Proceedings

COVID-19 and bioethics Part 3 : Pandemic and research ethics – Democracy, placebo and post-trial access*1

Lecturers: Day 1

Chieko Kurihara[1] Specially-appointed Professor, Kanagawa Dental University, Japan

Ruth Macklin Distinguished University Professor Emerita at Albert Einstein College of Medicine in New York City, the United States

Peter Lurie Center for Science in the Public Interest, Washington, DC, the United States

Ulf Schmidt Professor of Modern History, University of Hamburg, Germany

Lecturers: Day 2

Ames Dhai[2] Professor of Bioethics, University of the Witwatersrand, Johannesburg, South Africa

Tammam Aloudat Managing Director, Global Health Center, Graduate Institute of International Development Studies, Geneva, Switzerland

Dirceu Greco[3] Professor Emeritus, Infectious Diseases and Bioethics, Federal University of Minas Gerais, Brazil

Francis P. Crawley Executive Director of the Good Clinical Practice Alliance – Europe (GCPA) and Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Leuven, Belgium

Special guests

Ramin Parsa-Parsi Workgroup Chair of the 2013 revision of the Declaration of Helsinki, World Medical Association; German Medical Association

Otmar Kloiber Secretary General, World Medical Association

Discussants

Rihito Kimura[4] Professor Emeritus of Bioethics, Waseda University, Japan

Sandor Kerpel-Fronius[5] Professor of Clinical Pharmacology, Semmelweis University, Hungary

Moderators

Takeo Saio[6] COVID-19 Task Force, Japan Association for Bioethics

Kyoko Imamura[7] Past President of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and former President of the Japanese Association of Pharmaceutical Medicine (JAPhMed)

Co-organized by the COVID-19 Task Force, Japan Association for Bioethics and the Brazilian Society of Bioethics

Supported by the Japanese Association of Pharmaceutical Medicine (JAPhMed) and the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)

Cooperation: Clinical Evaluation; Bioethics Policy Study Group; Pharmaceutical Study Group; Clinical Research Risk Management Study Group

(Friday, 4 and Friday, 11, June, 2021, Webinar by Zoom system)

*1 This is a record of the webinar, of which related information and video-recorded version is available at: http://cont.o.oo7.jp/sympo/covidandbioethics.html
Japanese translation is published in this journal issue: http://cont.o.oo7.jp/49sup38/49sup38contents.html

Abstract

In the 1990s, the HIV/AIDS pandemic raised substantial discussions of research ethics, mainly a long-lasting debate on placebo-controlled clinical trials and post-trial access after the establishment of safe and effective interventions. In 2019, some argued that this debate was outdated and that we should drive ourselves forward to a new trend of research ethics. Just at this occasion, the world was confronted with the COVID-19 pandemic. In this webinar we have discussed to explore what is the internationally agreed ethical standard on placebo-controlled clinical trial and post-trial access considering the COVID-19 situation.

The invited speakers and special guests who took historically critical roles in the above discussion made presentations and engaged in debate exploring and clarifying local and global situations. The discussion provided insights into (1) future direction for possible revisions of the paragraphs in the World Medical Association's Declaration of Helsinki on placebo use and post-trial access; and (2) emphasized need for global, collaborative efforts for structural reformation of the mechanisms of research and development to correct inequity and to achieve access to necessary medicines for all who need it.

Key words

The Declaration of Helsinki, COVID-19, human rights, global health, clinical trial, placebo, post-trial access

Rinsho Hyoka（*Clinical Evaluation*）. 2021；49 Suppl XXXVIII：9-109.［Epub ahead of the issue publication］

[1] COVID-19 Task Force, Japan Association for Bioethics; Working Group on Ethics, International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP); National Institutes for Quantum and Radiological Science and Technology

[2] Founder of the Steve Biko Centre for Bioethics, University of the Witwatersrand, Johannesburg, South Africa; Member and Vice-chair of International Bioethics Committee of United Nations Educational, Scientific and Cultural Organization (UNESCO) (2018-2021)

[3] Chair of the Brazilian Society for Bioethics (2019-2021); Member and Vice-chair of International Bioethics Committee of United Nations Educational, Scientific and Cultural Organization (UNESCO) (2018-2021)

[4] Faculty Affiliate, Kennedy Institute of Ethics, Georgetown University; Past President, Japan Association for Bioethics (2009-2012); President , Keisen University (2006-2012)

[5] Chair of the Working Group on Ethics of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) (2014-2021)

[6] Department of Internal Medicine and Psychiatry, Fuji Toranomon Orthopedic Hospital

[7] Project Professor, Social Cooperation Program of IT Healthcare, The Graduate School of Pharmaceutical Sciences, The University of Tokyo; Japanese Institute for Public Engagement