

Basic ethical policy on the handling of human tissue and cells in research and development

Japan Tissue Engineering Co., Ltd.

1. Purpose

“Basic ethical policy on the handling of human tissue and cells” (hereinafter referred to as “this basic ethical policy”) stipulates the matters with which our company must comply in research activities and product development (hereinafter referred to as “R&D”) of regenerative medical products using human tissue and cells (hereinafter referred to as “human tissue, etc.”) from an ethical viewpoint.

Our company has established and complies with this basic ethical policy in order to ensure respect for the goodwill of donors of human tissues, etc., protection of their personal information, and occupational safety for workers in the spirit of maintaining human dignity and respect for human rights.

The R&D referred to in this basic ethical policy does not include clinical trials. Moreover, the human tissue, etc. that is referred to in this basic ethical policy does not include commercially available human tissue, etc.

2. Responsibilities as a corporation

Our corporate philosophy is to “contribute to improved quality of life for patients through industrialization of regenerative medicine”. By fulfilling the following responsibilities in R&D using human tissue, etc., we are sincerely accepting and responding to the demands and expectations of society.

1. We ensure the human rights and safety of donors by conducting R&D using human tissue, etc. in compliance with laws, ordinances, and related standards.
2. We show respect for the goodwill of donors and endeavor to recycle the goodwill of donors back into society through R&D using human tissue, etc.
3. We make efforts to spread information on R&D using human tissue, etc. so as to gain the understanding of society.
4. We strive to ensure occupational safety through a facility environment that gives consideration to biosafety while at the same time preventing contamination from the external environment.

3. Role of the Ethics Committee

We have established an ethics committee (hereinafter referred to as the “J-TEC Ethics Committee”) in order to develop our business in a manner consistent with socially accepted standards, including ethical values, and we respect the opinions of the committee.

The J-TEC Ethics Committee reviews the ethical validity of this basic ethical policy and the company’s research plans, etc., and confirms that R&D is conducted in compliance with this basic ethical policy.

4. General principles in the handling of human tissue, etc.

1. Explanations for donors
We ask the medical institution that collects human tissue, etc. from the donor (hereinafter referred to as the “collection facility”) to obtain advance consent for donation of human tissue, etc. from the donor or from a legal representative* if it is difficult for the donor to give informed consent, after providing a sufficient explanation of the necessary matters.
2. Respect for free will
We show the greatest respect for the free will of the donor when obtaining consent for donation of human tissue, etc.**

3. Principle of uncompensated donation

As in blood donation, human tissue, etc. is donated out of goodwill, and the donor does not profit from donation.

4. Limitations on purposes of use

Use of human tissue, etc. is limited to the purpose that was explained to the donor in advance, and it is not appropriated to other purposes.

5. Revocation of consent

Within the time window during which revocation of consent is possible, donors can still revoke consent even after donating human tissue, etc.** If the donor revokes consent, we will dispose of the donated human tissue, etc., appropriately. However, results that have already been obtained cannot be destroyed.

<Note>

*The legal representative is the person who is judged most capable of representing the wishes and interest of the donor, and it may be a person with parental authority, a spouse, a guardian, or other similar party.

**Persons who do not consent to donation of human tissue, etc. and donors who revoke consent will not be disadvantaged in medical treatment.

5. Acceptance of human tissue, etc.

We accept surgically* removed unnecessary human tissue, etc. from collection facilities that meet the following conditions.

1. Have facilities and equipment suitable for collection of human tissue, etc.
2. Have personnel capable of properly harvesting human tissue, etc.
3. Have a system for reviewing donations of human tissue, etc. (hereafter referred to as the “external ethics committee”), which has confirmed the ethical validity of research plan, etc. When review by an external ethics committee is not possible, the plan is reviewed by the J-TEC Ethics Committee.

We provide donors with a full explanation of the purpose of use, the time window during which consent can be revoked, and the handling of personal information, etc. through the collection facility.

<Note>

*In this case, “surgery” refers only to operations performed as treatment, and does not refer to operations performed to harvest human tissue, etc., or to surgery for which the surgical plan has been changed (to extensive resection, etc.).

6. R&D using human tissue, etc.

We conduct R&D on regenerative medical products using human tissue, etc. within the scope of the purpose of use explained to the donor in advance. Human tissue, etc. is not used for other purposes.

R&D and the recording, retention, and management of study data are conducted in accordance with the legal compliance requirements for non-clinical studies of regenerative medical products. Human tissue, etc. that is not suitable for use or is left over after use is properly disposed of.

7. Handling of information

All information obtained in R&D using human tissue, etc., is properly managed, and every effort is made to prevent it from being leaked.

The information obtained from collection facilities is limited to that which is necessary in R&D using human tissue, etc., and does not include information that could identify the donors.

<Note>

This stipulation includes results of tests performed on human tissue, etc., other information obtained in R&D, and

content that our company is prohibited from disclosing at the request of the donor. However, submitting information on human tissue, etc. and regenerative medical products to regulatory authorities in connection with an application for marketing approval for regenerative medical products, pursuant to the law, is not prohibited.

8. Other

Human tissue, etc. that has been harvested overseas is also handled in accordance with this basic ethical policy. However, matters to which this basic ethical policy does not apply for reasons of differences in the related legal regulations or bioethics of the country involved, will be reviewed by the J-TEC Ethics Committee after as much related information as possible has been obtained from the country involved.

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