



Bioethics policy for Lions World Vision Institute

Updated 2024

1. Purpose and Scope

Purpose

The primary purpose of this bioethics policy is to ensure that all activities related to the collection, storage, handling, and utilization of human tissues from deceased donors are conducted with the highest ethical standards. The policy aims to respect the dignity of the donors, protect their confidentiality, and ensure that their generous contributions to scientific research are used to advance medical knowledge and improve public health outcomes. This policy serves as a guide for all employees and affiliated researchers to adhere to ethical practices in the course of their work with the Lions World Vision Institute.

Scope

This policy applies to all aspects of research operations at Lions World Vision Institute, including but not limited to the procurement, documentation, storage, and distribution of human tissues from deceased donors for research purposes. It covers the responsibilities of Lions World Vision Institute staff, researchers, and any other personnel involved directly or indirectly with tissue handling and research. The guidelines outlined herein are intended to be comprehensive and apply to all current and future projects and activities involving deceased donor tissues at the institution. Compliance with this policy is mandatory for all staff and affiliated personnel, ensuring that every stage of Lions World Vision Institute, from donation to research adheres to ethical, legal, and professional standards.

2. Consent

Informed Consent Process

Informed consent is a cornerstone of our ethical practices, and the Lions World Vision Institute is committed to adhering to the tenets of the Declaration of Helsinki. For deceased donors, informed consent for persons making an anatomical gift in the state of Florida is covered under s. 765.512 and the mechanism for making an anatomical gift is covered under s. 765.514. This consent process involves providing clear, understandable information about the specific types of research that may be conducted with the donated tissues, including potential future research that may not yet be planned. Upon collection of tissue, Lions World Vision Institute becomes the donee of the anatomical gift except as provided by s. 765.517.

Documentation of Consent

Consent must be documented in a manner that is legally and ethically sound. In addition to the donor being identified as donor, as detailed in s. 765.514. Copies of the consent form will be kept on file at the Lions World Vision Institute.



Right to Withdraw Consent

Pursuant to s.765.512(7), and s.765.517 Lions World Vision Institute becomes the donee of the anatomical gift at the time of collection. Lions World Vision Institute may allow right to withdraw the gift on a compassionate basis but is not obligated to.

3. Donor Anonymity and Confidentiality

Ensuring Anonymity

To uphold the dignity and privacy of our donors, the Lions World Vision Institute is committed to maintaining strict donor anonymity. Once tissues are donated, all identifying information is removed and replaced with a unique code. This coding system prevents any direct association between donor tissues and personal information, ensuring that researchers and other parties involved in handling or studying the tissues cannot identify the donor. This practice is crucial to maintain trust in the donation process and to protect the privacy of donors and their families.

Data Protection and Security

The Lions World Vision Institute implements robust data protection measures to secure all personal and medical information related to donors. Access to identifiable information is strictly limited to authorized personnel who require it to perform their duties, and is protected by advanced security systems including encryption, access controls, and regular security audits. These precautions prevent unauthorized access and ensure compliance with relevant data protection laws and regulations.

Confidentiality Training

All staff members at the Lions World Vision Institute, including administrative personnel, researchers, and management, undergo comprehensive training on confidentiality and privacy protections. This training emphasizes the importance of respecting donor anonymity and outlines the procedures and behaviors expected of staff to safeguard this information. Regular refresher courses are provided to ensure that all team members remain aware of the latest protocols and ethical obligations regarding donor confidentiality.

Compliance with Legal Standards

The Lions World Vision Institute adheres to all national and international laws regarding the handling of personal and health information. This includes compliance with the General Data Protection Regulation (GDPR) in the European Union, the Health Insurance Portability and Accountability Act (HIPAA) in the United States, and other similar regulations globally. Regular reviews of compliance are conducted to ensure that our policies remain up to date with any changes in legal standards.



These measures collectively ensure that the Lions World Vision Institute upholds the highest standards of anonymity and confidentiality, protecting the privacy and dignity of donors while facilitating valuable medical research.

4. Ethical Review and Oversight

Institutional Review Board (IRB) Approval

We ask that outside research projects involving tissues from deceased donors must receive approval from an Institutional Review Board (IRB) or equivalent ethical review committee before commencement. Lions World Vision Institute has its own internal IRB for internal research projects and standing principles and directives that govern what research is acceptable with anatomical gifts. The IRB is responsible for reviewing the research proposals to ensure that they meet ethical standards, respect the dignity of the donor, and follow both the scientific and ethical guidelines established by the Lions World Vision Institute and regulatory bodies. This process includes evaluating the scientific validity of the study, the potential benefits and risks, and the consent procedures involved.

Regular Audits and Monitoring

To ensure ongoing compliance with ethical standards and operational integrity, the Lions World Vision Institute will conduct regular audits of all tissue collection, storage, and research activities. These audits are designed to verify adherence to the bioethics policy, assess the effectiveness of current practices, and identify areas for improvement. External auditors may also be engaged to provide an independent assessment of the Lions World Vision Institute's operations.

Ethical Training and Continuing Education

The Lions World Vision Institute is committed to providing continuous education on ethical issues related to tissue donation and research. All staff and affiliated researchers are required to participate in regular training sessions that cover ethical practices, recent changes in regulations, and case studies highlighting ethical dilemmas in tissue research. This training ensures that all personnel are equipped to handle ethical challenges and maintain high standards in their work.

Feedback Mechanism for Ethical Concerns

A formal mechanism is established for staff, researchers, donors' families, and the public to express any ethical concerns or grievances related to Lions World Vision Institute activities. This feedback mechanism is managed by an ethics officer or committee, who is responsible for addressing these concerns promptly and effectively. Ensuring an open and responsive communication channel reinforces the Lions World Vision Institute's commitment to transparency and ethical accountability.

5. Handling and Disposal of Tissue

Respectful Handling of Tissues

The Lions World Vision Institute is committed to treating all donated tissues with the utmost respect and dignity. This commitment extends throughout the entire process of handling—from



collection and storage to research use. Personnel are trained in specific protocols designed to minimize tissue damage and degradation while respecting the biological and symbolic significance of the tissues. These protocols are regularly reviewed and updated to align with best practices in tissue handling and to reflect advances in technology and methodology.

Ethical Disposal Protocols

When tissues are no longer needed for research, or when they are deemed unusable, it is essential that they are disposed of in a manner that is respectful and ethical. The Lions World Vision Institute follows stringent disposal protocols that are developed in consultation with bioethicists, legal experts, and in compliance with environmental and health regulations. These protocols ensure that tissue disposal minimizes environmental impact and upholds the respect owed to the donors. Methods such as incineration are carried out in facilities that adhere to the highest standards for environmental protection and dignity.

Documentation and Traceability

The Lions World Vision Institute maintains detailed records of tissue handling and disposal to ensure complete traceability from the point of donation to the final disposal. These records help to monitor the integrity of the tissues throughout their lifecycle and ensure that all procedures are performed according to the established ethical standards. Documentation also supports compliance audits and provides transparency for regulatory bodies and donor representatives seeking assurance of ethical practices.

Continuous Improvement and Policy Review

The Lions World Vision Institute commits to continuous improvement in handling and disposal practices. Feedback from staff, researchers, and external auditors is regularly solicited and used to refine and enhance the protocols. Additionally, the Lions World Vision Institute periodically reviews and updates its disposal methods to incorporate new ethical insights and technological advancements. This dynamic approach ensures that the Lions World Vision Institute remains at the forefront of ethical practice in the biomedical field.

6. Compliance with Legal and Ethical Standards

Adherence to Regulatory Requirements

The Lions World Vision Institute is committed to full compliance with all applicable legal and regulatory requirements at the local, national, and international levels. This includes adhering to laws and regulations pertaining to tissue donation, storage, research, and privacy such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States, the General Data Protection Regulation (GDPR) in the European Union, and other similar health and data protection laws worldwide. In addition, we adhere to the Good Tissue Practice (GTP) regulations established by the FDA for control of infections and contaminations. Regular audits are conducted to ensure ongoing compliance and to adapt to any legislative changes that might affect our operations.

Alignment with Ethical Guidelines



In addition to legal compliance, the Lions World Vision Institute adheres to ethical guidelines established by relevant professional and scientific organizations, such as the World Health Organization (WHO) and the International Society for Biological and Environmental Repositories (ISBER). These guidelines provide a framework for conducting Lions World Vision Institute research activities in a manner that respects the dignity of donors, protects their privacy, and considers the welfare of society. The Lions World Vision Institute's ethics committee regularly reviews these guidelines to ensure that our policies and procedures are aligned with the best practices in the field.

Training and Awareness Programs

To support compliance with both legal and ethical standards, the Lions World Vision Institute invests in comprehensive training and awareness programs for all staff members. These programs cover the legal responsibilities and ethical obligations of handling donor tissues, including updates on any changes in relevant legislation or ethical standards. By fostering a culture of compliance and ethical awareness, the Lions World Vision Institute ensures that all team members are knowledgeable and capable of upholding our high standards.

Transparent Reporting and Accountability

The Lions World Vision Institute maintains a transparent reporting system to document compliance efforts and to address any deviations from legal or ethical standards. This system allows for accountable governance and provides a clear record of compliance for regulatory bodies, donor families, and the public.

7. Conflict of Interest

Identification and Disclosure

The Lions World Vision Institute requires all employees, researchers, and board members to proactively disclose any potential conflicts of interest that might influence their duties or decisions related to Lions World Vision Institute activities. This includes financial interests, affiliations, and relationships that might appear to impact their impartiality. A formal declaration of interest must be completed annually, or more frequently if new potential conflicts arise. The Lions World Vision Institute ensures that these disclosures are maintained in a confidential database, accessible only to the ethics committee or designated compliance officers.

Management and Resolution

Upon disclosure of a potential conflict, the ethics committee is responsible for evaluating the situation and determining an appropriate response. Options may include reassigning responsibilities, monitoring the conflicted individual's involvement in specific projects, or requiring divestment from conflicting interests. The primary goal is to manage, reduce, or eliminate any influence that could compromise the integrity of the Lions World Vision Institute's operations or the validity of its research outputs.

Training and Guidelines



The Lions World Vision Institute provides comprehensive training on conflict-of-interest policies to all new hires and offers ongoing education for all staff. These training sessions help clarify what constitutes a conflict of interest, how to disclose it, and the steps the institution takes to manage conflicts. Clear guidelines and examples are provided to ensure that all staff understand their ethical obligations and the importance of maintaining trust in the integrity of the Lions World Vision Institute.

Transparency and Oversight

To maintain public trust and accountability, the Lions World Vision Institute commits to transparency in its handling of conflicts of interest. This transparency reassures donors, research participants, and regulatory bodies that the Lions World Vision Institute operates with integrity and ethical rigor.

8. Communication and Public Engagement

Transparency in Operations

The Lions World Vision Institute is committed to maintaining a high level of transparency in all its operations. This includes regular updates on research activities, achievements, and breakthroughs made possible by tissue donations. Information is communicated through various channels such as the Lions World Vision Institute's website, annual reports, newsletters, and public forums. Each communication is designed to provide clear, accessible information to the public, ensuring that the community is well-informed about how donated tissues are used and the benefits they bring to scientific research and public health.

Public Involvement and Feedback

Engaging with the community and incorporating public feedback are fundamental aspects of our operational ethos. The Lions World Vision Institute seeks public feedback through our foundation to gather input and discuss ethical considerations with community members. These interactions help to align our research activities with public expectations and foster a collaborative environment.

Educational Outreach

The Lions World Vision Institute undertakes educational outreach programs aimed at increasing public awareness about the importance of tissue donation and the ethical practices that govern our work. These programs target schools, universities, healthcare providers, and community groups, offering presentations, workshops, and informational materials that demystify the processes and benefits of tissue donation. By educating the public, we aim to dispel myths, address concerns, and build a supportive community for biomedical research.

Crisis Communication

In the event of a crisis or significant issue related to Lions World Vision Institute operations, the Lions World Vision Institute has a crisis communication plan to address public concerns promptly and effectively. This plan ensures that accurate and timely information is provided to the public, preventing misinformation and maintaining trust. The communication strategy involves



coordination with health authorities, media, and other stakeholders to ensure unified and factual dissemination of information.

9. Training and Awareness

Comprehensive Training Programs

The Lions World Vision Institute commits to ensuring that all employees, from administrative staff to senior researchers, receive comprehensive training on ethical practices, bioethics policies, and regulatory compliance. Training programs are designed to cover a wide range of topics, including donor consent, confidentiality, handling and disposal of tissues, and conflict of interest management. These programs are mandatory and are conducted during onboarding, with refresher courses provided annually or more frequently as needed to address updates in policies or regulations. Interactive workshops and scenario-based learning help to reinforce key concepts and ensure staff are well-prepared to uphold our ethical standards.

Awareness Campaigns

To foster a deeper understanding and appreciation of the role of tissue donation in advancing medical research, through our foundation the Lions World Vision Institute initiates awareness campaigns targeting both the public and specific groups such as potential donors and their families. These campaigns use various media, including social media, print brochures, and community presentations, to disseminate information about how donated tissues are used, the safeguards in place to protect donor information, and the impact of donations on medical research. These efforts aim to demystify the processes involved and encourage more informed discussions about tissue donation.

Continuous Professional Development

Recognizing that ethical standards and legal requirements can evolve, the Lions World Vision Institute supports continuous professional development for its staff. Supporting ongoing education not only keeps the staff up to date with the latest developments but also reinforces the Lions World Vision Institute's commitment to excellence and ethical compliance.

10. Continuous Improvement

Regular Policy Review

The Lions World Vision Institute is committed to the principle of continuous improvement in all its operational and ethical practices. To this end, the bioethics policy is subject to regular review and revision at least once every two years, or more frequently if significant changes in the regulatory landscape or in best practices occur. These reviews are conducted by an ethics committee that includes ethicists, legal experts, medical professionals, and community representatives. The aim is to ensure that the policy remains relevant, effective, and aligned with the latest ethical standards and societal expectations.

Feedback Mechanism



An integral part of our continuous improvement process is the feedback mechanism established to gather input from various stakeholders including staff, researchers, donor families, and the public. All feedback is reviewed by the ethics committee, and where applicable, is used to inform changes to policies and practices. This open loop of communication ensures that the Lions World Vision Institute remains responsive to concerns and ideas from its community.

Quality Assurance and Benchmarking

The Lions World Vision Institute engages in regular quality assurance activities, including internal audits and participation in external benchmarking with peer organizations. These activities help identify areas for improvement in tissue handling, storage, and research practices. By comparing operations with industry standards, the Lions World Vision Institute can adopt best practices and innovate processes to enhance the quality and safety of its operations.

Training and Development

Continuous improvement also extends to the development of our staff's capabilities. The Lions World Vision Institute invests in ongoing training programs that focus on emerging trends in bioethics, new technologies in tissue preservation and research, and changes in the legal environment. These training sessions ensure that staff are not only compliant with current standards but are also forward-thinking in their approach to bioethics at the Lions World Vision Institute.