

Policy on Stem Cell Research and Development

Background

Stem cell research and development has demonstrated significant progress in recent years. It is anticipated that achievements in this field will contribute to the development of new therapies for serious diseases that were previously untreatable.

Stem cells are the cells that not only have the potential to self-renew but also to differentiate into a wide variety of cells that form tissues and organs of the body (an ability called multipotency). In the adult body, stem cells function as a repair system to replenish tissues for the maintenance of homeostasis. Given their unique regenerative ability, stem cells offer potential to serve as research tools in drug discovery. In addition, stem cells or stem-cell-derived cells can be utilized directly as therapeutic agents, thereby opening a new field in medicine — cell therapy.

Policy

Astellas is investigating the use of stem cells as therapeutic agents and believes that they have the potential to address previously untreatable diseases.

Although promising, we fully recognize that ongoing research with human stem cells may give rise to sensitive issues. We are especially cognizant of the social and bioethical concerns surrounding research with human embryonic stem (ES) cells.

Accordingly, this policy states our policy regarding human stem cell research and development activities. This policy applies to research and development activities performed by Astellas as well as work done in collaboration with other institutions.

- 1. All stem cell research and development activities will comply with the applicable laws and regulations of the countries or regions in which they are conducted.
- 2. A committee consisting of internal and external experts will oversee the ethics and scientific rigor or merit of human stem cell research and development activities. Research and development proposals will be reviewed and approved to ensure these activities are conducted ethically and for appropriate scientific purposes.
- 3. Regarding human ES cells, we will use only those cell lines that meet the ethical standards set by leading scientific authorities around the world, for example, the Guidelines developed by the National Academy of Sciences in the USA.



Astellas will neither utilize human stem cells for human reproductive cloning nor endorse or support any such efforts.