



---

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

Leading the Industry in Quality and Safety for Over 30 Years.

## TISSUE ELIGIBILITY

### POTENTIAL DONORS

Federally-designated Organ Procurement Organizations and qualified tissue recovery partners are made aware of potential donors. Our Call Center and Recovery Staff have 24/day medical and technical assistance provided by a Medical Director. The goal is to identify potential medically-suitable donors.

### DONOR PROFILE

All tissue meets the FDA, AATB and specific LifeNet Health standards. The final decision is determined by the LifeNet Health Medical Director.

### 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

LifeNet Health reviews the potential donor past medical history for cancer, diabetes, renal disease, CJD, auto-immune diseases as well as numerous other diseases and illnesses. LifeNet Health utilizes a medical conditions database of over 1,100 diseases and medical conditions that affect donor suitability.

### REPORT BEHAVIORAL & SOCIAL RISK FACTORS

LifeNet Health will review the medical history reports 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), but we have a comprehensive range of measures in place to ensure the safety of our allograft bio-implants, including stringent donor screening methods. We utilize a multi-step process designed to virtually eliminate disease transmission. To obtain suitable donors, LifeNet Health maintains an extensive network of recovery partners.

LifeNet Health only accepts donors from federally designated Organ Procurement Organizations and qualified tissue recovery partners. These partners are regularly audited to guarantee that their recover process meets current U.S. Food and Drug Administration (FDA) regulations, American Association of Tissue Banks (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 in a stringent medical examination and screening process. Recovery technicians perform positive identification and review available medical documents. A physical inspection 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>

Blood cultures, tissue cultures, required FDA tests for HIV, Hepatitis, Syphilis, Recovery Biopsy results, 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 Director and LifeNet Health's full-time, multi-disciplinary Medical Assurance Board. The Medical Director reviews the autopsy results, the donor chart and the recovery record. After the 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 virtually eliminate disease transmission.

Quality Assurance reviews 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.



LifeNet Health helps to 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 bio-implant 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.

1864 Concert Drive  
Virginia Beach, VA 23453  
Toll Free: 1-800-847-7831  
OUS: 757-464-4761

**[www.LifeNetHealth.org](http://www.LifeNetHealth.org)**

The LifeNet Health logo is a registered trademark of LifeNet Health, Inc.  
©2015 LifeNet Health. All rights reserved.

68-40-197 .00