Cell Tissue Bank
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Linking organ donors and the medical/scientific research community: a US perspective

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Abstract The International Institute for the Advancement of Medicine (IIAM) provides non-transplantable organs and tissues for medical and scientific research, education, and drug & device development. The benefits of using human organs and tissues for research are vast, and donating for research provides donor families with a valuable option if their loved one's organs are unsuitable for transplantation. The use of these organs and tissues enables the faster development of more efficacious drugs with improved safety profiles, and enhanced understanding of basic disease processes that directly affect humans. Human organs and tissues offer unique advantages over the use of animal organs and tissues as it is human diseases and conditions which we seek to treat, and so logically the results can be more directly applied. The added advantage of accessing non-transplantable, human organs is that they are in superb condition, and so experiments can be conducted in a very physiologically-relevant system. Although the US is a sizeable country with a large population and individual regulations governing human tissue collection and usage for each of the 50 states comprising the US this article will discuss how IIAM succeeds in immediately linking organ donors and qualified researchers, ultimately to the great benefit of patients.

Keywords Non-transplantable organs · Consent · Medical research · Organ and tissue donation

About IIAM

The International Institute for the Advancement of Medicine (IIAM) is a link between the organ donor and medical/scientific research communities. It is only through an intimate understanding of each community's needs, and close collaboration with all stakeholders/participants, that the system can work across a country of vast distances and with a large and diverse population, governed by regulations unique to each of the 50 states.

IIAM is one of the world's largest providers of non-transplantable organs and tissues for research, supplying qualified researchers in academia (39%) and industry (61%) with high quality, healthy and diseased tissues that are authorized for research purposes.

IIAM operates within the established network of organ procurement organizations (OPOs) for transplantation. Key factors in our success are our ability to operate on the same timetable as the OPOs—24/7, and the OPOs' commitment to obtain consent and recover organs for research in addition to their responsibilities for transplantation.

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About the organs

Non-transplantable organs for research experience virtually no warm ischemia, and minimal cold ischemia: 12–24 h to courier the organs in a preservation medium directly from the Operating Room (O.R.) to the researcher's lab. With full access to the donor's medical chart, IIAM can relay all pertinent information about the donor without compromising their anonymity. Organ recovery for research and transplantation is performed simultaneously, resulting in extremely high quality organs being recovered for research. These provide unique opportunities to study human physiology in as physiologically relevant a system as possible.

About the researchers

All researchers must complete and receive approval of a Biomaterial Transfer Agreement (BMTA) demonstrating medical and/or scientific merit, and constituting an appropriate use of human tissue for research. The tissue must also be feasible to recover: e.g. cancerous tissues are not available since donors with active cancer are excluded from donation for transplantation.

The BMTA is reviewed both internally and externally; approval takes 1–2 weeks whereupon the researcher is entered into IIAM's placement rotation. Where there is a question about the research purpose, the BMTA may also be reviewed by the Ethics Committee, comprising an ethicist, donor family members, and several OPO and Tissue Bank Directors. Additionally, IIAM ensures donor protection by means of a Donor Family Council that reviews research studies from the standpoint of donor advocate, and an External Review Committee that assesses BMTA's from a medical perspective.

The process

When a potential organ donor for transplantation presents, hospitals inform their local OPO, who reviews the clinical information and speaks with hospital staff about facilitating the examinations for brain death and serological testing.

If the patient's prognosis is near or at death which can include brain death and cardiac death, and within the hospital's protocol, the OPO coordinator and/or hospital staff will speak with the patient's family. At this time, the family is presented with options including donation for transplantation and research.

Upon receiving consent, the OPO will contact IIAM with the organ referral for research. When screening the referral, IIAM must first ask if consent for research has been granted and documented in writing, whereupon they can proceed in asking about any consent restrictions, which may include but are not limited to: For-Profit companies, international end-users, and cosmetic use.

Barring any restrictions, IIAM then contacts researchers, both domestic and international, whose criteria (including organ type, medical and social history, cause of death, serological results, anticipated ischemic time prior to delivery, etc.) match. If a researcher accepts the referral, IIAM provides the recovery team with the researcher's protocol, and arranges for courier collection and delivery. OPOs do not recover organs for research without a confirmed placement outcome.

Consent and legislative bodies

Each of the 58 OPOs across the US operate under standards established by the Centers for Medicare/Medicaid Services (CMS) and the United Network of Organ Sharing (UNOS), and in accordance with each state's Uniform Anatomical Gift Act (UAGA). OPOs are closely monitored for every organ recovered to ensure proper authorization, recovery and allocation. Each OPO operates under its own Standard Operating Procedure (SOP) to obtain consent. These SOPs must conform to each respective state's UAGA as well the policies of each individual hospital such as brain death declaration.

Significantly, in 2007 a new measurement pertaining to organs placed for research was implemented by CMS, a division of the federal government's Department of Transplantation which oversees all matters related to transplantation. CMS subsidizes the overall operations of the OPOs. CMS reimbursement to OPOs is contingent upon successful outcomes of the CMS guidelines. To demonstrate the impact of this new measurement, IIAM has seen a 189% increase of

organ referrals for research since 2006; this year IIAM is on track to receive over 11,000 referrals for research.

Lessons learned from the US experience

It is possible to work across distances, populations and regional regulations to accommodate the specific needs of diverse researchers who have a multitude of tissue criteria including: donor age, race, gender, disease state, medical/social history, etc., all with the presence of dedicated staff cognisant of the needs of the communities they serve.

Invaluable information leading to the prevention of, and cures for, human diseases have been uncovered through the study of human organs and tissues for research while at the same time saving an infinite amount of time, effort, money and risk on unsuccessful trials with animals.

We are most thankful to the donors and donor families of organs and tissues for research; they epitomize the meaning of "altruism", and to the researchers who so diligently work to discover cures and treatments for human diseases.