

# Basic ethical policy on allogeneic cultured products

Japan Tissue Engineering Co., Ltd.

## 1. Purpose

Allogeneic cultured products are regenerative medical products made by culturing cells provided by someone other than the patient who is to receive the treatment (hereinafter referred to as “allogeneic human tissue, etc.”). “Basic ethical policy on allogeneic cultured products” (hereinafter referred to as “this basic ethical policy”) stipulates the matters with which our company must comply in the product development of allogeneic cultured products (including clinical research and clinical trials), their manufacture and post-marketing management, and other related activities (hereinafter referred to collectively as “product supply activities”), from an ethical viewpoint. Our company has established and complies with this basic ethical policy in order to ensure respect for the goodwill of the cell donors and the protection of their personal information, as well as to ensure the safety of the products for patients, and occupational safety for workers in the spirit of maintaining human dignity and respect for human rights.

## 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 product supply activities for allogeneic cultured products, we are sincerely accepting and responding to the demands and expectations of society.

1. We ensure the human rights of donors and the safety of patients by conducting product supply activities for allogeneic cultured products 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 product supply activities for allogeneic cultured products.
3. We make efforts to spread information on product supply activities for allogeneic cultured products 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 confirms that product supply activities for allogeneic cultured products are conducted in compliance with this basic ethical policy.

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

### 1. Explanations for donors

We ask the medical institution that collects allogeneic human tissue, etc. (hereinafter referred to as the “collection facility”) to obtain advance consent for donation of allogeneic 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 allogeneic human tissue, etc.\*\*

### 3. Principle of uncompensated donation

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

#### 1. Limitation on purposes of use

Allogeneic human tissue, etc. is used only for the purpose that was explained to the donor in advance and is never appropriated to other uses.

#### 2. Revocation of consent

Within the time window during which revocation of consent is possible, donors can still revoke consent even after donating allogeneic human tissue, etc.\*\* If the donor revokes consent, we will dispose of the donated allogeneic 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 allogeneic human tissue, etc. and donors who revoke consent will not be disadvantaged in medical treatment.

## 5. Acceptance of allogeneic human tissue, etc.

We accept surgically\* removed unnecessary allogeneic human tissue, etc. from appropriate collection facilities. In addition to the legally required explanation, donors are provided 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 allogeneic human tissue, etc., or to surgery for which the surgical plan has been changed (to extensive resection, etc.).

\*\*This section stipulates that allogeneic human tissue, etc. can only be accepted after the purpose for which the manufactured allogeneic cultured products will be used has been explained to the donor in advance.

## 6. Construction of cell banks

J-TEC constructs the cell banks\* needed in production supply activities for allogeneic cultured products, using donated allogeneic human tissue etc.

In the construction of cell banks, we ensure product safety and occupational safety by evaluating the suitability of the allogeneic human tissue, etc. through testing methods selected on the basis of the latest findings. Allogeneic human tissue, etc. that is not confirmed to be suitable is properly disposed of.

<Note>

\*As indicated in the preceding notes, "cell bank" in this basic ethical policy refers to the cell bank constructed as the raw material for the intended allogeneic cultured product. The cells in the cell bank are not genetically modified through gene transfer, etc.

## 7. Product development of allogeneic cultured products

We conduct product development of allogeneic cultured products within the scope of the purpose of use explained to the donor in advance. Allogeneic human tissue, etc. is not used for other purposes.

In clinical research and clinical trials of allogeneic cultured products, the ethical appropriateness of the clinical research or clinical trial is reviewed in advance by the ethics committee, etc. of the clinical site.

## **8. Manufacture and post-marketing management of allogeneic cultured products**

J-TEC has established criteria based on laws and ordinances related to manufacture and quality control. We manufacture allogeneic cultured products in accordance with these criteria and release only those allogeneic cultured products that meet the release criteria. Moreover, we make continued efforts in the areas of quality control and quality improvement for allogeneic cultured products, based on the obtained data.

J-TEC has also established safety control criteria based on laws and ordinances. We collect information on the safety of allogeneic cultured products in accordance with these criteria and take the greatest care to prevent health injuries from occurring. In the unlikely event of a health injury, arrangements have been made to report it to the related organizations immediately and take the necessary action.

## **9. Handling of information**

All information obtained in product supply activities for allogeneic cultured products 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 product supply activities for allogeneic cultured products and does not include information that could identify the donors. In the unlikely event that there is an unexpected problem with an allogeneic cultured product and it becomes necessary to obtain information about a donor from a medical institution, due consideration will be given to the strict management of that information.

<Note>

This stipulation includes results of tests performed on allogeneic human tissue, etc., other information obtained in product supply activities, and content that our company is prohibited from disclosing at the request of the donor. However, submitting information on allogeneic human tissue, etc. and allogeneic cultured products to regulatory authorities in connection with an application for marketing approval for allogeneic cultured products, pursuant to the law, is not prohibited.

## **10. Other**

Allogeneic 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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