מכון ון ליר בירושלים
THE VAN LEER JERUSALEM INSTITUTE
معهد فان لير في القدس

האקדמיה הלאומית הישראלית למדעים
المجمع الوطني الإسرائيلي للعلوم والآداب
THE ISRAEL ACADEMY OF SCIENCES AND HUMANITIES

The Israel Academy of Sciences and Humanities
and The Van Leer Jerusalem Institute
cordially invite you to an international conference on

האקדמיה הלאומית הישראלית למדעים
ומכון ון ליר בירושלים
מתכבדים להזמינכם לכינוס בין־לאומי משותף בנושא

2050: מה צופן העתיד לסוגיות הביו־אתיות של המחקר הביו־רפואי

2050: What the Future Holds for Bioethical Issues in Biomedical Research

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

בימים שני–רביעי י"ח–כ' בכסלו תשפ"ג
12–14 בדצמבר 2022
בבית האקדמיה, רחוב ז'בוטינסקי 43, ירושלים

Monday, December 12, 2022

16:30 **Gathering**

17:00 **Opening Session**

Chair: Prof. Aharon Ciechanover, Nobel Laureate and Academy Member; Technion – Israel Institute of Technology

Greetings

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

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

Introduction of the speaker:

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

Keynote Lecture

Prof. Allan Brandt, Harvard University, USA

Looking Backward, Looking Forward: Biomedical Research Ethics in Historical Perspective

18:30 **Dinner Reception**

Tuesday, December 13, 2022

8:30 **Registration**

9:00 **Session I** Is biomedical research over-regulated or under-regulated? A comparative perspective

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

Scientists and pharmaceutical companies often complain about overly burdensome bioethical regulation that hinders the progress of science. Others believe that certain areas of biomedical research are underregulated and that important bioethical questions – including those concerning equity and privacy – are insufficiently covered by current regulations. Regulation differs between countries, and it is important to understand where different countries stand from a comparative perspective.

Dr. Sivan Tamir, Israel Tech Policy Institute; The International Center for Health, Law and Ethics, University of Haifa
Over-Regulation or Under-Regulation of Biomedical Research: Is that the Question?

Round Table

Prof. Eitan Friedman, Sheba Medical Center; Head of the Helsinki Committee, Israel Ministry of Health; Tel Aviv University

Prof. Vardit Ravitsky, Université de Montréal, Canada

Dr. Sivan Tamir, Israel Tech Policy Institute; The International Center for Health, Law and Ethics, University of Haifa

11:00 **Coffee break**

11:20 **Session II** Lost in translation? The ethics of shifting from translation to implementation

Chair: Prof. Yechiel Michael Barilan, 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 new healthcare interventions. Proper monitoring of the outcome of implementation extends research to implementation in diverse patients, each with his or her own medical profile. This may fragment research/follow-up to the point of N=1 trials. How are novel interventions in the care of patients with complex diseases to be implemented and monitored? How can we evaluate the effect, scope, and burden of care on the patient and provider? Is it possible and desirable to differentiate experimental care ("off-label") from clinical experiments on humans? Does a right to healthcare extend to a right to "try out" the "best possible"?

Prof. Søren Holm, Centre for Social Ethics and Policy, Department of Law, University of Manchester. UK
Precision Medicine and Patient Rights

Prof. Jonathan Kimmelman, School of Population and Global Health, McGill University, Canada
The Moral Economy of Drug Development

Prof. Yechiel Michael Barilan, School of Medicine, Tel Aviv University
The Therapeutic Therapeutic Misconception

13:00 **Lunch break**

14:00 **Session III** Experimenting or treating? Drawing a fine line in times of a worldwide pandemic

Chair: Prof. Nadav Davidovitch, School of Public Health, Ben-Gurion University of the Negev

During the unprecedented global pandemic, the lines between medical treatment and medical experimentation became blurred at times. Epidemic vaccine trials are arguably an example. Human challenge trials may be a different kind of example. What are other examples of such a blurring of boundaries? Do emergency conditions legitimatize exceptions to existing rules?

Prof. Dror Mevorach, Hadassah Medical Center, Jerusalem
Emergency Use Authorization (EUA): Between Strengthening a Nation's Public Health and Abuse of Drug Licensing

Dr. Sharon Alroy Preis, Israel Ministry of Health, Head of Public Health Service
Between Research and Public Health Intervention - The Case of COVID19

Prof. Jonathan M. Metzl, Department of Medicine, Health, and Society, Vanderbilt University, USA
Covid, Healthcare, and the Ideologies of Illness

Prof. Dorit Nitzan, School of Public Health, Faculty of Health Sciences, Ben-Gurion University of the Negev
Ethical Considerations in Emergency Preparedness and Response

16:00 **Coffee break**

16:20 **Session IV** 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, 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 to biobanks. 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.

Round Table

Prof. Allan Brandt, Harvard University, USA

Prof. Dror Harats, Tel Aviv University; Sheba Medical Center, Tel-Hashomer

Prof. Vardit Ravitsky, Université de Montréal, Canada

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, Chief 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 Filc, 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. Effy 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 Ela, 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
Prof. Ephrat Levy-Lahad, Shaare Zedek Medical Center, Jerusalem

The conference will be live-streamed on the Israel Academy website and the Van Leer website

The conference will be in English

הרשמה
Registration

הכינוס ישודר בשידור חי
באתר האקדמיה
ובאתר מכון ון ליר

ההרצאות יהיו בשפה האנגלית

הכניסה ללא תשלום, בהרשמה מראש | מספר המקומות באולם מוגבל – הכניסה על בסיס מקום פנוי

Please register in advance | Admission is free of charge, on the basis of available seating

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