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## **LIFENET HEALTH'S RIGOROUS TISSUE SAFETY PROCESS**

Leading the Industry in Quality and Safety for More Than 35 Years.

## TISSUE ELIGIBILITY

### POTENTIAL DONORS

Federally-designated Organ Procurement Organizations (OPO) and qualified tissue recovery partners are made aware of potential donors. Our call center and recovery staff have 24 hour medical and technical assistance provided by a Medical Director. The goal is to identify potential medically-suitable donors.

### DONOR PROFILE

All tissue meets FDA, AATB and specific LifeNet Health standards. The final decision is determined by a LifeNet Health Medical Director or Recovery Team Member.

### CONSENT & AUTHORIZATION

If a donor meets all LifeNet Health's specific standards, the donor family is contacted regarding tissue donation.

### PAST MEDICAL HISTORY & CURRENT ILLNESS

The potential donor's medical history is reviewed for unacceptable conditions that can include cancer, diabetes, renal disease, CJD, or auto-immune diseases. LifeNet Health utilizes a medical conditions database of more than 1,100 diseases and medical conditions that affect donor suitability.

### REPORT BEHAVIORAL & SOCIAL RISK FACTORS

LifeNet Health reviews the medical history to determine if the donor's lifestyle included drugs, certain sexual behaviors, tattoos and other high-risk lifestyle qualifiers. LifeNet Health uses the Incidence-Window Period Model to determine the risk of recent infection undetectable by routine biologic testing.<sup>1</sup>

Not only does LifeNet Health hold the longest continuous accreditation from the American Association of Tissue Banks (AATB), we also have a comprehensive range of measures in place to ensure the safety of our allografts, including stringent donor screening methods. We utilize a multi-step process designed to assess risk of disease transmission. To obtain suitable donors, LifeNet Health maintains an extensive network of recovery partners.

LifeNet Health only accepts donors from federally designated OPOs and qualified tissue recovery partners. These partners are regularly audited to guarantee that their recovery process meets current U.S. Food and Drug Administration (FDA) regulations, AATB standards and LifeNet Health's own stringent guidelines. You can have confidence in the safety of LifeNet Health's allografts

## MEDICAL SUITABILITY

Once the initial screening and consent processes are complete, the potential donor is then recovered and reviewed using a stringent medical examination and screening process. Recovery technicians perform positive identification and review available medical documents. A physical examination of the deceased donor is administered prior to recovery. LifeNet Health has trained its recovery personnel as well as LifeNet Health partners' recovery personnel to take pictures and perform biopsies of any suspicious lesions to rule out occult cancer or systemic infections.<sup>2</sup>

Our testing procedures include tissue cultures, required FDA tests for HIV, Hepatitis, Syphilis, recovery biopsy results, and initial chart review. As risks arise, we exercise judgment to perform additional testing.

The first disposition of tissue rests in the hands of the Medical Directors and LifeNet Health's full-time, multi-disciplinary Medical Assurance Board. A Medical Director reviews the donor chart, the recovery record and autopsy results (when applicable). After a Medical Director releases a final review, an administrative review is performed, with all records cross-checked for completeness.

LifeNet Health uses proprietary and validated disinfection processes designed to minimize the risk of disease transmission.

Our Quality division personnel review all pertinent information on each donor's allograft gift (donor suitability, test results, final packaging, etc.). Allografts are released when all LifeNet Health's rigorous tissue safety processes are met.

### DONOR RECOVERY

### BIOLOGICAL TESTING

### DONOR SUITABILITY

### PROCESSING

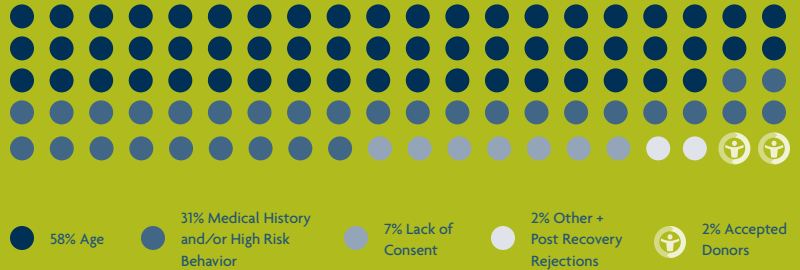
### FINAL REVIEW & RELEASE

1. The Incidence-Period Window Model and its Use to Assess the Risk of Transfusion-Transmitted Human Immunodeficiency Virus and Hepatitis C Infection. Kleinman, S., et.al. Transfusion Medicine Reviews, Vol. 11, No 3 (July), 1997: pp155-172.

2. Singh S, Blevins M, Wakeman M, Bergevin M. The Utility of Recovery Biopsies in Determining Donor Eligibility and Suitability. Presented at: American Association of Tissue Banks Annual Meeting. National Harbor, MD; September 2010.

# A PROVEN SCREENING PROCESS

LifeNet Health's guidelines for donor suitability are based on FDA requirements, AATB guidelines and applicable international criteria. When combined with LifeNet Health's proprietary and patented sterilization technology, aseptic recovery techniques, and donor screening process, these policies help to assure that only safe and effective tissue is released for transplantation.



**ONLY 2%** of total donors screened for transplantation are accepted by LifeNet Health.

## SPECIFIC SCREENING CRITERIA (INCLUDES ACTIVE AND HISTORY)

Infectious Diseases	AATB	FDA	EU
Chagas disease**	•	•	•
Ebola	•	•	•
Encephalitis	•	•	•
Epstein Barr virus/mononucleosis	•	•	•
Gonorrhea	•	•	•
Hepatitis B	•	•	•
Hepatitis C	•	•	•
Herpes	•	•	•
HIV 1/2	•	•	•
Infectious peritonitis	•	•	•
Infective endocarditis	•	•	•
Leprosy	•	•	•
Malaria	•	•	•
Meningitis	•	•	•
Mycosis	•	•	•
Polio	•	•	•
Rabies	•	•	•
Sepsis	•	•	•
Syphilis	•	•	•
Transmission spongiform encephalopathy (TSE)/CJD	•	•	•
Tuberculosis*	•	•	•
Vaccinia	•	•	•
West Nile Virus (WNV, 4 month exclusion from the time of onset)	•	•	•
Zika virus	•	•	•

Autoimmune Diseases	AATB	FDA	EU
Connective tissue disease	•		
Polyarteritis nodosa	•		
Rheumatoid arthritis (musculoskeletal deferral)	•		
Scleroderma	•		
Sjogren's disease	•		
Systemic lupus erythematosus (SLE)	•		
Systemic vasculitis	•		
Wegeners granulomatosis	•		

Neurodegenerative/ Demyelination Diseases	AATB	FDA	EU
Amyotrophic lateral sclerosis (ALS)/ Lou Gehrig's disease	•		
Dementia	•	•	•
Guillain-Barre syndrome	•		
Multiple sclerosis	•		•
Parkinson's disease	•		•
Unknown etiology	•	•	•

Inherited Diseases	AATB	FDA	EU
Ehlers-Danlos syndrome	•		
Marfan's syndrome	•		
Osteogenesis imperfecta	•		

High Risk Behavior	AATB	FDA	EU
Body piercing***	•	•	•
Chronic hemodialysis/peritoneal dialysis	•		
Crack cocaine	•		
Current or recent sexually transmitted disease	•	•	•
Gang member	•		
Heroin	•		
High risk sexual history	•	•	•
Homelessness	•		
Illicit drug use*	•	•	
IV drug use	•	•	•
Methamphetamine	•		
Recent vaccination with a live virus	•		
Tattoos***	•	•	•

Other	AATB	FDA	EU
Cancer	•		•
Clinically significant metabolic bone disease	•		
Clostridium difficile	•	•	
Sarcoidosis	•		

\*Constitutes a lifetime deferral by LifeNet Health.  
 \*\*Requires additional serology tests by LifeNet Health.  
 \*\*\*LifeNet Health exceeds AATB/FDA regulations by requiring a four month deferral.



LifeNet Health helps save lives, restore health and give hope to thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in allograft technologies and cellular therapies — a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

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