



The Organization for Transplant Professionals

NATCO, THE ORGANIZATION FOR TRANSPLANT PROFESSIONALS POSITION STATEMENT

NATCO STATEMENT ON XENOTRANSPLANTATION

STATEMENT OF THE PROBLEM:

NATCO recognizes the continuing shortfall of human donor organs for transplantation. Even with the use of living donation, the need for organs still exceeds the supply. Xenotransplantation, the transplantation of an organ from one species [animal] to another species [human] is a future possibility, yet it has many risks and unknowns.⁽¹⁾ At this time, it cannot be offered to patients as a clinical therapy, but rather only researched as an experimental technology. NATCO supports this research amid a defined program that follows ethical and regulatory guidelines.

POLICY:

NATCO supports clearly defined guidelines⁽²⁾ for the experimental use of cloned or uncloned animals for xenotransplantation. The following fundamental conditions must be employed:

- Concern for the well being of genetically modified animals must be guaranteed and the levels of stress, pain, suffering and anxiety of these animals limited.
- Consideration must be given to the potential effects of the xenotransplantation process on the animal's offspring as well as other conceivable repercussions.
- Constant supervision and herd management of the involved animals must be maintained and the animals kept quarantined.
- Quotas for the number of animals used in xenotransplantation studies must be kept to a reasonable minimum.
- Recovery of any animal organs must take place during a single operation in a proper surgical setting using anesthesia.
- Regulatory requirements for multi-disciplinary research ethics committee oversight of experimental xenotransplantation protocols must be followed.
- All research and animal care must be undertaken by personnel who are appropriately trained.
- Veterinary care must be available to all animals and a licensed veterinarian must be available. All such care must be thoroughly documented.
- The research team must use timely and compassionate euthanasia techniques.
- Because of the potentially serious public health risks of possible zoonotic infections, xenotransplantation should be limited to patients with serious or life-threatening diseases for whom adequately safe and effective alternative therapies are not available except when very high assurance of safety can be demonstrated. Patients should have the potential for a clinically significant improvement with increased quality of life following the procedure. The patients should also have the ability to comply with public health measures as stated in the protocol, including long-term

monitoring. At this time, xenotransplantation should not be promoted as a cure for any ailment, symptom or disease, but rather it is an experimental technology.

- Patients undergoing xenotransplantation (or their surrogates) must provide written informed consent. The information discussed during the consent process must include life-long surveillance, zoonotic risks, as well as, behavioral modifications (e.g., advice on the use of barriers to transmission of infectious agents during sexual activity and the use of appropriate precautions for nonsexual contacts.)
- All clinical xenotransplantation procedures should be performed in transplant centers with appropriate experience and expertise for comparable allotransplantation procedures and with the capability to culture and to identify viral agents using in vitro and in vivo methods either on-site or through active and documented collaborations.
- NATCO has concerns regarding the possible transmission of disease from animal populations to humans. The health of the animal caretakers and research personnel must be routinely monitored. The health of the organ recipients and their intimate contacts must also be monitored.
- Clinicians and researchers have an ethical responsibility to report infectious [zoonotic] and other serious complications to the appropriate regulatory authorities as well as the patient (or their surrogate) in a timely manner.
- Xenotransplant recipients have an ethical obligation to maintain contact with their transplant provider for the purpose of life-long health surveillance.

REFERENCES:

1. Bramstedt KA. Arguments for the ethical permissibility of transgenic xenografting. *Gene Ther.* 2000 Apr;7(8):633-4.
2. United States Food and Drug Administration. Guidance for Industry Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans. April 2003. Available on-line at <http://www.fda.gov/cber/gdlns/clinxeno.htm>.