Monday – Wednesday, December 12-14, 2022
at the Academy, 43 Jabirot St., Jerusalem

10:30 Gathering
11:00 Opening Session
Chair: Prof. Aharon Chechansky, Nobel Laureate and Academy Member; Technion – Israel Institute of Technology
Greetings
Prof. David Harel, President, The Israel Academy of Sciences and Humanities

Session I
Chair: Prof. Shai Lavi, Director, The Van Leer Jerusalem Institute; Professor of Law, Tel Aviv University

11:00-13:00 Registration

Introduction of the speaker:
Prof. Nadav Davidovitch, School of Public Health, Faculty of Health Sciences, Ben-Gurion University of the Negev

13:30 Lunch reception
14:00 Keynote Lecture
Prof. Allan Brandt, Harvard University, USA
Looking Backward, Looking Forward: Biomedical Research Ethics in Historical Perspective

Tuesday, December 13, 2022

Session II
Chair: Prof. Vardit Ravitsky, School of Public Health, Faculty of Health Sciences, Ben-Gurion University of the Negev

11:00 Coffee break
11:30-13:00 Session II Lost in translation? The ethics of shifting from translation to implementation
Chair: Prof. Yechiel Michael Barilán, School of Medicine, Tel Aviv University

Clear evidence of therapeutic value, authorization by regulatory bodies, and economic affordability do not always mark the end of a successful journey of translation from basic science to effective practice. Patients need to integrate care items in their daily routines and to accept the efforts and possible side effects, as part of a “career” of managing chronic illness. Implementation science and normalization process theory have been developed to understand the ultimate feasibility, efficacy, and acceptance of effective healthcare interventions. Proper monitoring of the outcome of implementation studies is key to understanding different ways of achieving outcomes of care in different settings.

Prof. Shai Lavi, Tel Aviv University

13:00 Round Table
Is that the Question?
Over-Regulation or Under-Regulation of Biomedical Research:
Farah, Kassir, Lavi, Ravitsky, Round Table Chair

14:00 Coffee break
14:30 Session III Experimenting or treating? Drawing a fine line in times of a worldwide pandemic
Chair: Dr. Sharon Alroy-Preis, Israel Ministry of Health, Head of Public Health Service

During the unprecedented global pandemic, the lines between medical treatment and medical experimentation became blurred at times. How can we evaluate the effect, scope, and monitored? How can we evaluate the effect, scope, and monitored? How can we evaluate the effect, scope, and monitored? How can we evaluate the effect, scope, and monitored?

Round Table

What social responsibilities, if any, should big-pharma companies (and other large private companies) have?

Co-Chairs and Moderators: Prof. Shai Lavi, Director, The Van Leer Jerusalem Institute; Professor of Law, Tel Aviv University

Prof. Nadav Davidovitch, School of Public Health, Faculty of Health Sciences, Ben-Gurion University of the Negev

Pharmaceutical companies invest heavily in developing new drugs and treatments. They often rely on the general public to volunteer for medical trials and donate samples. What responsibility, if any, do they have to individual participants in medical trials, and/or to the general public? Examples may include incidental findings in genomic research, the study of orphan diseases, open biobanks, and data-sharing.

16:00 Coffee break
16:30 Session IV What social responsibilities, if any, should big-pharma companies (and other large private companies) have?

Chair: Prof. David Harel, President, The Israel Academy of Sciences and Humanities

Moderators from the previous session.

Prof. Jonathan Kimmelman, School of Public Health, Faculty of Health Sciences, Ben-Gurion University of the Negev

Round Table

What social responsibilities, if any, should big-pharma companies (and other large private companies) have?
The conference will be live-streamed on the Israel Academy website and the Van Leer website.

The conference will be in English.

Wednesday, December 14, 2022

9:00 Registration

9:30 Session V When is biomedical research illegitimate? from human cloning to the stigmatization of vulnerable populations
Chair: Prof. David Heyd, Department of Philosophy, The Hebrew University of Jerusalem
What are the ethical limits of biomedical research? Are certain kinds of scientific studies unethical, even if they are safe?
Dr. Christine Grady, Chief, Department of Bioethics, National Institutes of Health, USA

Looking Forward: Why Certain Types of Biomedical Research Should Not Be Done
Prof. Jonathan D. Moreno, University of Pennsylvania, USA
Data, Genes, and Brains: New Challenges for Old Limits

11:10 Coffee break

11:30 Session VI New ethical challenges in the age of big data and digital precision medicine
Co-chairs: Prof. Dina Ben-Yehuda, Faculty of Medicine, The Hebrew University of Jerusalem; Hadassah Medical Center, Jerusalem
Prof. Ephrat Levy-Lahad, Medical Genetics Institute, Shaare Zedek Medical Center, Jerusalem

What unique bioethical challenges are posed by big data studies? Privacy has been a central concern for both experts and the general public. Observers have also raised concerns about bio-terrorism and the exploitation of public goods by private interest. When is there a rationale and a need for national management of genetic data, and how does it relate to the drive for international collaboration – specifically in making genetic and medical data available?
Dr. Sandra Soo-Jin Lee, Chair, of the Division of Ethics, Department of Medical Humanities and Ethics, Columbia University

The Ethics of Diversity, Inclusion and Global Data Harmonization in the Age of Precision
Prof. Michal Rozen-Zvi, Director, AI in Healthcare, IBM Research; Faculty of Medicine, The Hebrew University of Jerusalem
Xai and Causal Inference: Benefiting from the Technology When Applying it on Noisy and Biased Data of Patients With Parkinson’s Disease

Debate
Moderators: Prof. Dina Ben-Yehuda and Prof. Ephrat Levy-Lahad
Prof. Varda Shalev, Management Partner Team8, VC, School of Public Health, Sackler Faculty of Medicine, Tel Aviv University
Prof. Daniel Fiz, Department of Politics and Government, Ben-Gurion University of the Negev

13:20 Lunch break

14:15 Session VII Artificial intelligence [AI] and machine learning in biomedical research
Chair: Prof. Ephrat Levy-Lahad, Director, Medical Genetics Institute, Shaare Zedek Medical Center, Jerusalem
AI research is an emerging bioethical concern. What are the concerns, and how should ethical values and human rights be embedded in AI research?
Prof. Eddy Vayena, Deputy Head, Institute of Translational Medicine, Department of Health Sciences and Technology, ETH Zurich, Switzerland

Health AI Ethics: The Long Path from Principles to Action
Prof. Jeroen van den Hoven, Professor of Ethics and Technology, Delft University of Technology, The Netherlands

Ethics of Artificial Intelligence in Health Care

15:30 Coffee break

15:50 Session VIII The role of the Institutional Review Boards [IRBs]: Research, drug development, ethics and regulation – how to mediate between them all
Chair and Moderator: Prof. Dror Harats, Sackler Faculty of Medicine, Tel-Aviv University; Sheba Medical Center, Tel-Hashomer, Chairman of the IRB committee and Vice President for Research and Development

Biomedical research and more specifically translational research aim to develop new therapies and solutions for unmet medical needs. Eventually, all the new therapies are evaluated by the Institutional Review Boards [IRBs] to ensure that human clinical trials are carried out according to all the relevant rules and regulations, with the best ethical standards. The IRBs have multiple roles, including protecting the rights of research subjects; making sure that patients who need them get access to clinical trials and drugs in development [access programs and compassionate use]; assisting the development of new therapeutic modalities; and even protecting trial sponsors. Although all these roles come together in the principal goal of fulfilling the needs of research and development of new therapeutic modalities, there is a need to mediate between them. Drug development is evolving rapidly, with new technologies, new treatment methods, and new manufacturing processes. We are already able to offer personalized therapies for specific patients, some of them off the shelf and involving the classic pharma companies and others crafted at the site of care. How to approve and regulate such therapies involves a learning process. Clinical trials are evolving as well, with more focused and precise ways to shorten the time needed for drug development, increase the odds for a successful trial and reduce the costs. We intend to discuss all of these issues and more at a round table with experts in the field.

Round Table
Prof. Avraham Shlomo Berliner, Chair, IRB Committee, Tel Aviv Sourasky Medical Center [Ichilov]
Prof. Ilan Cohen, Chair, IRB Committee, Meir Medical Center
Dr. Catherine Elia, Director, Department of Clinical Trials, Israel Ministry of Health
Dr. Lee Goldstein, Chair, IRB Committee, and Head of the Clinical Pharmacology Unit, Haemek Medical Center

17:00 Closing Session Conclusions and a look to the future
Chair: Prof. Shai Lavi, Director, The Van Leer Jerusalem Institute; Professor of Law, Tel Aviv University

Conference Steering Committee
Prof. Aharon Ciechanover (Co-chair), Nobel Laureate and Academy Member; Technion – Israel Institute of Technology
Prof. Shai Lavi (Co-chair), Van Leer Jerusalem Institute; Tel Aviv University
Prof. Dina Ben-Yehuda, The Hebrew University of Jerusalem; Hadassah Medical Center
Prof. Nadav Davidovitch, Ben-Gurion University of the Negev
Prof. David Heyd, The Hebrew University of Jerusalem
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