Expectation for the bank of human tissues and cells from regenerative medicine viewpoint

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The expectation for the application to regenerative medicine has been enhanced these days thanks to the superb research results on stem cells. The taskforce composed by Japan Pharmaceutical Manufacturers Association (JPMA) has been ongoing as one of the entities to evaluate safety for medicines through the application of human iPS and cells. However, the cells induced differentiation from stem cells are too immature and instable for multiplying time and effectiveness for differentiation. It is indispensable for verifying how effective it will be together with matured cells on treatments. It is obvious that the comparison in vitro between the matured human tissues and cells and the cells induced differentiation is a MUST, the bank of human tissues and cells available for lots of related researchers should function properly. Furthermore, everything such as human cells & tissues resected from human including patients plus low invasive stem cell sources for the purpose of gathering peripheral blood and alike is provided for free with the goodwill. It is commonly agreed that the providers (healthy volunteers or patients) after the donation they will have nothing to do with the outcomes directly nor indirectly, which increases õRemoteö tendency eminently. Therefore, there exists a necessity to acquire the informed consent from the providers that they have no rights for the interests generated from the further researches and clinical trials. One of the criticisms against recent medical bank projects has been focused on its ethical issue. Hereafter, I explain the background how the bank of human stem cells and tissues should be.

In advanced countries the social system has been available that the organs and tissues incompatible for brain-death transplantation have been utilized for new medicine development. On the contrary, in our country due to the delay in establishing a brain-death transplantation system, the management of the bank of human tissues and cells itself has been immature to the degree that lots of related researchers are able to make use of it. I have been explaining the background between advanced countries and Japan from the differences in transplantation medicine as per attached (Figure 1).



Consequently, organs for transplantation from brain death are positioned as gifts for society in order to secure the fairness of the recipients as patients. Therefore, the system is handled by the society based on trust that organs compatible for transplant will be for medical treatment and organs medically incompatible will be for researches. However, the organs resected partially from the patient in most cases, they will be for treatments and become pathology specimen. In addition due to the fact that normal part of the organ is resected from anatomical reasons, the part is utilized for developing medicines (Kurokawa report in 1988). In this case, the patients need to make a decision during uneasy and depressing time before the operation whether the resected organs should be utilized for other patients or materials for researches.

I have been looking into the smooth management style how we handle human tissue banking system as a chief of research funds project hosted by the Ministry of Health and Labor since 2001. And in regard to the informed consent as well as the before-death consent in case of brain-death transplantation, I have been insisting that raising the public acceptance of the concept for the official banking of human cells and tissues as õGift for Societyö is an important factor (Figure 2).



Considering the current situation of applying the iPS cells as world-class stem cells into clinical practices, now is the time to initiate the development by ourselves for the-state-of-theart human cells and organs in collaboration with the existing banks of human tissues and cells.