

Opening Remarks

Presidential Symposium in the 40th Annual Scientific Meeting
of the Japanese Society of Clinical Pharmacology and Therapeutics, 2019
International Collaborative Research and New Trends of Research Ethics

Opening Remarks: The Declaration of Helsinki, CIOMS guidelines, ICH Renovation and New Trend of Research Ethics^{*1}

Organized & Chaired by: Kazutaka Shimoda¹, Hiroshi Watanabe²
Organized & Presented by: Chieko Kurihara³

(Wednesday, December 4, 2019, Keio Plaza Hotel Tokyo, Japan)

^{*1} The symposium was held with the cooperation of the Mochida Memorial Foundation for Medical and Pharmaceutical Research and Rinsho Hyoka Kankokai Inc. (Clinical Evaluation). Japanese version is included in *Clinical Evaluation*. 2020; 48(1). Other related articles in this issue:

http://cont.o.oo7.jp/48_1/48_1contents_e.html

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Abstract

Here we publish the record of the Presidential Symposium of the 40th Annual Scientific Meeting of the Japanese Society of Clinical Pharmacology and Therapeutics (2019), entitled “International Collaborative Research and New Trends of Research Ethics”. In this symposium two important guests were invited and presented the lecturers on: (1) Historical development of the Declaration of Helsinki and immediate challenges as well as future perspectives of research ethics, discussed by Dr. Otmar Kloiber, Secretary General of the World Medical Association; (2) Implications of the International Ethical Guidelines for Health-related Research Involving Humans by the Council for International Organizations of Medical Sciences (CIOMS) and other international documents, discussed by Dr. Dirceu Greco, Professor Emeritus, Infectious Diseases and Bioethics, Federal University of Minas Gerais, who is one of the working group members of the 2016 version of the CIOMS guidelines. We explored relationship between these ethical principles and recent perspectives of methodologies of clinical trial and clinical research, especially suggested in the ICH Renovation initiatives. The following points were specifically expected to be focused.

- Patient-driven research and patient, public involvement (PPI) in clinical trials
- Individual participant data (IPD) sharing and digital health
- Research in disaster situations
- Social determinants of health and universal health coverage
- Wellbeing of patients and physicians
- Research involving the vulnerable
- Placebo-controlled trial and post-trial access

The resulting findings from the lectures and discussions are recorded in this issue. We hope that this publication contributes to grasping the latest trends of research ethics in the world and to find a direction to go ahead in terms of clinical research infrastructure development and value generation both from domestic and global perspectives.

Key words

clinical pharmacology, research ethics, real world data, Declaration of Helsinki, CIOMS

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Graduated from Shiga University of Medical Science, received M.D.

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1983- Started working as a cardiologist in Hamamatsu University Hospital; received PhD in 1988.

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2016-2019, a cross-appointment with National Center for Global Health and Medicine as the Director of Center for Clinical Sciences.

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Chieko Kurihara, National Institutes for Quantum and Radiological Science and Technology

Graduated Department of Economics, School of Political Science and Economics, Waseda University

1984–2000 Editorial, book writing, theatre works

1994–2017 Rinsho Hyoka (Clinical Evaluation) (Since April of 2017, editorial member)

2003–2007 Researcher/Consultant, Center of Life Science and Society (CLSS)

2007–Present National Institute of Radiological Sciences, (since 2016) National Institutes for Quantum and Radiological Science and Technology (QST)

2019–Present Specially-appointed Professor, Kanagawa Dental University

Vice Chair, Certified Review Board, QST

Member, Ethics Working Group, International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine (IFAPP)

Member, Task Group 109, Ethics in radiological protection for diagnosis and treatment, International Commission of Radiological Protection (ICRP)

On December 4, 2019, we hold an international symposium entitled “International Collaborative Research and New Trends of Research Ethics” as the Presidential Symposium in the 40th Annual Scientific Meeting of the Japanese Society of Clinical Pharmacology and Therapeutics, 2019, and its record is published here. In this symposium we discussed the possibility of future revisions of the World Medical Association (WMA)’s Declaration of Helsinki (DoH), responding recent trend of research involving human subjects. International debate on the provisions of the DoH since around the year of 2000 until the latest revision in 2013 was also reviewed. In addition, the International Ethical Guidelines for Health-related Research Involving Humans by the Council for International Organizations of Medical Sciences (CIOMS) and other international ethical norms that play an important role same as the DoH were discussed. We deliberated in depth the recent trends of methodology of clinical trial as well as research ethics, considering public health issues from the global perspectives.

The World Medical Association’s “Declaration of Helsinki” was first adopted in 1964. After the latest amendment in 2013¹⁾, the 50th anniversary ceremony was held in 2014²⁾. In 2016, they adopted the Taipei Declaration on Health Database and Biobanks, which complements the Declaration of Helsinki³⁾.

In this symposium, one of the invited lecturers, Dr. Otmar Kloiber, M.D., Ph.D., Secretary General, World Medical Association, overviewed historical development of the WMA’s deontology and talked about the latest trends of research ethics, including increasing interests in health database and biobanks responding recent promotion of data-driven research; as well as positive and negative aspects of patient-driven research. He also provided the WMA’s perspectives for next revision of the Declaration as well as critical issues and activities which the WMA has been recently engaged in.

Meanwhile, the Council for International Organizations of Medical Sciences (CIOMS) produces another prominent international ethical guidelines for health-related research, the latest revision of which was in 2016⁴⁾. It deals with emerging issues such as research in resource-limited environments, including disaster



【Invited lectures】

“Declaration of Helsinki: Challenges and new trends ahead of us”

Dr. Otmar Kloiber, M.D., Ph. D., Secretary General, World Medical Association, Inc.

“The past, now and future of ethics of international health research as a stepping-stone to universal public health care access”

**Dr. Dirceu Greco, M. D., Ph. D., Professor Emeritus, Infectious Diseases and Bioethics,
Federal University of Minas Gerais; Chair, Brazilian Society of Bioethics (2017-2019)**

(Language: English)

【Chairpersons】

Dr. Kazutaka Shimoda, M.D., Ph.D.

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Meeting President of the 40th Annual Scientific Meeting of the JSCPT;

Current President of the JSCPT

Dr. Hiroshi Watanabe, M.D., Ph.D.

Professor, Executive Director / Vice President, Hamamatsu University School of Medicine;

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【Date and Venue】

Date: Wednesday, December 4, 2019 Time frame: 13:00-15:00

Venue: Keio Plaza Hotel Tokyo (Shinjuku, Tokyo, Japan) 4th Floor Room 4: Hana B

【Cooperation】

Mochida Memorial Foundation for Medical and Pharmaceutical Research

Rinsho Hyoka Kankokai Inc. (Clinical Evaluation)

situations; research using online information and biobanks.

Another invited lecturer, Dr. Dirceu Greco, M.D., Ph.D., Professor Emeritus, Infectious Diseases and Bioethics, Federal University of Minas Gerais, Brazil, is now the Chair of Brazilian Society of Bioethics, 2019-2021; Member and Vice-chair of International Bioethics Committee of United Nations Educational, Scientific and Cultural Organization (UNESCO), 2018-2021; and worked as a member of Working Group for the 2016 revision of CIOMS guidelines for health research. He overviewed the past, present, future of research ethics including international debate on the revision of the Declaration of Helsinki since 2000 version, and made important proposal toward universal healthcare access, as one of the fundamental human rights, and establishment of the research ethics guidelines of international agreement⁵⁾.

Prior to the two invited lectures, Chieko Kurihara, one of the organizers, presented the latest trends of research ethics in her presentation as Opening Remarks (Table 1), and provided a historical background,

Table 1 Recent trend of research ethics

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- ICH Renovation: IPD sharing, Real-world data⇒Mitigate the cost and ethical dilemma of “well-controlled comparative clinical trials”
 - Promotion of “patient & public involvement (PPI)” by industries and governments; expanding patient-initiated research utilizing IoT gathering their own data.
 - Privacy issues associated with genome-wide analysis gathering big data and human samples; responsibility of healthcare beneficiaries; ethics of AI development.
 - Ethical debate of studies in HIV/AIDS, then Ebola pandemic and in disaster/war conflict situations.
 - Collaborative studies toward Global Health; achievement of universal health coverage.
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most recent issues, and future perspective to be discussed more in depth, concerning the DoH and CIOMS Guidelines. Regarding the discussions on the DoH, she also introduced related interviews and reports so far. It includes Pros & Cons of placebo debate⁶⁾; 2000 revision of the DoH expanding the scope to studies on samples and data and its philosophical bases⁷⁾; issues of 2002 note of clarification of the DoH⁸⁾; latest revision of the DoH in 2013 and 50th anniversary in 2014 with expanding view of research ethics^{9, 10)}; the perspective of the United States Food and Drug Administration on scientific methodology and ethics of clinical trial including placebo use¹¹⁾; post-trial access, rejected “fair, additional benefit” and establishment of human rights in developing worlds^{12, 13)}; establishment of international consensus on ethics for health database and biobanks by the WMA Taipei Declaration; discussions towards disaster medicine, Universal Health Coverage and global health^{14~18)}.

We hope that this record of the symposium will provide the readers a valuable opportunity to discuss new trend of research ethics in accordance with ICH Renovation promoting digital health, as well as patient-driven research, research in disaster situations, facilitating global collaborative clinical trials and health research.

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