

Appropriate Implementation of Clinical Studies on Gene Therapy

Overview

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Gene therapy is a new medical technology that administers gene or gene-introduced cells into the human body to treat an illness and can be expected to be an innovative treatment method for serious hereditary diseases, cancer, other terminal diseases, and diseases that severely impair bodily functions. Many clinical studies on gene therapy have already taken place in a number of foreign countries.

For this reason the Ministry of Health, Labour and Welfare (MHLW) formulated “Guidelines for Gene Therapy Clinical Studies” in February 1994, and have been evaluating in a comprehensive manner the medical effectiveness and ethics of gene therapy clinical studies on terminal disease or diseases that severely impair bodily functions via the Committee on Science and Technology of Health Sciences Council. Considering that several years have elapsed since formulation of the Guidelines and that a number of study cases have been accumulated during this period the Guidelines were revised (Ministry of Education, Culture, Sports, Science and Technology (MECSST)/MHLW Notification No. 1 of 2002) in thereby accelerating evaluation procedures by limiting study plans that the said Committee evaluates as being of merely novelty value.

The first gene therapy clinical study in Japan was on adenosine deaminase deficiency, which took place at Hokkaido University. To date 29 applications clinical study implementation plans to be evaluated have been made by potential implementing entities, with 27 of them having been determined to be appropriate after being discussed by the Committee on Science and Technology.

In addition, and for the purpose of responding to the smooth implementation of the Act on Protection of Personal Information (Act No. 57 of 2003), MHLW in cooperation with MECSST revised the Guidelines in December 2004 from the point of view of protecting personal information by ensuring all the personal information protection measures prescribed in the said Act, in principle, were included (MECSST/MHLW Notification No. 2 of 2004).

Appropriate Implementation of Epidemiologic Studies

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Epidemiologic studies investigate the frequency and the distribution of health phenomenon, including the morbidity of diseases, and clarifies the factors associated with it. Epidemiologic studies are considered essential in investigating the causes of diseases, verifying the effectiveness of prevention/treatment methods used with diseases, or clarifying the relationship between environment/life styles and health, and thus play a significant role in the progress of medicine and the maintenance and improvement of public health. In recent years, however, providing research subjects with explanations and obtaining their agreement has been considered important. Furthermore, an increased awareness on the rights to privacy and social trends in private information protection has necessitated clarification of legally binding standards.

Because of the above reasons the Ministry of Health, Labour and Welfare (MHLW), in cooperation with the Ministry of Education, Culture, Sports, Science and Technology (MECSST), formulated “Ethical Guidelines for Epidemiologic Studies” (MECSST/MHLW Notification No. 2 of 2002) in June 2002. The Guidelines prescribe that, when conducting epidemiologic studies, informed consent shall be obtained from the research subjects, in principle, study plans reviewed by an Ethical Review Committee established at the pertinent research institute, and a personal information protection system established, etc., while also requiring researchers, etc. engaged in epidemiologic studies to observe the promotion of the appropriate implementation of epidemiologic studies.

In addition, and for the purpose of responding to the smooth implementation of the Act on Protection of Personal Information (Act No. 57 of 2003), the MHLW, in cooperation with MECSST, revised the Guidelines in December 2004 from the point of view of protecting personal information by ensuring all personal information protection measures prescribed in the said Act, in principle, were included (MECSST/MHLW Notification No. 1 of 2004).

Furthermore, provisions regarding the obligations of the directors of research institutions and protection of research subjects, etc. were established in August 2009 (MECSST/MHLW Notification No. 1 of 2009).

Appropriate Implementation of Clinical Studies

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Clinical studies are conducted on humans for the purpose of preventing diseases, improving diagnostic/treatment methods, improving understanding of the causes and pathologies of diseases, and improving the quality of life of patients. With the progress being made in science and technology in recent years their importance is further increasing.

In addition, medical advances will ultimately and inevitably depend on clinical studies, and therefore appropriate implementation of clinical studies needs to be promoted through obtaining social understanding and cooperation and with human dignity and human rights fully respected.

Because of the above reasons the Ministry of Health, Labour and Welfare (MHLW) formulated the “Ethical Guidelines for Clinical Studies” (MHLW Notification No. 255 in 2003) in July 2003, which cover all clinical studies, in thus promoting their appropriate implementation. The Guidelines prescribe that, when conducting clinical studies, sufficient explanations shall be provided to the research subjects before obtaining their consent, consideration be given to the protection of the personal information of the research subjects, and the appropriateness and consistency of any clinical studies reviewed by an Ethical Review Committee established at the pertinent research institute, etc. In addition, the Guidelines were revised in December 2004 to include the necessary provisions to ensure the appropriate handling of personal information in clinical studies. Furthermore, an overall review of the Guidelines took place in July 2008 in further improving study ethics and protecting the research subjects. All relevant parties involved in clinical studies are requested to observe the said Guidelines in thus promoting the appropriate implementation of clinical studies.

Appropriate Implementation of Clinical Studies Involving Human Stem Cells

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Appropriate Implementation of Clinical Studies Involving Human Stem Cells

Clinical studies on human stem cells play an important role in maintaining public health and preventing, diagnosing, and treating diseases through organ function regeneration, etc.

Because of the above reasons the Ministry of Health, Labour and Welfare (MHLW) formulated “Guidelines for Clinical Studies using Human Stem Cells” (MHLW Notification No. 425 in 2006) in July 2006 in thereby ensuring that all clinical studies involving human stem cells are appropriately implemented/promoted through obtaining the understanding of society and get implemented with human dignity and human rights fully respected, and effectiveness and safety secured based on scientific knowledge.

Since enforcement of the Guidelines anyone engaging in clinical studies involving human stem cells has been requested to observe the aforementioned guidelines. However, revisions have been made to the relevant laws and ordinances, as well as new stem cell technologies developed, which include human embryonic stem cells (human ES cells) and human-induced pluripotent stem cells (human iPS cells), etc., with progress also having been made in basic research, etc. In order to respond to these changes in the environment surrounding clinical studies involving human stem cells an overall review of the Guidelines took place in November 2010 (MHLW Notification No. 380 of 2010) to newly cover human ES cells and human iPS cells, etc. in addition to somatic stem cells.