

United States Code, 2019 edition
Title 42 - Public Health & Welfare
Presented by the Senate Committee on Public Health
Codified by Senators Haleh Mawson, Irika Sinha, & Priya Uppal

Equitable Porcine-Human Kidney Modification & Transplantation Act

THE CONGRESS OF THE UNITED STATES

MAY 21st, 2019

Section 1.1 - Preamble:

The Congress finds that:

According to the United Network for Organ Sharing (UNOS), there are about 93,000 people who need kidney transplants in the Nation. This national agency which governs transplants in the Nation also maintains all other organ transplant waiting lists, of which the list for a kidney is the longest. It is over 6 times as long as the list to receive a liver and 24 times as long as the list to receive a heart. The time to receive a human kidney on the waitlist is projected to exceed a decade. CRISPR is a new technology that can be used to grow human kidneys in modified pigs to address this need. That said, there is currently little regulation governing the CRISPR process, rendering Federal intervention essential.

Section 1.2 - Introduction:

Given that the people of this Nation:

- (1) need to begin safe kidney transplants when necessary as soon as possible, to ensure national good health;
- (2) believe black market sales of organs are a serious threat to national health and safety, and are encouraged by the current paucity of legal kidney transplantations; and
- (3) Current dialysis treatment for those on the waitlist is expensive and requires frequent treatment, costing the Nation as a whole,

We propose that CRISPR technology be used in pigs to grow human kidneys and that the following legislation govern funding, research, and its procedures. Pigs are the ideal organism to grow kidneys intended for human transplantation in, given that pigs can reach sexual maturity in only five through six months, at which time we will assume that we can harvest fully grown human kidneys. Pigs are also large enough to grow appropriately sized organs for humans, which would contribute to the success of growing human kidneys in pigs. Furthermore, already “heart valves from pigs are used to replace diseased or damaged ones from people” across the country and this process has have been successful thus far. This indicates that pursuing further research into the possibility of growing entire human kidneys in the pigs may also be successful. CRISPR will be used to alter the pig’s immune system allowing for human tissue to be implanted in the fetal pig, allowing the kidney to later be accepted by human immune systems. The resulting human kidney would grow in the fetal pig and be harvested for transplant upon maturity, with the pig sacrificed through euthanasia in the process and safely discarded as biohazardous waste. This research requires Federal regulation and funding because:

- (1) The Nation needs a consistent and persistent supply of funding dedicated to this research to ensure it is completed in a timely manner;
- (2) The research must be done by leading facilities and experts across the country to ensure efficacy and safety of this technique; and
- (3) The research must be done in such a way that pig and human lives are not mistreated in the research process.

Section 2.1 - Governing Bodies:

(1) Let it be known that funding will be Federally regulated through the National Institute of Health (NIH), which is under the jurisdiction of the United States Department of Health. US researchers

and labs can apply for grants to pursue this research and will be approved for funding based on an objective review by the NIH of their proposal.

Section 2.2 - Funding:

(1) Research into this technique will be allocated 10 percent of the Federal funding estimate for organ transplants by the NIH. In 2018 total funding for organ transplant will amount to 16.7 million USD. This funding will go in full to research until successful clinical trials have been completed. A successful clinical trial entails a six-month period without rejection of the transplanted kidney, and will follow standard clinical trial protocols, including being approved by an Institutional Review Board (IRB). Patients will be monitored for at least one year more. At this time, research will receive a diminishing proportion of total funding each year, with funding transferred to Medicare and Medicaid to pay for kidney transplants using this technique, given that current true cost per transplant is over 250,000 USD. The funding for research will decrease by 2 percent each year after a successful clinical trial, until it reaches half the amount of original allocated funding. At this point, the amount of funding for research and towards transplants will be equivalent. Beyond this, clinical trials and their procedures fall outside the scope of this law and their funding will not be addressed herein. The end of this grant opportunity will be determined in the future and not by this law.

(2) An annual number of 9,300 pigs will be born for the purposes of growing human kidneys, calculated as 10% of the total number of people on the waiting list for human kidney currently, as of 2018. The percentage of pigs used in research will remain constant, or decrease as needed in accordance to the decrease in research funding. Each grant will be, at maximum, 500,000 USD.

Section 2.3 - Clinical Trials:

(1) Clinical Trial subjects will be chosen based on their position on the UNOS list, which includes both citizens and non-US citizens in the US. Patients with a higher listing and no other major complications will be asked first to participate in clinical trials. A subject has the ability to deny research participation and remain on the waiting list to receive a human kidney, in which case the next person on the list will be asked if they would like to participate. The process will be repeated until enough patients have agreed to participate. Citizenship status will not be considered when selecting subjects.

Section 3.1 - Grant Eligibility:

(1) Principal investigators (P.I.s) and investigators with experience in independently setting up projects who belong to U.S. institutions and complete research in the U.S. are eligible to apply. There is no limitations on lab demographic; the P.I. or investigator may choose workers as he or she sees fit. Funds should be requested to directly support research on pig kidney transplants and may be used only for valid research expenses which include, but are not limited to, data collection, specialized research equipment, and the creation of kidneys within pigs. Funds are to be used exclusively for the actual conduct of research. Proposals will be reviewed by the NIH and be subject to the grant review process already in place.

Section 4.1 - Scope of Law:

(1) Let it be known that the capabilities of CRISPR technology are limitless, and this law serves only to govern research of using CRISPR to modify kidneys for human transplant using pigs as the medium.

(2) All other research into using CRISPR to modify other organisms for transplants, or into transplantation of organs other than kidneys, will be subject to a moratorium until the efficacy of

human-porcine transplants is proved beyond reasonable doubt, at which point the matter will be reviewed and this law taken as a template. Enforcement of the moratorium will be outlined in subsequent legislations during this session of Congress.

Sources

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