Basic ethical policy on autologous cultured products

Japan Tissue Engineering Co., Ltd.

1. Purpose

Autologous cultured products are regenerative medical products made by culturing the cells of the patient who is to receive the treatment (hereinafter referred to as “self-derived human tissue, etc.”).
“Basic ethical policy on autologous cultured products” (hereinafter referred to as “this basic ethical policy”) stipulates the matters with which our company must comply in the manufacture and post-marketing management of autologous culture products 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 the protection of patients’ personal information, the safety of the products, 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 autologous cultured products, we are sincerely accepting and responding to the demands and expectations of society.

1. We ensure the safety of patients by conducting product supply activities for autologous cultured products in compliance with laws, ordinances, and related standards.
2. We make efforts to spread information on product supply activities for our autologous cultured products so as to gain the understanding of society.
3. 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 autologous cultured products are conducted in compliance with this basic ethical policy.

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

1. Explanations for patients
   We ask the medical institutions to obtain advance consent for treatment from the patient or from a legal representative* if it is difficult for the patient to give informed consent, after providing a sufficient explanation of autologous cultured products.
2. Respect for free will
   We ask the medical institutions to show the greatest respect for the free will of the patients and their legal representatives when obtaining informed consent for treatment with autologous cultured products.
3. Limitation on purpose of use
   Self-derived human tissue, etc. is used only for the purpose that was explained to the patient in advance and is never appropriated to other uses.
4. Withdrawal of consent
   We ask the medical institutions to ensure that patients and their legal representatives have the opportunity to revoke this consent, even after patient-derived human tissue etc. has been collected for use in the manufacture of autologous cultured products.

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

5. Product supply activities for autologous cultures products

We engage in product supply activities for autologous cultured products within the scope of the purpose of use explained to the patient in advance. Self-derived human tissue, etc. is never used for any other purposes. However, if the patient consents to it, some in-process cells and culture supernatant may be used for quality control and quality improvement once manufacture has begun.* In this case, we report the status of use to the J-TEC Ethics Committee and seek their understanding.

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

Some of the self-derived human tissue, etc. used in manufacture is retained as test samples for future infection testing, as required by law. Leftover self-derived human tissue and nonconforming items are properly disposed of.

J-TEC has also established safety control criteria based on laws and ordinances. We collect information on the safety of autologous 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.

<Note>
* Workers receive education on the following to ensure continuous quality control and quality improvements in the manufacture of autologous cultured products.

（1）Use of human tissue, etc. for the purpose of manufacturing autologous cultured products

（2）Use of some in-process cells and culture supernatant for the purposes of quality control and quality improvement, including investigation of the cause of nonconforming items, etc.

6. Handling of information

All information obtained in product supply activities for autologous cultured products is properly managed, and every effort is made to prevent it from being leaked.

The information obtained from medical institutions is limited to the information that is necessary in product supply activities for autologous cultured products, and does not include information that could identify the patients. In the unlikely event that there is an unexpected problem with an autologous cultured product and it becomes necessary to obtain information about a patient 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 self-derived human tissue, etc., other information obtained in product supply activities, and content that our company is prohibited from disclosing at the request of the patient. However, submitting information on self-derived human tissue, etc. and autologous cultured products to regulatory authorities in connection with a re-examination application for autologous cultured products, pursuant to the law, is not prohibited. Moreover, information on manufacturing status as it pertains to surgical plans may be provided to medical institutions upon request.

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