

Novartis Position on Ethical Principles for Transplantation Studies

GPP 202.V1.0.EN

The mission of Novartis is to discover new ways to improve and extend people's lives. Using science-based innovation, Novartis delivers better outcomes for patients and addresses the evolving healthcare needs of society.

For more than 30 years, Novartis has placed a high priority on developing medicines to protect and extend the lives of organ transplant recipients. Transplant physicians, patients and families alike recognize our pioneering in immunosuppressive therapies as essential components in the "gift of life".

It is encouraging that advances in surgical techniques, immunosuppressive drugs and supportive medical care have greatly increased the success of organ and tissue transplantation in recent decades. However, the supply of solid organs for transplantation does not match the demand for them, and is not expected to do so in the foreseeable future. Donation and procurement of solid organs and tissue raises a number of ethical challenges and concerns with the issue of obtaining the donor's (or next of kin/ other authorized representative) informed and non-coerced consent being paramount amongst them. The question at stake is what principles need to be applied in the conduct of clinical trials in response to the ethical challenges in organ transplantation.

Novartis Position

Novartis, as a study sponsor, consistently adheres to [Good Clinical Practices](#). The implementation of this set of standards provides public assurance that the rights, safety and well-being of trial subjects are protected (including review and oversight by independent ethical board/committee, and the ability for the sponsor and concerned Health Authorities to perform audits/inspections).

Specifically, when conducting clinical trials in transplantation, Novartis upholds the principles outlined in:

- The [Declaration of Istanbul](#): a Transplantation Society sponsored initiative prohibiting transplant commercialism, organ trafficking and transplant tourism,
- The World Health Organization statements on "[Human Organ and Tissue Transplantation](#)" which urge member states specifically to protect the poor and vulnerable from transplant tourism and sale of tissues and organs, and in
- The Organ Procurement and Transplantation Network report on "[Ethical Principles in the Allocation of Human Organs](#)" which defines the foundational ethical principles that create a framework for the equitable allocation of organs for transplantation.

Novartis does not sponsor or otherwise support any clinical studies which do not follow the standards and principles outlined in the above documents and which may be linked to organ transplant commercialism, organ trafficking and/or transplant tourism.

In a broader context:

- Novartis supports ethical, legal and non-commercial efforts to promote organ donation and specifically condemns all practices for obtaining human organs that do not follow these principles.
- Novartis supports organ donation by living donors as an acceptable means to alleviate the shortage of deceased donor organs available for transplantation, provided the highest standards of protection for the health and human rights of organ donors are preserved.

Last updated on Feb 2017