

# EXECUTIVE SUMMARY

## Informing Ethical Translation of Xenotransplantation Clinical Trials

■ Karen J. Maschke, PhD  
The Hastings Center for Bioethics

■ Elisa J. Gordon, PhD, MPH  
Vanderbilt University Medical Center

■ Michael K. Gusmano, PhD  
Lehigh University

**Background:** The United States has a shortage of human organs for transplantation. For years, xenotransplantation—transplanting organs from nonhuman animals into humans—has been proposed as a strategy to alleviate the scarcity of human organs. We conducted a four-year study that examined ethical and policy challenges to the development, oversight, and conduct of first-in-human pig kidney xenotransplant clinical trials (henceforth pig kidney clinical trials).

**Purpose:** The multi-site study was designed to engage key stakeholders—including kidney patients waitlisted for a human kidney, transplant clinicians, and human subjects research experts—to assess their perceptions of ethical and policy challenges to conducting a pig kidney clinical trial. Engagement activities included conducting: in-depth interviews with 28 kidney patients; an online survey of 142 kidney patients; in-depth interviews with 28 transplant experts; and in-depth interviews with 23 chairs of Institutional Review Boards (IRBs) and other research ethics experts.

**Practical Tools:** The findings from data collection—along with input from our Ethics and Policy Advisory Committee that included allotransplant recipients and a living kidney donor—informed the development of several practical tools:

- A [decision-aid](#) to support kidney patients' decisions whether to enroll in a pig kidney clinical trial.
- An [informed consent prototype](#) that addresses kidney patients' information needs about a pig kidney clinical trial to support patient-centered informed consent for clinical trial participation.
- [Case studies](#) to help transplant teams reflect on ethical issues about pig kidney clinical trials to help them become better prepared to conduct such trials.
- A [checklist](#) to assist IRB members to review research study protocols and informed consent forms for pig kidney clinical trials.
- [Ethics and policy recommendations](#) about the ethical translation of pig kidney clinical trials.

**Publications:** To date, we published 4 papers. One peer-reviewed paper was published in *The American Journal of Transplantation* about ethical considerations for heart and lung xenotransplant research. Three peer-reviewed papers were published in *Xenotransplantation* about: [patients' decision-making](#) about enrolling in a pig kidney clinical trial; [patients' information needs](#) for considering whether to enroll in a pig kidney clinical trial; and ethical issues regarding [patients' voluntariness](#) to participate in a pig kidney clinical trial. We published an [Op-Ed in the Washington Post](#) in 2022 following the first pig heart xenotransplant in which we called for an urgent look at the ethics and policy implications of xenotransplantation.



**Presentations:** We gave several paper and poster [presentations](#) at professional meetings of the American Transplant Congress and the American Society for Bioethics and Humanities. We also created and presented two Collaborative Institutional Training Initiative (CITI) webinars on: research and clinical ethics considerations for pig kidney clinical trials; and the ethical and policy challenges of performing xenotransplants under the FDA's Expanded Access/Compassionate Use program.

The study was supported by an award from the National Center for Advancing Translational Sciences of the National Institutes of Health (R01TR003844) to Karen J. Maschke, The Hastings Center for Bioethics; Michael K. Gusmano, Lehigh University; and Elisa J. Gordon, Vanderbilt University Medical Center, multiple Principal Investigators.

© 2025 The Hastings Center