Confederation of Medical Associations in Asia and Oceania

CMAAO Resolution on Ethical Frameworks for Health Databases and Human Genetic Databases

Adopted by the CMAAO General Assembly in Manila, the Philippines on September 24-26, 2014

Rapid advancement in information and communication technology (ICT) has enabled vast amounts of health related information including genetic information to be collected, processed, analyzed and integrated, which in turn has contributed to unprecedented breakthroughs in medicine.

At the same time, an individual's health related information including physical condition, illness, treatment, medical history, family history and genetic information is one of the most sensitive types of personal information to be fully protected.

For such reasons, any ethical framework on the handling of personal health information including genetic information should follow strict principles designed to guarantee individual rights by taking into full consideration such special characteristics.

This resolution aims to reaffirm the special characteristics involved in the collection and use (for both research and non-research purposes) of health and genetic information and to propose an ethical framework that reflects such special characteristics. The resolution's primary objective is to propose principles that reflect the regional characteristics of Asia and Oceania in order to provide direction and guidelines to NMAs in this region in their efforts to play a leading role in related fields. Ultimately, CMAAO hopes to contribute to public health and human rights by encouraging the governments and all the related people to urgently develop the statutes that clearly require protection of personal health information and explicitly stipulate the permitted scope of usage of such health information.

Security and Confidentiality

Health databases, including human genetic databases shall be collected and used for only ethical and medically justified purposes and shall never be used for purposes that may lead to infringement of individual freedom and rights.

Medical information confidentiality of the information donor ("donor") shall be protected in all cases, and information shall not be divulged to third parties without consent.

Personal identifiers shall be stored in an encrypted form so as to guarantee their security and confidentiality and shall be used for research only when absolutely necessary within a scope that does not harm individual rights.

All physicians and researchers that handle health databases including human genetic databases have a solemn responsibility and duty to guarantee their confidentiality and shall exert efforts to manage such databases securely.

The number of researchers and assisting staff with access to the information shall be main-

tained at a minimum level at which the research is possible. Unauthorized creation or distribution of data copies or the use of data for purposes other than originally intended shall be prevented.

Personal identifiers shall be used only when the data is linked for the first time and shall be separated from the integration process and the output.

An organization that builds or stores the database independently from the researchers shall conduct the integration of data, and researchers should be provided with the data without any personal identifiers.

Results of research should only be reported in aggregate terms.

Informed Consent

The entire process of collection, storage and use of data that are included in health databases including human genetic databases shall be conducted using methods that are ethical and compliant with each country's laws and guidelines. In particular, the WMA Declaration of Helsinki on Ethical Principles for Medical Research (DoH) involving Human Subjects shall be adhered to.

In collecting an individual's health or genetic information, consent from the donor or his/her legal agent shall be the result of a voluntary decision reached based on sufficient explanation and understanding of details related with the donation including the clear present purpose of research, possible future research purposes, the type of genetic information collected, the method of collection and the entire donation related process from collection to use. The informed consent, in principle, shall be obtained in advance, using an explicit, written form.

The donor's right to determine the use of information that he/she provided shall be respected. Therefore, even after a donor provides his/her informed consent, he/she still reserves the right to withdraw such consent at any time for whatever reason without any restriction and without concerns of suffering from any disadvantage due to withdrawal. All information provided by a donor who has withdrawn his/her consent shall be immediately destroyed.

A donor has the right to know of the current status of the research that is related with the information he/she provided as well as whether his/her information is being managed properly.

Fair Access and Sharing

The data incorporated into health databases including human genetic databases shall be treated as public goods. Access to such databases shall be guaranteed to researchers who are pursuing research for ethical and publicly beneficial purposes.

Also, the results of research related with health databases including human genetic databases shall be shared among nations as much as possible in order to maximize the benefit to the entire human race and to minimize research redundancy and the risks inherent in this field of research.

Any research that uses health databases or human genetic databases shall ultimately contribute to enhancing equality in health and in society.

Protection of Vulnerable Groups

Research that uses health databases or human genetic databases also require devices designed to protect vulnerable groups.

Researchers must provide sufficient consideration for such donors in all stages of research. The Research Ethics Committee must also identify any potential vulnerable group during its review process and examine whether the planned research properly provides devices for the protection of such groups.

Ethics Committee

With regards to research using health databases including human genetic databases, the Ethics Committee shall examine whether the research purpose, scope of data collection and the entire collection process are ethical and whether the collected information has been used for the correct purpose and verify the capabilities and qualification of the research team that is conducting the research.

An international Research Ethics Committee shall be formed in the case where multiple nations collaborate on research that uses health or genetic information from databases.

International Cooperation

The creation of human genetic databases and the results of research emanating from its use is potentially powerful technology that may change the quality of life for the entire human race. However, it also raises issues of inequality because many developing countries are blocked from participating in such research due to cost issues. Thus, international cooperation including creation of related infrastructure and support for technology development and participation in research activities is necessary to enable even developing nations to participate in research that uses health databases including human genetic databases and to benefit the achievements from such research.

Recommendations for CMAAO Members

1. Each NMA shall urge each government to prepare the necessary legal systems and procedures so that the principles proclaimed in this resolution are shared and realized, and if necessary, is responsible for providing related advice as an expert group.

2. Also, each NMA shall exert efforts in the development and distribution of education and training programs for not only health database or human genetic database researchers, related personnel and physicians but also the general public so that the principles proclaimed herein are widely communicated.

3. Also, each NMA shall exert efforts to support research activities on ethical approaches to this issue and also to monitor whether such ethical principles are being well followed. For this purpose, member NMAs shall build broad and close cooperative relationships with each of the governments, health authorities, academia and related organizations.