

**Informed Consent Form for
Adult Subjects / Parents / Legal Guardians**

Sponsor / Study Title: Dono Vivo, LLC. / “Prospective study aimed at obtaining diseased state human biological specimens for use by researchers in laboratory studies assisting in the development of diagnostic testing and future therapeutics.”

**Principal Investigator:
(Study Doctor)** Chad Link, D.O.

Telephone: (888) 694-4380 (24 Hours)

Address: Dono Vivo, LLC
46430 Peary Court
Novi, MI 48377

Introduction:

You, or your child (as applicable), may be eligible to participate in the research study as described in this informed consent form. This form gives you important information about the risks and benefits of participation. If there is anything in this form you do not understand, please ask the study phlebotomist. In this form, the word “we” means the study phlebotomist and any other representatives of Dono Vivo. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

Approximately 200 people will participate in this study.

Investigators on this study serve in executive positions for and have ownership interest in companies sponsoring this study. Please speak with your study doctor if you have questions about this.

Research Use of Samples and Medical Information

You are being asked to take part in this collection because you have been diagnosed with a disease-state of interest to researchers (or, if applicable, you are a family member of such a patient). This collection is for future use in *in vitro* medical research, and you do not have to take part. If you choose to take part, you can leave the study at any time and no further samples will be collected from you. Please note, however, that any samples that have already been placed with researchers may not be withdrawn, as they have likely already been used or consumed during research activities.

Dono Vivo collects samples and related medical information of interest, and shares them with research scientists, pharmaceutical companies, biotech firms and academic institutions for furthering of scientific

discovery. The research performed by these entities will involve various types of genetic testing. Genetic tests involve examination of pieces of deoxyribonucleic acid (“DNA”) called genes. These genes provide the instructions that our bodies use to perform bodily functions.

Researchers examine these samples to learn more about the presence of certain “biomarkers.” Biomarkers are substances found in the blood or body that are associated with the presence of disease. In cancers, specific biomarkers (sometimes called “tumor markers”) can point to the presence of specific types of cancer. Researchers will examine any biomarkers, including but not limited to the effect that your treatment has had on these biomarkers. The field of genetic testing and biomarker evaluation is advancing rapidly, which precludes us from predicting all of the tests that will be done on your samples. Your samples may also be used to create cell lines for further study. Cell lines are collections of cells developed from a single cell and therefore consisting of the same genes. Cell lines offer researchers another way to study biological processes.

What will happen if I take part in this study?

This study involves the collection of blood samples and related medical information. If you agree to be in this study, you can either go to a clinic or be visited in your home to give a blood sample. The blood will be drawn by putting a needle into a vein in your arm. Up to four small tubes of blood will be taken, about 40 mL total. This process of blood collection will take about five minutes. Any tissue or bodily fluid that is removed during this medical procedure is not needed for your medical care and will be stored in a biorepository.

To ensure the best data is available for scientists we will validate your condition with your regular doctor and match it to your medical records to ensure the study doctor knows of the treatments in which you are engaged.

You will be given an optional feedback survey to ensure Dono Vivo’s continuous improvement after your donation is complete. Within that Survey, should you opt to fill it out, you will have the option to sign up for future donations. Should future donations be requested, Dono Vivo will contact the donor to reschedule at your preferred timing. If the future donation is not selected or the survey not returned, Dono Vivo will not contact you.

What information will I need to provide?

Genetic information and the medical information may be shared broadly in a coded form for future genetic research or analysis. We may give certain medical information about you (for example, diagnosis, blood pressure, age (if less than 85) to researchers, including, but not limited to, to researchers who manage or use a government health research database. However, we will not give them your name, address, phone number, birth date, social security number or any other identifiable

information. Instead, samples and personal medical information will be assigned a unique code. Only qualified individuals at Dono Vivo will know the name that correlates to each code. Research results from these studies will not be returned to you.

Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

When you sign and date this form, you give Dono Vivo permission to use and share all of the information from your samples, questionnaire and medical record, as described in this consent form.

Are there risks?

The needle stick may hurt. There is a small risk of bruising and fainting, and a rare risk of infection from getting your blood drawn.

Research that uses health information and that involves genetic testing can affect your privacy. Your participation in this study will be held strictly confidential and only a code number will be used to identify your stored samples and data. However, because there will still be a link between the code and your identity, complete confidentiality cannot be guaranteed.

Since future research studies will involve genetic analyses, potential risks include discrimination or impact on insurance coverage. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. The protections set forth for your medical information minimize those risks, as only coded samples and data will be stored and used for future research. Further, Dono Vivo uses industry standard physical and information security practices to protect all data related to this study. In addition, a federal law makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information (the Genetic Information Nondiscrimination Act, "GINA").

There may be other study risks that are unknown.

Are there benefits?

There will be no direct benefit to you from allowing your data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and

understanding of health and disease. If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits or compensation relating to such products, tests or discoveries.

Can I say “No”?

Yes, participation is voluntary and you do not have to donate a blood sample for this work. If you decide not to participate there will be no penalty and you will not lose any of your regular benefits to which you are otherwise entitled, and you can still receive medical care as you have.

Alternatives to participation

This research study is for research purposes only. The only alternative is to not participate in this study.

New findings

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Will my medical information be kept confidential?

We will do our best to protect the information we collect from you and your medical record. Information that identifies you will be kept secure and restricted. However, your personal information may be given out if required by law. Dono Vivo uses appropriate systems to protect your identify from being revealed. It is kept only to ensure future references may be validated if necessary. If information from research done with your sample is published or presented at scientific meetings, your name and other identifiers will not be used. Only designated administrators of the system will be able to decode your information in case of legal requirement. However, under certain circumstances the regulatory agencies and the institutional review board (IRB) will be able to copy and inspect your study-related records.

Are there any costs or payments?

You will be paid \$25.00 in the form of a gift card for taking the time to donate a blood sample. It will be sent to you directly within a week of your collection and completed consent forms. You will not be charged for the blood sample. There are no costs to you for participation in this study. While you are in this study, the cost of your usual medical care (including procedures, medications, and doctor visits) will continue to be billed to you or your insurance.

What if I get injured?

Tell the Study Phlebotomist if you feel that you have been injured because of being part of this research. You can tell the Study Phlebotomist in person or call the phone number listed on the first page of this consent form.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, you will be provided necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or potentially by Dono Vivo depending on a number of factors. Dono Vivo does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board using the contact information listed in the “Whom to Contact About This Study” section.

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

If applicable, to pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
Study Subject Adviser
Advarra IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00043269.

Withdrawing Permission to Use and Disclose Health Information

If you decide later that you do not want your information to be used for future research, you can notify the study doctor using the telephone number listed on the first page of this form. A document will be sent to you to sign and date, and any remaining data will not be used for any new research or tests. However, please note that the FDA requires that any information collected up to the point of your

withdrawal cannot be removed from the study, and we cannot retract any samples that have been shared with other researchers.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you.
- If you fail to follow directions for participating in the study.
- If it is discovered that you do not meet the study requirements.
- If the study is canceled.
- For administrative reasons.

CONSENT

1. You have been given a copy of this consent form to keep.
2. If the below statements are true, please sign and date this consent form:
 - a. I have read this entire consent form, and all of my questions have been answered to my satisfaction.
 - b. I understand that participating in the Dono Vivo biorepository is voluntary, and I agree to join.
 - c. I have had the chance to consider the risks of my participation and agree to participate.
 - d. I know that I can withdraw from the Dono Vivo biorepository at any time.

If you wish to submit your sample, please sign and date below.

Date	Subject's Name (Printed)

Date	Subject's Signature/or Legal Guardian for Consent

Date	Printed Name of Person Obtaining Consent

Date	Signature of Person Obtaining Consent