which holds the chemical codes that cells need to grow and live). The research might include whole genome sequencing [determining the order of DNA building blocks (nucleotides) in your genetic code]. The research may also include creation of cell lines. It is possible that cell lines, which can live indefinitely, may contain all or part of your DNA. These tests are not intended to diagnose or treat your current or possible future medical conditions. Your biospecimens may also be used to create cellular therapies to treat patients.

What Is Involved?

If you agree to participate in the Program, here is what will happen:

1. Signed Informed Consent. You will need to understand and sign this consent form. We will give you a signed copy to keep. You may withdraw consent at any time.

2. Screening Process. You will need to be screened to be sure that you qualify to participate in the Program. This may involve all or some of the following: giving personal and family medical history information, having some measurements taken, blood tests, and other tests. The test procedures are described in detail below. We will need to copy your government-issued photo identification, a Federal W-9 IRS form, and we will need your contact information so that you can be contacted by telephone, postal mail, and e-mail. All information that identifies you will be kept in secure files or data storage that is only available for internal Bloodworks use.

3. Screening and Qualification Results. Your screening results will be seen by Bloodworks staff and the Medical Staff. If a blood test is ordered, a Bloodworks representative will contact you by e-mail and/or telephone, to let you know whether you have qualified to participate in the Program. The Medical Staff does not provide health care and will not give any definite opinions about diagnosis or treatment. You may be advised to discuss a result with your personal physician. It is important to understand that Washington State law requires Bloodworks to report some test results (e.g., positive tests for HIV, hepatitis B, hepatitis C, syphilis) to the public health authorities, with personal identification.

4. If You Qualify. If you qualify to participate in the Program, Bloodworks staff will contact you to let you know what will happen next. They may arrange and give instructions for your first sample donation visit. They may talk with you about the type of sample donation that is needed and ask about your health and use of medicines. They will discuss the reimbursement that you would receive for completing the Sample Donation Visit. There may be other messages to remind you of your donation time and place, and other preparations (fasting, medication use, etc).

5. Your Sample Donation Visits (please check applicable donations below). A sample donation visit happens at a Bloodworks collection site, Bloodmobile, or temporary collection site. The

staff will confirm your identity, review what sample donation is needed, ask questions, and check any tests that may be needed (e.g., a quick blood test) to be sure that you are suitable to undergo the planned biological sample collection. The staff who do the procedures are trained and authorized by the Principal Investigator and have any certifications required by Washington State regulation.

- Whole Blood donations: For a blood sample donation, you may be asked to rest in a recliner chair. You will be asked to tell the staff member if you have any symptoms during or after the procedure, such as: more than just a little pain with the needle, lightheadedness, etc. A blood pressure cuff or elastic band may be used as a tourniquet, to keep blood in the veins. In the phlebotomy procedure, the skin will be disinfected, and blood will be collected through a sterile needle placed in a vein in your arm or hand. The blood will be drawn into one or more syringes, tubes or other collection containers. After the needle is removed, a gauze pad and tape will be used to put pressure on the vein. You will be asked to help keep pressure on the site for at least 5 minutes. The whole procedure will take 15 to 30 minutes. You can remove the tape and gauze after 20 minutes. If you report any unpleasant symptom or other side effect of a procedure (e.g., bruise at a blood draw site), the staff will plan to follow up with you.

- Apheresis donations: During apheresis, your blood will be removed through one needle ("draw") in a vein in one arm and processed by an apheresis machine that separates the blood into the four components. The donation component, either red blood cells, white blood cells, platelets, and/or plasma, will be collected in a collection bag and the other blood components will be returned to you by the machine through another needle ("return"), usually in the other arm. A blood thinner solution is given to make sure the blood does not clot in the apheresis machine. The apheresis collection process usually takes 1-4 hours. A nurse will be caring for you throughout the procedure to make sure you are comfortable and your needs are met.

- Other types of biospecimen donations: Urine will be collected after giving the volunteer donor a clean specimen cup, showing them the restroom, allowing them to void into the cup, and return the sample. Sputum and saliva will be collected after giving the volunteer donor a clean specimen cup, and allowing them to cough or spit a sample into the cup. Cheek cells will be collected by gently rubbing the inside of the volunteer's cheek with a clean swab for a minimum of 30 seconds, and then placing it in the swab holder when done.

6. 6. Yearly Update. At least once in each calendar year that you have a Sample Donation Visit, and at other times as needed, it may be necessary to repeat or do additional lab tests and measurements (e.g., blood pressure, pulse, weight), and to ask about personal, family and medical history, for Bloodworks to know whether you qualify to continue in the Program or to participate in some parts of the Program. These updates will be scheduled by Bloodworks staff and may sometimes happen at the same time as a Sample Donation Visit. The Medical Staff will review results, contact you and advise, as described above.

7. Sample Processing. Bloodworks may process the donated samples in various ways (e.g., adding anti-clotting chemicals, separating cells with specialized devices) to make them useful for Client Investigators' research. Samples are labeled with code numbers, and never with any personal identifiers.

8. Sample Storage. Bloodworks may store your cells or products derived from your cells (e.g., by freezing) for future use within this study or for use by other Client Investigator studies.

9. Participant Database. Bloodworks stores participant data in a secure physical and/or electronic database(s). Bloodworks uses this information to determine whether or not a participant qualifies according to client investigator requirements and/or other research related purposes. This database has information that you have provided to Bloodworks or that Bloodworks has obtained through your community donations and/or lab testing regarding your demographics, medical history, blood type, etc. Bloodworks may also transfer your data from other databases and research protocols within the Bloodworks Northwest organization to this protocol participant database. Your identity will remain confidential and protected. Only authorized Bloodworks staff members will have access to participant records.

10. Providing Samples to Client Investigators. Bloodworks may transfer samples and related information to Client Investigators for research and/or clinical use. The Client Investigators pay Bloodworks for this service. The information given with the samples may include your age, medical history, family history, racial or ethnic background, etc. However, information given by Bloodworks will never include your personal identifiers (ex. Name), and every Client Investigator is required by contract, law, and regulation to never try to identify you through samples or information provided by Bloodworks. That is, Bloodworks takes great care to protect your privacy, and we require all Client Investigators protect the confidentiality of your personally identifiable information.

11. Communicating with You. To participate in the Program, you must allow Bloodworks to contact you in different ways. For example, the staff must be able to contact you about scheduling Sample Donation Visits and to update information about the Program. That may include giving you the opportunity to increase your participation in the Program. If Bloodworks is unable to contact you for those purposes, you may be withdrawn from the Program. When it is optional for you to receive certain kinds of information, Bloodworks will ask you to make your choice.

12. Withdrawing from the Program. You may decide not to be screened for the Program, or you may decide to not complete screening. After you have been qualified for the Program, you may withdraw from it at any time. See more details below. It is also possible that the Principal Investigator may decide to withdraw you from the Program for your own health and safety.

More Details

Testing and Qualification - Requirements

For you to participate in the Program, certain requirements must be met, including:

1. Age of at least 18 years at time of providing informed consent
2. Capable of reading, discussing and understanding study-related information in English
3. Capable of providing valid informed consent
4. Legally qualified to receive donor reimbursement
5. Reliably capable of receiving US mail, electronic mail and telephone calls
6. Anticipated to be available for scheduled sample donation(s)
7. Weigh more than 110 pounds (50kg)

Also, you will not be able to participate in the program or a particular donation if in the judgment of the Principal Investigator (the “PI”), any of the following criteria is met and considered to significantly compromise participant safety or study integrity:

1. Presence of acute or chronic health condition not suitable for participation in all or part of the Study
2. History of an adverse reaction to phlebotomy procedure that is considered to compromise the donor’s safety, in the judgment of the PI or designee
3. History of unresolved anemia – i.e., a hematocrit not within acceptable range as determined by the PI or designee, in accordance with current standard blood banking practices [whole blood donation, apheresis]
4. Laboratory test result outside of acceptable range from a routine metabolic chemistry panel as determined by the PI or designee
5. History of or test positive for currently excluded relevant communicable disease agents or disease
6. Weigh less than 110 pounds (50 kg) [whole blood donation, apheresis]
7. Vital signs not within acceptable range as determined by the PI or designee, in accordance with current standard blood banking practices [whole blood donation, apheresis]

In addition, you will not be scheduled for Sample Donation Visit when:

1. in the judgment of the PI, you have a condition that would have disqualified you from entering the Program;
2. in the judgment of the PI the result of a laboratory test disqualifies you from a sample donation; or
3. according to Bloodworks’ policies (e.g., limit on amount of blood donated within a recent period of time), sample donation must not occur.

If you are pregnant or become pregnant during the Program, you will be disqualified from donating more than 50 mL (a little less than 2 ounces, or 4 tablespoons) of blood during any 14 day period, unless specifically cleared by the PI/medical director, and you may be disqualified from some other sample collection procedures. By signing this Informed Consent Form, you accept the responsibility of notifying Bloodworks staff before a sample donation if you are pregnant.

At Sample Donation Visits

Before samples are collected at each visit, you will be asked some questions about your current medical condition, and you may need to have some measurements (e.g., blood pressure, heart rate, weight) and laboratory tests, possibly including a urine pregnancy test. You will **not** be allowed to participate in a blood sample donation, if you have:

1. lost or donated a total of 200-mL or more of blood in the last week (whole blood donations);
2. lost or donated 525-mL of whole blood in the last 56 days (whole blood donations);
3. other blood collection procedures that have deferral limitations, as defined by Bloodworks current standard practices
4. symptoms of an infection, including a “cold”;
5. taken prescribed or over-the-counter medications, herbal products, or supplements if the donation restricts them;
6. had a change in medical condition that has not been approved by the PI;
7. a red blood cell test result that is not acceptable; or
8. weigh less than 110 lbs (50 kg).

Risks of Participation

Risks, Hazards and Discomforts of Procedures

Severe Medical Events. If you experience a severe medical event following any donation or procedure, please seek urgent medical attention. Please follow-up with the study coordinator(s) to report any severe medical events.

Phlebotomy. You may experience side effects during a procedure. For example, there may be pain, bruising, vein clotting, or bleeding where a needle was inserted to draw blood. Lightheadedness, sweating, nausea and fainting can happen and can require lying down and resting to recover. If you have side effects during a procedure, or change your mind about wanting to have it performed, you may ask for the procedure to be stopped at any time.

You may feel tired after having blood drawn. If you feel tired or lightheaded, you should use caution in performing activities that may be dangerous, such as driving a car or operating machinery.

The most common side effect of blood sample donation is temporary decrease in your red blood cell count. New cells will replace the blood cells removed by this procedure. This procedure should not affect your blood’s ability to form clots when cuts or injuries happen. The long-term effect of repeated blood donation may include decrease in the amount of iron in your body.

Other possible effects are not completely known. If you have any medical conditions, and especially if you are in treatment by a doctor, you should discuss the Program with your personal physician before beginning to participate and at least once yearly while you participate in the Program. Bloodworks follows standard blood banking practices and advises you not to lose or donate more than 525-mL of whole blood in the last 56 days (Reference: AABB Standards for Blood Banks and Transfusion 5.4.1A allows maximum of 10.5 ml/kg of whole blood volume collected, including samples).

Apheresis. Possible risks specific to Apheresis may include, but are not limited to:

- Risks and side effects similar to those during blood donation such as light-headedness, dizziness or even fainting. We can slow down the machine and/or give fluids to lessen these effects.
- Risks and side effects associated with the blood thinner used during the procedure, such as tingling of the hands and lips, chest pain, and involuntary muscle contractions (tetany). Slowing the rate of fluid return usually lessen these side effects. If needed, we may give you calcium to lessen these side effects even more.
- A sense of coolness due to the return of blood which has cooled to room temperature. Blankets and blood warmers are used to alleviate this effect.
- Tenderness and/or bruising at the needle site due to the large needle used during the procedure. It is usually treated by applying a cold compress.
- Very rarely, clotting or leaks in the tubing may prevent the return of blood to the patient. Blood counts are monitored at each treatment, and appropriate fluids will be given as replacement if necessary.

If side effects occur, please report them to the nurse. The procedure may be paused or stopped, and a Bloodworks medical provider will monitor and treat you as needed. You can withdraw from donation at any time.

Reporting Negative Effects. Bloodworks intends to recognize, help manage, and record any negative effects of procedures in the Program. Bloodworks urges you to report to staff members any negative effect of your participation in the Program.

Emotional or psychological stress. Emotional or psychological stress can be associated with testing for certain conditions, such as infection with HIV, or hepatitis B or C. You may also feel anxious or upset if the initial test results are positive or unclear. Follow-up tests by your personal physician may be necessary to establish a diagnosis. If you have concerns or questions about your test results, please call Bloodworks at the numbers listed on this consent form**,** and the Medical Staff will contact you. Copies of your screening test results can be given for you to share with your physician, but are **NOT** intended for diagnostic purposes. Alternatively, you may use your personal medical or psychological urgent care resources, if needed.

Risks to Privacy and Confidentiality. Bloodworks intends to conduct activities (conversations, interviews, Sample Donation Visits) in privacy. Bloodworks intends to store all information about you in secure files and databases that can only be accessed when needed by Bloodworks. The link between your identity and your Donor Number and any samples you have donated will be kept in separate, secure files. Though Bloodworks judges that the risk is very small, there is risk that someone could get access to the data about you that has been stored by Bloodworks. The data could be misused – for example, to make it more difficult for you to get insurance, or as "identity theft." There are laws against such misuse, and both civil and criminal legal actions can be taken. Bloodworks will never give your personal identifiers (ex. Name) to Client Investigators. Additional detail is given below.

Because your DNA is unique to you, it is possible that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential. We do not think that there will be further risks to your privacy and confidentiality by sharing your whole genome analysis with public or restricted databases. However, we cannot predict how genetic information will be used in the future. In the future, someone could develop ways to link your genetic or medical information in a database back to you. It is possible that you could be identified from the sample if someone already has genetic information from you to match to information in a study.

There is a risk that someone could get access to the data we have stored about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. The Genetic Information Nondiscrimination Act of 2008 (GINA) says that group and individual health insurers may not use your genetic information to determine whether you are eligible for insurance, how much you have to pay, nor can they request or require that you take a genetic test. We cannot guarantee that this will fully protect you. Your privacy and the confidentiality of your data are very important to us; we will make every effort to protect them. As with any research project, there may be additional risks that are unknown or unexpected.

Required Disclosures. Certain laboratory test results (e.g., HIV, hepatitis) must be reported by Bloodworks to public health authorities. Records of the Program may be inspected by regulatory auditors or by the Independent Review Board. Bloodworks records may be subject to discovery by court order. In general, your personal health information remains protected by Washington State and Federal law (e.g., the Health Insurance Portability and Accountability Act, or HIPAA).

You will be told about any new information that might change your decision to be in this Program.

Benefits of Participation

Research done with your donated samples may increase knowledge to help people in the future. You may feel positive about contributing to that research and/or treatment of patients.

Screening Test Results. It is not intended for you to receive any direct medical benefit from screening for or participating in the Program. Results of screening or tests or periodic retests may be useful to you and your personal physician, but are not for diagnostic use.

Research and Research Test Results. There are no plans to give you the results of any research or tests done with your samples by Client Investigators. Client Investigators are not obligated to and are not planning to determine whether information associated with your samples may be important to your individual health or your family members' health. If a Client Investigator becomes aware of such a finding and decides to notify Bloodworks, if Bloodworks still has the ability to determine (from the sample code numbers) that you donated the sample, and if you have given permission for Bloodworks to contact you with such information, then Bloodworks will attempt to contact you, using the most recent contact information you have provided.

By signing this consent form, I give Bloodworks permission to attempt to notify me if they are made aware of a research finding regarding my sample donation(s) that may be related to my current health status. I understand this is not a diagnostic result if I am contacted, and will address any questions and/or arrange follow up with my primary care provider.

Costs of Participation

You will not be charged for participating in the Program. Bloodworks will pay all costs of procedures in the Program. Client Investigators or their sponsors will pay for the costs of their research.

Reimbursement for Participation

Reimbursement. You will be reimbursed for initial screening, when that screening involves blood testing. You will be reimbursed for each Sample Donation Visit. The reimbursement may be different, depending on the time and biospecimen collection procedures being done. You should discuss the reimbursement with Bloodworks staff when you schedule a Sample Donation Visit. To be reimbursed, you must provide a completed, signed and dated Internal Revenue Service W-9 IRS form to Bloodworks. The reimbursement may be taxable; it is your responsibility to check with your tax advisor to determine your tax liability. If you receive reimbursement amounting to $600 or more in a calendar year, you will receive a 1099-MISC tax form in the mail.

Expenses. Bloodworks does not uniformly offer **additional** reimbursement for expenses (e.g., travel) due to participating in the Program. Under exceptional circumstances, when prior approval has been given by the PI, Bloodworks may choose to reimburse specific expenses. It is your responsibility to provide your own transportation to and from appointments, and to avoid fines for parking tickets.

Compensation for Injury

If you incur any costs associated with treating an injury or medical condition that arises directly from your participation in the Program, seek appropriate medical treatment and submit claims through your health insurance to cover any costs resulting from that appropriate medical treatment. No money has been set aside to pay for things like lost wages, lost time, or pain or suffering. However, you do not waive any rights by signing this consent form.

Commercial Issues – Ownership, Discoveries, Business & Product Development

Sample Ownership. When you donate a sample, Bloodworks becomes the sole owner of that sample, of its value, and the value of its association with any information you have given. Bloodworks may sell this sample to Client Investigators, who then become the sole owner of that sample.

Discoveries, Business & Product Development. You should know it is possible that through the use of your blood samples in research, a discovery may be made, a business may be developed, or a commercial product (e.g., a diagnostic test, drug, vaccine) may be developed. By signing this consent form you are authorizing the use of your samples for the research purposes described above. The Client Investigators that use your samples may patent or sell discoveries that result from this research. In no event will you receive any additional financial compensation from Bloodworks or the Client Investigators in connection with your blood donation.

Program is Independent of any Employment Criteria

Your participation in the Program is on a strictly voluntary basis.

Bloodworks management does not urge, influence, or encourage anyone who works for the company to take part in the Program. Your decision to not participate in the Program, or a decision on your part to withdraw from the Program, will have no effect whatsoever on your employment status at Bloodworks.

Alternatives to Participating in the Program

Your alternative is not to participate in this Program.

Source of Funding

Bloodworks will provide funding for the Program. Bloodworks' Client Investigators pay Bloodworks for its services and biospecimen samples.

Confidentiality

In Bloodworks' confidentiality procedures, you will be assigned a donor number. Bloodworks holds the key of donor numbers and donors' identity securely and will not disclose donors' identity to any of its Client Investigators. Bloodworks will provide the donor number along with the collected samples to its client. Any research and publications that may arise from the research use of your samples will never be associated with your name. You will not be given access to your donor number.

Your coded genetic and health information could be placed into one or more restricted scientific databases. Only researchers who apply and are approved can use restricted databases. One such restricted data base is funded by the National Institutes of Health and is called dbGaP. This stands for Database for Genotype (genes) And Phenotype (things observed or measured by examination or laboratory tests).

Client Investigators’ research results may also be given to the U.S. Food and Drug Administration (“FDA”) or other federal agencies, for regulatory purposes. Research records that identify you and the consent form signed by you may be looked at and/or copied for research or regulatory purposes by:

- Bloodworks and agents of Bloodworks

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA, Washington, D.C.;
- Department of Health and Human Services (“DHHS”) agencies, Washington, D.C.;
- Governmental agencies in other countries; and
- the Western Institutional Review Board® (WIRB®) – the Independent Review Board that oversees the Program, Puyallup, Washington.

Absolute confidentiality cannot be guaranteed because of the potential need to provide information to these parties. The results of research from your donation may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

Certificate of Confidentiality

To help protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation for projects funded by the federal government or for information that must be given in order to meet the requirements of the Federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily providing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent, in incidents such as child abuse, and intent to harm yourself or others. A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

Voluntary Participation and Withdrawal

Your decision to participate in the Program is voluntary.

If you participate, you may stop at any time, for any reason. You do not have to explain why you decide to withdraw. The consent remains in effect until you withdraw from the Program verbally or in writing. Alternatively, if you do not respond to contacts for blood draw appointments within 14 days, we will send a letter or email asking if you want to continue to be contacted for participation in the Program. If we do not get a response within 30 days, then we may remove you from the Program. Any data collected prior to when you withdraw from the Program will be retained.

Your decision not to participate or to withdraw will not result in any penalty or loss of benefits to which you are entitled.

If you withdraw from the Program, you may instruct Bloodworks to:

- have no further contact with you [Bloodworks could still use any stored samples that you have donated, with associated information.];
- no further use [Bloodworks would destroy all of the samples in its possession that can be identified as yours. Bloodworks would not be able to get back samples or information already given to Client Investigators.]

Your participation in the Program may be stopped at any time by the program coordinator, sponsor, or Principal Investigator, without your consent for any reason, including if it is in your best interest or if you do not consent to continue in the Program after being told of changes in the research that may affect you.

Questions

If you have any further questions, concerns, or complaints about the research or a research-related injury, contact:

David M. Lin, MD, MHA, Principal Investigator
206-689-6117

Main Research Donor Program
206-568-3637

Mobilized Research Donor Program
206-689-6616

Apheresis MD On Call
206-689-6525 (24 hours)

If you have any questions regarding your rights, safety or welfare as a research participant, 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, WA 98374-2115
800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is an organization of people who perform independent reviews of research. WIRB complies with federal law, regulations, international standards and ethical standards to protect the rights, safety and welfare of people who participate in 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 participate in this research program, you will receive a signed and dated copy of this consent form for your records.

Consent

I have carefully read this consent form and have asked from others all of the advice I feel that I need. All my questions about the research program and my participation in it have been answered. I freely consent to participate in this research program.

By signing this consent form, I have not waived any of the legal rights that I otherwise would have as a participant in a research program.

Participant Signature	Date
Participant Printed Name	

The contents of this consent form were verbally presented to the subject and all questions were answered completely.

Signature of Person Conducting Informed Consent Discussion	Date
Investigator/Program Coordinator (if different from above)	Date