Frequently Asked Questions

A. General FAQs about the LDB Tissue Collection Program

What is the Lyme Disease Biobank?
Lyme Disease Biobank (LDB) is a collection of human biological samples created to help investigators studying Lyme disease and other tick-borne infections. Samples are available to researchers and companies creating new diagnostic tests or working to better understand this complex disease. LDB is partnering with National Disease Research Interchange (NDRI) and the MyLymeData Registry to collect tissue samples and detailed information from people with Lyme disease and other tick-borne infections. Lyme Disease Biobank's Tissue Collection Program is the only national initiative collecting tissue samples for Lyme disease research. LDB is a program of Bay Area Lyme Foundation, a national non-profit organization dedicated to making Lyme disease easy to diagnose and simple to cure.

What is NDRI?
The National Disease Research Interchange (NDRI) is a 501(c)(3) not-for-profit that provides human biospecimens to scientists studying a variety of diseases. NDRI was founded in 1980 by the mother of a child with diabetes who was frustrated by the lack of information about her son's condition and hoped for a cure. For 40 years, NDRI has been the nation's leading source of human tissues, cells, and organs for a wide range of scientific research. Committed to expanding the horizons of medical knowledge, NDRI has developed an unparalleled tissue recovery network, helping to fulfill the wishes of donors and their families.

What is MyLymeData?
MyLymeData is a patient registry and research platform that was developed and launched by LymeDisease.org. Over 17,000 patients have enrolled in the registry, which uses big data research tools to allow patients to pool their data quickly and privately to help find a cure. Patients interested in enrolling in the MyLymeData Patient Registry should visit MyLymeData.org.

Why has LDB partnered with NDRI?
NDRI has extensive experience collecting human biospecimens for scientists in academic, corporate and independent research organizations throughout the world. NDRI's biorepository facility is accredited by the College of American Pathologists (CAP), and the National Institutes of Health (NIH) has supported NDRI for more than 35 years. In addition, their tissue recovery network is extensive, allowing us to access medical facilities all over the country. NDRI is a trusted partner of more than 140 organizations.

Why is LDB collecting tissue?
Human tissue can help us understand the disease process and answer questions that cannot be answered in a test tube or an animal model. Tissue samples can also be used to identify biomarkers and further our understanding of infection and inflammation in Lyme disease. This program was created from a significant research need for tissue samples to advance the science around Lyme disease and other tick-borne infections.

How will you use the information I provided to MyLymeData?
By choosing to link your tissue sample with the clinical information provided to MyLymeData, researchers working with your sample may be able to obtain further insights to better understand this complex disease. In

addition, the Big Data collected by MyLymeData is helping to inform the first large-scale, patient-powered study of chronic Lyme disease, so you are able to assist even more researchers in their understanding of these complex diseases. All clinical information shared with researchers will be de-identified so your identity remains unknown.

What will happen to my tissue once it is donated?
Tissue will be sent to LDB's biorepository to be stored until it is distributed to researchers who are studying Lyme disease and other tick-borne infections. Researchers must apply to LDB to access tissue, and all applications will be reviewed and approved by LDB. These tissue samples will help researchers answer questions about the role of infection and the role of inflammation in people with Lyme disease and other tick-borne infections and help identify solutions for these diseases.

How will my sample be used?
Donated samples are made available to LDB-approved researchers studying Lyme disease and other tick-borne infections. At the time of the donation, LDB cannot predict which researchers will request tissues or what these researchers will be studying.

Will I receive any individual testing results?
Researchers who use LDB samples are not able to provide individual research results back to participants or families. LDB is able to provide you with a summary of the research being conducted, and we are greatly appreciative of your contribution to science.

How is the Lyme Disease Biobank Tissue Program funded?
The LDB Tissue Program is funded by the Bay Area Lyme Foundation.

B. General FAQs about the donation process

Why do donors participate?
The decision to participate and donate tissue is a very personal one for patients and families. Donating tissue is voluntary. Some patients and families feel that contributing to this vital research need is an opportunity to leave a meaningful legacy and improve the lives of people with Lyme disease in the future.

Who is eligible to donate tissue?
Individuals must be 18 years of age or older, reside in the continental US, and be diagnosed with Lyme disease by a health care provider. Additional information including medical history, Lyme disease testing results, and consultation with clinical experts will be part of the eligibility determination process.

What information do you request from me?
LDB will request the following information: medical history, social history, and Lyme disease specific information, such as symptoms, coinfections, laboratory testing results, other medical conditions, treatment information, and disease burden. Donors can also elect to enroll in the MyLymeData registry and connect their data with their tissue sample.

When do I need to update my health information?
After enrollment, it is important that you, or someone you have appointed, inform NDRI of any new medical conditions or significant changes in the original information provided. This includes chemotherapy/radiation treatments, surgeries, medications, or change in medical status (e.g., insulin requirement for diabetes). NDRI will follow up with you annually as well.

Do I need Lyme serology testing results?
Lyme serology tests are not required, but having access to the test results, along with clinical history, helps LDB evaluate eligibility.

What if I don't have a copy of my Lyme testing results?
If you do not have a copy of your Lyme testing results, you can request them from your provider or you can authorize NDRI to ask the lab or your provider for the results.

What happens once I complete the consent and medical forms?
When you complete the forms in this packet, someone from NDRI will contact you with additional information about the process and your future donation. When NDRI contacts you, please let them know of your current health status, as eligibility determination may take several weeks (or longer if additional information is requested). A member of the NDRI team will assist you throughout the eligibility process, as well as provide support through the donation process.

What happens if I am eligible to donate tissue?
NDRI will contact you about your eligibility. NDRI will maintain a registration list of individuals who are eligible to donate tissue. Once registered and eligible, NDRI will send you a donor card with your registration number.

What happens if I am not eligible to donate tissue to the LDB Tissue Program?
NDRI will contact you and ask about your interest in participating in other NDRI research programs.

Is there a cost to donate my tissue?
There is no cost to the donor/donor family for donating tissue after death (post-mortem) or from surgical procedures. However, the donor/donor family is responsible for any cost associated with the funeral or the surgery.

C. Surgical Donation FAQs

What surgical specimens are being collected?
LDB collects tissue leftover from surgeries, and currently has protocols in place for the collection of tissue from total knee or hip replacements. Other surgical collections may be considered on a case-by-case basis. Surgical donation must be arranged in advance of the surgery, ideally at least 1 month prior. If you have questions regarding other types of surgeries, please contact NDRI.

Can I donate tissue from a previous surgery?
No – we are unable to accept tissues from previous surgeries.

When should I contact NDRI about a surgical donation?

You should contact NDRI as soon as you decide to have surgery, even if the surgery date has not been scheduled. NDRI appreciates as much advance notice as possible to make arrangements for the tissue donation.

What information must I provide when calling with a pending surgery?
When calling with a pending or scheduled surgery, let the coordinator know where, when, and by whom the surgery will be performed. Contact information for the hospital and physician/surgeon will also be needed.

Do I need to have surgery at a certain facility or by a certain surgeon?
No. While you do not need to have the surgery at a certain facility or by a certain surgeon, you will need to inform your medical team of your plans to donate. You will also need to alert NDRI of the timing and location of your planned surgery, and the names of your medical team members.

You are not responsible for providing instructions to your medical team regarding the tissue collection nor are you responsible for shipping the donated tissue. The staff at NDRI will coordinate and work with your surgeon and hospital to receive your donation.

How is the hospital where my surgery takes place involved in my donation?
NDRI will work with the hospital or surgical center to facilitate the donation process. The hospital may require additional approvals from their administrative or legal departments prior to authorizing the release of donated samples. Since these approvals can take time, we ask that you let NDRI know as soon as you decide to have surgery. It is also important to let your medical team and the hospital know of your intention to donate.

D. Post-Mortem (after death) Donation FAQs

What tissues are being collected after someone has died?
LDB tissue collection includes neurologic tissue (brain, spinal cord, and nerves), cardiovascular tissue (heart and arteries), musculoskeletal tissue (muscle, cartilage, and synovial membrane), lymph nodes, liver, bladder, and spleen. Cerebral spinal fluid (CSF) and blood are also collected.

How will someone know, upon my death, that I want to donate to the LDB Tissue Collection Program?
Please make your family, doctors, caregivers, and attorney aware now of your registration with NDRI. At least one person should be designated as a contact for NDRI. This person will be responsible for notifying NDRI at the time of death, so that timely arrangements can be made for your tissue donation. NDRI will make every effort to facilitate the tissue donation pending the time frame and logistics. It is helpful to finalize these arrangements in advance, if possible, since rapid recovery of this precious gift is very important.

How much time does the NDRI need for notification of death?
As some fragile tissues, such as the heart, need to be recovered within a few hours after death, it is critical for your loved ones to notify NDRI as quickly as possible at the time of death, or in some cases, immediately prior to death at the direction of your care team. To help with this process, please be sure that the persons close to you or caring for you are aware of your wishes. Also contact NDRI if there are any significant changes to your health. Our staff are available 24-hours a day at 800-222-NDRI (6374).

How does the recovery process work?
NDRI will work with your family members, funeral director, hospital or nursing home staff to arrange for the transfer of the body, if applicable, and the tissue recovery at an appropriate location. Recovery takes about 4

hours and does not delay funeral arrangements. Most tissues need to be recovered within 12-24 hours of death.

Is the body transported to NDRI for the recovery of organs and tissues?
No, the recovery of tissues and organs is performed at your local hospital, funeral home, or other designated institute. It is helpful in the coordination of the donation to have permission from the hospital pathology department, the funeral director, etc. ahead of time. Please let NDRI aware of any imminent changes to your health status, therefore all parties would be notified, and a donation plan can be finalized.

Does NDRI dispose of the remains of the body?
No, NDRI arranges the recovery of tissues and organs for research, unlike medical institutions that use complete cadavers for instructional purposes. NDRI is not able to perform memorial, or burial services. Your family is financially responsible for these funeral arrangements and expenses. NDRI does NOT have a whole-body donation program.

Will the body be suitable for viewing and/or available for a timely funeral after donation?
Yes. A traditional, open-casket funeral service can still take place if many organs and tissues have been donated. Highly skilled professionals perform the recovery procedures, and the appearance of the donor is unchanged. You may indicate in the authorization form if you intend to have a viewing after donation, closed casket, or a direct cremation.

Does donating tissue for research prevent me from becoming a transplant donor?
No. If you are registered as an organ donor, you can still donate for research. NDRI works closely with eye, organ, and tissue procurement organizations to ensure that all organs needed for transplantation are retrieved first, and then non-transplanted donated tissues are utilized for research. The gift of life through organ and tissue transplant donation is one of the most precious gifts that someone can give. There are, however, instances when tissues and organs cannot be used for transplantation, but your donation can give hope and promise to medical research.

Will my religion support organ and tissue donation?
As with transplant and surgical donations, many faiths openly encourage it, and see this type of donation as a final act of giving and as an expression of hope. For further guidance, contact your religious leader.

For more information,
contact NDRI's Private Donor Program: (800) 222-NDRI (6374), Option 5 or
PrivateDonor@ndriresource.org or
visit www.ndriresource.org/lyme-disease