

Japan has two storied system of national ethics committee. The one is Expert Panel of Bioethics established in the Council for Science and Technology Policy, and the other is ethics committees constituted in each relevant ministries, such as Ministry of Education or Ministry of Health.

Japan has first established its Bioethics Committee in the Council for Science and Technology (CST) in September 1997. The first result of its work was the Report on the human reproduction by cloning technique, which led to the enactment of the Law regulating the application of cloning technique to human beings.

The Bioethics Committee of Japan issued successively two other important reports, namely Report on Human Embryo Research, focused on Human Embryonic Stem Cells, and Report on Fundamental Principles of Research on the Human Genome.

Since 2001, we have the current system of national bioethics committees in plural. The reform of the governmental system in Japan established a new body named “Expert Panel on Bioethics (EPB)” in the Council for Science and Technology Policy (CSTP), the highest policy making body on science and technology. EPB is thus in the framework of science and technology promotion and act as an advisory body to this Council.

Current composition of the EPB is shown in the Formulaire. As for the function, EPB mainly give advice to the consultation on the drafted policies and regulations requested by a relevant ministry. EPB has also competence to choose the topics by itself.

Main works until now are firstly the advices on the draft Guidelines on

Human Embryonic Stem cell Research and on the draft Guidelines on the Research of Specified Embryos, including their revisions, both requested by the Ministry of Education, and, secondly and in particular, the Report on Fundamental Policy on Handling of Human Embryos, which thoroughly examined the ethical and scientific issues concerning human embryos in the context of the Japanese society and lifted the ban on human therapeutic cloning research.

The future activities of the EPB are under discussion. Some number of topics is currently referred, such as neuro-ethics, non-scientific use of personal genetic information, ethics of biobank, ethics of iPS cells and status and function of institutional review board.

Ethics Committees in the relevant ministries have their own process of establishment and development. The only ministry who has a permanent committee is the Ministry of Education (MEXT). Its Bioethics and Biosafety Committee deals with ethical issues of the research of life sciences and technology. The Committee was established in January 2001 with the reform of the whole governmental structure.

As for the composition, you may refer to the Formulaire. The Committee is mandated to study of ethical issues involved in scientific research and in particular to draft the guidelines of relevant fields, like genomic research and regenerative medicine research. The works achieved by this Committee are, firstly as regulating function, the Guidelines of Derivation and Utilization of Human Embryonic Stem Cell, the Guidelines of Research on Specified Embryos, and the Revised Guidelines on Research on Human Genome and Genetic Analysis. Secondly as studying function, the Report on the therapeutic Cloning, the draft Report on the Research on Assisted Reproductive Medicine, and the Report on the Creation of Gametes from Stem Cells.

For these activities, sub-committees and working groups are often constituted, such as Expert Commission on Human ES Cell Research and Commission on Research on Assisted Reproductive Medicine as well as Working Group on Therapeutic Cloning.

Future activities of the Committee will be, first, revision of the two relevant guidelines relating to the therapeutic cloning research, and second revision of the Guidelines on Human ES cell Research in order to regulate the creation of gametes differentiated from stem cells, especially so-called artificial gametes from iPS cells.

Two important topics under discussion are: 1) drafting of the relevant provisions concerning therapeutic cloning by the MEXT. Main points are already set in the Report on Fundamental Policy on Handling of Human Embryos established by the EPB. There will be provisions on limitation of research purposes, requirement for institutions and researchers, procurement of eggs and somatic cells and protection of donors, in particular of women. 2) Examination of the scope of creating artificial gametes from different kind of stem cells. The MEXT should revise the ES Cell Guidelines.

Other bodies at ministerial level of other ministries, in particular of Ministry of Health are in general constituted and work on ad hoc and issue by issue basis. Although the Ministry of Health is competent in medical science and medical treatment and has already established important regulations and guidelines and reports, there was no case of consultation from this Ministry. It is unfortunate that the Ministry of Health do not easily come into the framework of the EPB, although the EPB has competence on all matters concerning bioethics, partly due to the history of establishment of EPB.

Thank you very much for your attention.