Guidelines on the transparency of collaborative and cooperative activities with medical institutions, etc.

Japan Tissue Engineering Co., Ltd. (hereinafter referred to as “J-TEC”) conducts R&D and provides a stable supply of “regenerative medical products” to improve patients’ QOL (Quality of Life) under the motto of “industrialization of regenerative medicine”.
Collaboration and cooperation with research institutes like universities, medical institutions, and healthcare professionals is indispensable to the discovery of “regenerative medical products” that meet the needs of patients and medical institutions. The importance of these efforts goes beyond the development stage, and post-marketing collaboration and cooperation among industry, government, and academia can contribute to the improvement of medical care through the promotion of proper use and safety assurance measures.
At the same time, these collaborative and cooperative activities are required to have high levels of ethicality and transparency, because in some cases there is monetary compensation of medical institutions and healthcare professionals. J-TEC has established “Guidelines on the transparency of collaborative and cooperative activities with medical institutions, etc.” to garner broad understanding of the fact that we adhere to high ethical standards in our corporate activities, and we describe the following types of information in accordance with these Guidelines.

1. Purpose

J-TEC guarantees transparency by properly disclosing information related to funding and other payments that accompany collaborative and cooperative activities with medical institutions, etc., in accordance with these Guidelines.

2. Method of disclosure

Information is disclosed through the J-TEC website.

3. Timing of disclosure

Information is disclosed within 1 year after the end of each business year.

4. Objects of disclosure

Funding in the preceding fiscal year is disclosed according to the following items.

A. R&D expenses, etc.

J-TEC discloses expenses involves in research and surveys, etc. independently conducted by J-TEC (joint research expenses, commissioned research expenses) and various studies, reports, and surveys, etc. conducted in accordance with official regulations such as GCP/GVP/GPSP ordinances (clinical trial expenses, post-marketing clinical study expenses, defect and infection case report expenses, and post-marketing surveillance expenses).
Among these, information that we are obligated to publish pursuant to the Clinical Trials Act* is disclosed separately.

B. Grants

J-TEC discloses research grants and other payments made to promote learning in medical science and technology (scholarship donations, general donations) as well as funding to support joint sponsorship of conferences with academic societies (donations to academic societies, co-sponsorship funding).
Among these, information that we are obligated to publish pursuant to the Clinical Trials Act* is disclosed separately.

C. Manuscript writing fees, etc.

J-TEC discloses payments related to manuscript writing and lectures for providing information on proper use of our medical devices, etc. (honoraria, manuscript writing fees, editorial supervision fees) and consulting and other outsourcing expenses
Among these, information that we are obligated to publish pursuant to the Clinical Trials Act* is disclosed separately.

D. Expenses related to provision of information

J-TEC discloses expenses involved in the lecture meetings, simulated practical training, and explanatory meetings, etc. that are necessary in order for healthcare professionals to use our medical devices properly and safely (co-sponsorship funding for lecture meetings, explanatory meeting expenses, fees for submission of papers on medical sciences and medical engineering to scientific journals, etc.).

E. Other expenses

J-TEC discloses social expenses involved in reception and other social courtesies.

5. Effective date

These Guidelines apply to all payments, starting with those made in fiscal year 2019, before which the pre-revision Guidelines were followed.

Established: December 11, 2012
Revised: March 28, 2019

Japan Tissue Engineering Co., Ltd.

The information that we are obligated to disclose under the Clinical Trials Act is as follows (Article 90, Enforcement Regulations of the Clinical Trials Act).

Research funds, etc. (Includes research funds, etc. provided by organizations that manage research, etc. (limited to situations where a marketing authorization holder provides research funds for a specific clinical study) to medical institutions that conduct specified clinical studies.)	1. Identification number registered in jRCT (Japan Registry of Clinical Trials) 2. Recipient 3. Clinical site 4. For each specified clinical study: organization that manages the research and number of contracts with clinical sites

	5. For each specified clinical study: organization that manages the research and total amount of research funding for each clinical site
Donations (Limited to those provided to principal investigator of the specified clinical study, to the organization to which the principal investigator belongs (medical institution, university or other research institute, learned society, general incorporated association, general incorporated foundation, or specified nonprofit organization) or to the organization that managed the specified clinical study, where the donation has been made within the period of implementation of the specified clinical study or within 2 years after the completion of the study, and excluding those where it is deemed certain that the donation was not made to the principal investigator.)	1. Recipient 2. Number of contracts per recipient 3. Total amount donated per recipient
Compensation for manuscript writing, lecturing, and other work (Limited to that provided to principal investigator of the specified clinical study within the period of implementation of the specified clinical study or within 2 years after the completion of the study.)	1. Name of principal investigator that performed the work 2. Number of tasks performed by each principal investigator 3. Total amount of compensation for work performed by each principal investigator