

האקדמיה הלאומית הישראלית למדעים المجمــع الوطــــي الإســــرائيلي للعلــوم والآداب THE ISRAEL ACADEMY OF SCIENCES AND HUMANITIES



The Israel Academy of Sciences and Humanities and The Van Leer Jerusalem Institute

Presents an international conference on

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

# **Program and Abstracts**

Jerusalem, 12-14 December, 2022



# The Israel Academy of Sciences and Humanities

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# The Van Leer Jerusalem Institute

The Van Leer Jerusalem Institute fosters innovative interdisciplinary research in the humanities and social sciences and develops new ways of addressing questions of global concern that have special import for Israeli society and the region. Research and public engagement at the Van Leer Jerusalem Institute currently take place in three thematic clusters: Science, Technology, and Society; Sacredness, Religion, and Secularization; and Israel in the Middle East. Alongside work in thematic clusters, the Institute fosters a largescale project promoting gender equality in Israel, and serves as a platform for thinking through and beyond challenges to liberal democracy in our time. In all areas, work at the Institute seeks to break down some of the obstacles to social change by overcoming dichotomies that have become stifling, and offering new terms through which to think about contemporary issues. Our commitment to free and open inquiry is reflected in our maintaining a deeply diverse body of staff and researchers who model civil discourse even as they facilitate and engage in scholarship and relate it to civil society. The Van Leer Jerusalem Institute is home to the Polonsky Academy, the leading international post-doctoral program in Israel, as well as to the Van Leer Institute Press, which publishes leading academic journals in Hebrew as well as key works in cutting-edge social and political thought and Middle East culture, mostly in Hebrew for an Israeli audience.



The Van Leer Jerusalem Institute

### Program

#### Day One / 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

### Day Two / 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

**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**, Head of the Helsinki Committee, Israel Ministry of Health; Tel Aviv University

**Prof. Vardit Ravitsky**, Université de Montréal, Canada Centre for Bioethics, Harvard Medical School, USA

**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

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

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

#### **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 Centre for Bioethics, Harvard Medical School, USA

### Day Three / 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

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

Prof. 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

**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

### **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 of IRB, Head of Internal Medicine C, Haemek Medical Center, Afula

### 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



# Abstracts

(in order of presentation)

# Abstracts

### Day One / Monday, December 12, 2022

**Opening Session** 

# Keynote Lecture Looking Backward, Looking Forward: Biomedical Research Ethics in Historical Perspective

Prof. Allan Brandt, Harvard University, USA

This lecture will examine the rise of the post-World War II regime for the bioethical management of research ethics. Following the Nazi crimes against humanity, a new set of regulations and expectations arose in the domain of research ethics, especially relating to the use of human subjects. These protocols centered on the invocation of informed consent, individual autonomy, and heightened peer and public review of proposed research. In the early 21st century fundamental questions have been raised about the efficacy of this system and its "fit" with emerging new trends of precision therapeutics; complications of randomized protocols; and rising demands for the "right to try" experimental interventions. The paper will assess current trends for revision of the historical foundations of bioethics.

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## Day Tow / Tuesday, December 13, 2022

### Session I Is biomedical research over-regulated or under-regulated? A comparative perspective

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.

# Over-regulation or under-regulation of biomedical research – is that the question?

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

The regulation of biomedical research is an intricate web of regulations and practicalities of ethical oversight mechanisms. The cross-jurisdictional nature of many clinical trials makes familiarity with the intricacies of national legal and ethical frameworks of biomedical research - essential for researchers and sponsors, alike. Ideally, regulation of biomedical research - clinical trials in particular - provides clarity, consistency, and research ethics guidance for researchers and sponsors, as well as for Research Ethics Committees (REC) members. But, determining how much regulation (including ethical oversight) is 'sufficient' for allowing public interests in safety, autonomy, and transparency, to coexist with societal interests in promoting medical science and innovation - is challenging. This paper first comparatively highlights selected practical and ethical aspects of research regulatory regimes in Israel, the UK, and the US. It then addresses claims of over- or underregulation of biomedical research, typically made by researchers and sponsors. The paper argues that the grievance of 'over-regulation', or concern over 'under-regulation', may be too simplistic a way to look at things. A favorable regulatory climate for biomedical research is measured not only by the weight of the regulation, the regulatory (over) load, or regulatory intelligibility but also by a) its flexibility and adaptability (e.g., by revitalizing regulatory frameworks of clinical trials and health data research); and b) its endorsement of scientific advances (e.g., human genome editing).

# **Session II** Lost in translation? The ethics of shifting from translation to implementation

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"?

## Precision medicine and patient rights

**Prof. Søren Holm**, Centre for Social Ethics and Policy, Department of Law, University of Manchester. UK

This lecture will analyze how likely developments in precision medicine will impact on patient rights in relation to medical research and clinical treatment. A distinction will initially be made between precision medicine and personalized medicine and it will be argued that the most likely future scenario for medicine consists of a large expansion of hyper-stratified precision medicine, but only a limited amount of truly personalized medicine.

The analysis will then move to the question of how developments in precision medicine are likely to impact on medical research. It will be argued that the promissory of precision medicine is likely to lead to an increase in therapeutic misconceptions among research participants, and that it will complicate other issues around consent by making it more difficult to confidently identify the 'standard treatment' that is given to the control group in RCT designs. The hyper-stratification inherent in precision medicine may also have other more fundamental implications for the way in which research evidence is generated.

The third part of the talk will analyze to what extent it makes sense in the future to claim that a patient (in a well-functioning healthcare system) has a right to the best possible treatment for their condition. This raises issues in relation to a putative 'right to try', and issues of resource allocation; but it also raises some more fundamental epistemological issues concerning how (and if) we can determine that a particular treatment is the best possible for a particular patient.

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### The Moral Economy of Drug Development

**Prof. Jonathan Kimmelman**, School of Population and Global Health, McGill University, Canada

It is commonly said that drug development is failure prone process, with only one in ten drugs successfully running the gauntlet from phase 1 trials through to approval. Such descriptions of drug development, however, fail to adequately capture some of the most important moral and scientific dimensions of drug development. In this talk, I will sketch a theoretical understanding of drug development that foregrounds several of its moral dimensions, including its reliance on a large volunteer force of trial participants, its role in reducing medical uncertainty, and the role of drug development in distributing the costs and burdens of medical uncertainty. I will then present several examples from my own research of how current drug development systems under-perform on these moral dimensions by overexposing patients to the burdens of research participation, fostering medical uncertainty, or distributing it unfairly. I will close by describing reforms to research oversight and drug regulation that might better align drug development with its moral goals.

### The Misconception of the Therapeutic Misconception

Prof. Yehiel Michael Barilan, Sackler Faculty of Medicine, Tel Aviv University

Contemporary biomedicine relies heavily on the "travelling on a road metaphor". Good medical care is the end of an arduous journey from basic science to clinical research and then, following the peak achievement of approval, the road goes on towards implementation and integration in patients' routines. This road is beset by hurdles, mainly the "valley of death" between basic science to human studies. My talk will tackle the philosophical and ethical aspects of this set of metaphors, mainly the image of a one-way road, and the division between clinical research and care in the free market.

Forty years ago, the concept "therapeutic misconception" was introduced into psychiatric clinical research to highlight the epistemic and normative gap between "research" and "standard care". I will show how this concept has contributed to the one-way road-metaphor, why it fails to fit contemporary notions of "translation science" and "personalization of care", and how revisiting misconception in research and therapy suits contemporary development and implementation of medical research. We need to revise both epistemic and ethical standards of clinical practice.

# Session III Experimenting or treating? Drawing a fine line in times of a worldwide pandemic

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?

# Emergency Use Authorization (EUA): Between Strengthening a Nation's Public Health and Abuse of Drug Licensing

Prof. Dror Mevorach, Hadassah Medical Center, Jerusalem

The Emergency Use Authorization (EUA) originated in 2004 because of the need for emergency medical countermeasures against potential bioterrorist attacks. The EUA

also proved useful in dealing with subsequent pandemics and has emerged as a critical regulatory pathway for therapeutics and vaccines throughout the Coronavirus Disease 2019 (COVID-19) pandemic. We witnessed expansion of emergency authorization for the first group of COVID-19 vaccines, as well as withdrawal of previously authorized products, like hydroxychloroquine, which exemplifies the dynamic nature of scientific review of EUA products. EUAs may be vital but could induce suspiciousness from some sections in the public. We will try to analyze its role in regard to efficacy and safety using the cases of hydroxychloroquine, and mRNA vaccine-induced myocarditis.

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# Between Research and Public Health Intervention - The Case of COVID19

Dr. Sharon Alroy Preis, Israel Ministry of Health, Head of Public Health Service

COVID-19 pandemic turned the world into turmoil. The new deadly virus claimed lives requiring countries to take drastic measures., such as lockdown and school closure, to halt transmission. Pharmaceutical companies raced to find therapeutics to treat the disease, as well as vaccines to prevent it. mRNA platform, that had been developed and researched for many decades prior to the pandemic, was quickly utilized to create COVID-19 mRNA vaccines in record time. These vaccines, along with other traditional platform vaccines that followed, underwent required regulatory steps prior to FDA approval. Israel Ministry of Health (MoH) approved the first COVID-19 vaccine in December 2020. The national vaccination campaign was initiated during the third disease surge and while Israel was in lockdown, similar to other countries around the globe. Thanks to the strong public healthcare system in Israel, and a well-orchestrated campaign led by MoH, the national effort was extremely effective leading the nation to be the first country in the world to achieve 50% coverage of at-risk population. As vaccine coverage expanded, disease rate came down and allowed lifting restrictions without disease wave resurge. Data coming from Israel was the first real-world data showing high vaccine effectiveness and safety. Continues pandemic monitoring by MoH allowed later on to recognize waning immunity and the need for booster dose to maintain protection against the virus.

### Covid, Healthcare, and the Ideologies of Illness

**Prof. Jonathan M. Metzl**, Department of Medicine, Health, and Society, Vanderbilt University, USA

The COVID pandemic has produced paroxysms of recrimination about the best ways to convey scientific information to the public. With each variant and wave arise new debates about how to effectively communicate data about disease prevalence or vaccine effectiveness to increasingly polarized and sceptical groups of people. Often lost in these debates, however, are understandings of or strategies for addressing divergent beliefs about illness itself. The presented study explores how ideology, political affiliation, race and gender, geographic locale, and access to healthcare impacted how people understood their own covid illness across two states in the U.S. South. Data comes from extensive series of focus groups and in-depth interviews across Tennessee and Kentucky during the height of the Delta wave in 2020-21. Groups and subjects divided by political affiliation were asked a series of in-depth questions meant. We aimed to assess how factors such as political, racial, or class identity impacted someone's understanding of their own symptoms; what types of disease identities/politics/inequities emerged from the pandemic; and what types of messages partnerships best mobilized people and communities to work collectively to preserve health.

Among key findings: In Tennessee, which did not adopt the Affordable Care Act (ACA), participants indicated that responsibility for healthcare sat primarily with individuals rather than institutions; White Republican participants rarely talked about community (or communal) responsibility for health, and were less likely than other groups to consider the health and welfare of others during discussions of COVID-19; African Americans in both states viewed people and communities as responsible for health, placing less emphasis on the responsibility of institutions; and Republicans across both states focus primarily on individual and family responsibility for health, Democrats make more room for the responsibility of institutions. Underlying these findings are notions that, in times of crisis, public health understandably moves immediately to directives—mask or vaccine mandates e.g.—without fully addressing ways that diseases such as COVID might "mean" different things to different groups of people or reflect different structural or ideological realities; and that future public-health messaging will need to adjust accordingly.

# Ethical Considerations in Emergency Preparedness and Response

**Prof. Dorit Nitzan**, School of Public Health, Faculty of Health Sciences, Ben-Gurion University of the Negev

The decision to prepare for and respond to emergencies is rooted in societal norms and values and requires expertise and partnerships, engaging communities, investing in the health and public health workforce and ensuring universal health coverage. Preparedness is a public good which requires the implementation of the International Health Regulations (IHR) (2005) in states, communities, households and individuals. It is based on the humanitarian values of humanity, neutrality, impartiality, independence and the notion of human responsibility, solidarity, mutuality and accountability.

The response to the COVID-19 pandemic revealed important layers of bioethical dilemmas and considerations: 1. First do no harm - to oneself and to others, 2. Leaving no one behind - distributive justice: who to vaccinate, treat and provide special care, 3. Autonomy, dignity and human rights - punitive vs rewarding, 4. Life course and age considerations. 5. Intensive care – prioritization, 6. COVAX and globalization, 7. Clinical trials – How and reporting. 9. Adverse event post vaccinations - active or passive, 8. Implementation of global standards - why? 8. The health workforce and volunteers- obligations and compensations, 8. Community engagement - what does it mean, 9. No Regrets policy - To whom? For how long? 10. Public health investments and professionalism - in peaceful times. 9. Personal responsibility 10. Humanity and One Health considerations. 11. Links with producers- why and how, 12. Technical guidance - in times of uncertainty, 13. Tracking and tracing

Including the ethical lens in all stages of the emergency management cycle would improve decision-making, that weigh the impact of "paternalistic/top-down" measures vs. those which are accepted by the communities and/or individuals. Bioethical considerations could contribute to building trust between the state and the community, help to control outbreaks, reduce the risk of epidemics evolving into pandemics, and stop emergencies from becoming crises.

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

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.

### Day Three / Wednesday, December 14, 2022

# **Session V** When is biomedical research illegitimate? from human cloning to the stigmatization of vulnerable populations

What are the ethical limits of biomedical research? Are certain kinds of scientific studies unethical, even if they are safe?

# Looking Forward: Why Certain Types of Biomedical Research Should Not Be Done

**Dr. Christine Grady**, Chief, Department of Bioethics, National Institutes of Health. USA

Biomedical research progresses our understanding of health and disease and identifies ways to prevent, diagnose, treat, and ameliorate diseases. But not all biomedical research that promises progress in understanding health and illness is justified. More than 50 years ago, Hans Jonas cautioned that "...progress is an optional goal", and "...not even the noblest purpose abrogates the obligation" to research participants and to society. These obligations guide the ethics of biomedical research. Looking to the future, in this talk I will explore several reasons we should limit the progress of biomedical research with examples of kinds of research that should be foregone given our current knowledge.

## Data, Genes, and Brains: New Challenges for Old Limits

Prof. Jonathan D. Moreno, University of Pennsylvania, USA

Once we thought we knew what a human experiment looked like, that "eugenics" was unacceptable, and when our thoughts were our own. In this talk I identify how physiologic monitoring, gene editing and brain organoids are challenging each of these assumptions in turn. These problems will make the human cloning debate pale in comparison while also creating novel worries about stigmatization and uncertainties that may be considered to reach the level of unjustifiable risk. I conclude with some observations about the geopolitics of biomedical research that could leave the post-Nuremberg framework of norms vulnerable as the international rules-based order is in jeopardy.

# Session VI New ethical challenges in the age of big data and digital precision medicine

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?

# The Ethics of Diversity, Inclusion and Global Data Harmonization in the Age of Precision

**Prof. Sandra Soo-Jin Lee**, Chief of the Division of Ethics, Department of Medical Humanities and Ethics, Columbia University

Human genetics has a gap problem. Samples from individuals of European ancestry continue to make up over 80% of data sets. Scientists warn these biases limit their ability to make generalizable inferences about the relationships between genes, behaviors, environmental exposures, and disease risks, and threaten the equitable translation of precision medicine. As an intervention, public and private funding

agencies have issued calls increasing diversity through targeted recruitment of "under-represented" groups into research and the scientific workforce. In this paper, I argue that the problem of the gap surfaces both functional trouble for scientific goals for procuring global genetic variation and moral trouble of epistemic erasures that prevent the ethical inclusion of marginalized groups. Drawing on empirical data from a multi-sited study in the US of the "diversity gap", I argue that the problem of the gap is inextricable from forms of epistemic injustice, which must be understood in terms of structural inequities. Taking seriously the assumption that any claim of injustice must rely on shared understandings of lived experience, I explore the ethics of solidarity as a necessary condition for an equitable genomics.

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# Xai and Causal Inference: Benefiting from the Technology When Applying it on Noisy and Biased Data of Patients With Parkinson's Disease

**Prof. Michal Rozen-Zvi**, Director, AI in Healthcare, IBM Research; Faculty of Medicine, The Hebrew University of Jerusalem

Explainable AI (XAI) is a growing research area in the field of AI in biomedicine. Causal inference technologies play a central role in XAI. These technologies aim at inferring from data how much would the effect variable(s) change as a result of modifying the value of input variable(s). Building causal models of the world can support the understanding of why a model selects a certain intervention as an optimal one, which in turn can help the AI developer in improving the technology, can make the technology itself more trustworthy and potentially lead to an expansion of the medical knowledge. However, unlike the supervised learning paradigm, performance assessment of causal inference methods is not straightforward. In this talk I will present an overview of the research of XAI in general and causal inference in particular in the biomedical domain, and share tools to assess performance that were made publicly available by my team; The usage of the tools would be illustrated in the context of finding new indications for existing drugs through causal inference applied to noisy and biased patients data.

# Session VII Artificial intelligence (AI) and machine learning in biomedical research

AI research is an emerging bioethical concern. What are the concerns, and how should ethical values and human rights be embedded in AI research?

# Health AI Ethics: The Long Path from Principles to Action

**Prof. Effy Vayena**, Deputy Head, Institute of Translational Medicine, Department of Health Sciences and Technology, ETH Zurich, Switzerland

The ethics of AI has attracted significant interest by scholars and institutions. As a result there has been a proliferation of AI ethics principles and guidelines aiming to promote AI technologies that meet ethical standards. These efforts did not specify a domain of application but were rather based on high level action guiding principles that were meant to be relevant for any possible application of AI. These efforts have been welcomed by many and also heavily criticized as ethics washing. Against this backdrop domain specific ethics guidance is being emerging. In this talk I will report on some of these developments that are specifically relevant for health and will investigate questions around gaps in guidance, challenges in the implementation of principles into actual policies, and remaining open questions about health AI and our collective responsibility to address them.

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### Ethics of Artificial Intelligence in Health Care

**Prof. Jeroen van den Hoven**, Professor of Ethics and Technology, Delft University of Technology, The Netherlands

The pervasive use of AI in medicine and healthcare has brought ethical and epistemic values into sharp focus for researchers, medical personnel, healthcare providers, policymakers, regulators, and industry. 'Responsible AI', 'trustworthy AI', and 'explainable AI', 'algorithmic fairness', 'equitable AI' are ideals that are widely recognized and advocated. If we want these moral ideals to guide the development and use of AI effectively we will have to be able in practice to design for our moral values, continuously, systematically, transparently and demonstrably along the life cycle of AI Health Applications. This implies the ability to perspicuously represent the processes of decomposing our abstract values into multiple specific requirements. The WHO in its global report on the Ethics and Governance of AI (2021) has embraced this 'ethics by design' approach as the way forward. This gives a new direction to the further development of the research agenda and curriculum of medical ethics in a digital age. I will discuss the design approach to ethics of digital technology in some detail with health related examples.

The ethical problems that advanced digital technology will give rise to require more than the competence to design for our values. Among other things, they also will require us to revisit our ideas about human dignity and respect for persons and our ideas about the boundaries of AI for profit and power and AI for health, wellbeing and human flourishing.

# Session VIII The role of the Institutional Review Boards (IRBs): Research, drug development, ethics and regulation – how to mediate between them all

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.



# Biographies

(in alphabetical order)

# **Biographies**

### **Conference Steering Committee**



# **Prof. Aharon Ciechanover** (Co-chair) Nobel Laureate and Academy Member; Technion – Israel Institute of Technology

Aaron Ciechanover was born in Haifa, Israel in 1947. He is currently a Distinguished Research Professor in the Faculty of medicine at the Technion - Israel Institute of Technology

in Haifa, Israel. He received his M.Sc. (1971) and M.D. (1973) from the Hebrew University in Jerusalem. He then completed his national service (1973-1976) as military physician, and continued his studies to obtain a doctorate in biological sciences in the Faculty of Medicine in the Technion (D.Sc.; 1982). There, as a graduate student with Dr. Avram Hershko and in collaboration with Dr. Irwin A. Rose from the Fox Chase Cancer Center in Philadelphia, USA, they discovered that covalent attachment of ubiquitin to a target protein signals it for degradation. They deciphered the mechanism of conjugation, described the general proteolytic functions of the system, and proposed a model according to which this modification serves as a recognition signal for a specific downstream protease. As a post-doctoral fellow with Dr. Harvey Lodish at the M.I.T., he continued his studies on the ubiquitin system and made additional important discoveries. Along the years it has become clear that ubiquitin-mediated proteolysis plays major roles in numerous cellular processes, and aberrations in the system underlie the pathogenetic mechanisms of many diseases, among them certain malignancies and neurodegenerative disorders. Consequently, the system has become an important platform for drug development. Among the numerous prizes Ciechanover received are the 2000 Albert Lasker Award, the 2002 EMET Prize, the 2003 Israel Prize, and the 2004 Nobel Prize (Chemistry; shared with Drs. Hershko and Rose). Among many academies, Ciechanover is member of the Israeli National Academy of Sciences and Humanities, The European Molecular Biology Organization (EMBO), the American Academy of Arts and Sciences (Foreign Fellow), the American Philosophical Society, the National Academies of Sciences (NAS) and Medicine (NAM) of the USA (Foreign Associate), the Pontifical Academy of Sciences at the Vatican, the Chinese Academy of Sciences (CAS; Foreign Member), the Russian Academy of Sciences (Foreign Member), and the German Academy of Sciences (Leopoldina).

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# Prof. Shai Lavi (Co-chair) Director, The Van Leer Jerusalem Institute; Professor of Law, Tel Aviv University

Prof. Shai Lavi is the director of the Van Leer Jerusalem Institute and a professor of law at Tel Aviv University. Professor Lavi earned his doctorate in law at the University

of California, Berkeley. His research explores bioethical issues from historical and contemporary perspectives, with an emphasis on the use of technology in the beginning of life and at its end. He also engages in comparative research—in Germany, Turkey, and Israel—on issues related to legal regulation of the body and the tension between religion and secularity. His book on the end of life, The Modern Art of Dying: A History of Euthanasia in the United States, won the 2006 Sociology of Law Distinguished Scholarly Book Award of the American Sociological Association. He has been a visiting professor at Cornell University, the University of Toronto, Yeshiva University in New York, and Humboldt University of Berlin.

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# **Prof. Dina Ben-Yehuda** Dean, Faculty of Medicine, The Hebrew University of Jerusalem

Director, Hematology Division, Hadassah Medical Center

Professor Dina Ben-Yehuda, MD, is an internationally recognized physician-scientist, hematologist and acclaimed

investigator in hematological malignancies research. She is the director of the Hematology Division at Hadassah University Medical Center and the Dean of the Faculty of Medicine, Hebrew University of Jerusalem, Israel. A graduate of the Ben-Gurion University Health Sciences Faculty, Ben-Yehuda completed her internship in internal medicine and hematology at Hadassah and did two years of post-graduate studies at the Center for Cancer Research at Memorial Sloan-Kettering in New York City. She is treating patients with hematological malignancies and is leading innovative research in the treatment of malignant lymphoma using innovative approaches in combination with extensive clinical work. Prof. Ben-Yehuda is the leader of the Jerusalem Center for Computational Precision Medicine and Co-founder of the Sagol Program for Computational Medicine of the Medical School, Faculty of Medicine of the Hebrew University of Jerusalem.

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**Prof. Nadav Davidovitch** MD, MPH, PhD, Director, School of Public Health, Ben-Gurion University of the Negev; Chair, Health Policy Program, Taub Center

Prof. Nadav Davidovitch, MD, MPH, PhD is an epidemiologist and public health physician and Director of Ben-Gurion

University of the Negev's School of Public Health. In the past, he has served as Chair of the Department of Health Systems Management at the University and as Chair of the Association of Public Health Physicians in Israel. His research focuses on health policy, health equity, global health and public health history and ethics. He is currently serving on several national and international committees, including the Israeli National Health Services Basket Committee, the official Israel representative on the Executive Committee of the European Public Health Association and chairing the Task Force on the Coronavirus of the Association of the Schools of Public Health in the European Region. Prof. Davidovitch has authored a more than 160 articles and 6 edited volumes on the subject of public health, health policy, medical history, public health ethics and sociology of health. Since the outbreak of COVID-19 in Israel, he has been involved in research and the formulation of health policy and has advised various agencies in Israel and abroad on the need to make structural changes in the health system, with an emphasis on social issues and addressing health gaps.

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# **Prof. David Heyd** Chaim Perelman Professor of Philosophy (emeritus) The Hebrew University of Jerusalem

Heyd's expertise is in ethics, political philosophy and bioethics. He taught in the 1980's the first course on medical ethics in the Faculty of Medicine of the Hebrew University,

and then served in many bioethical committees, including the Hadassa hospital Helsinki committee, and governmental committees on surrogacy, euthanasia, organ transplantations, as well as the Israel Academy commission on ethics and genetics and the National Council of Bioethics. Heyd is still teaching bioethics in the medical school and wrote a widely read general introductory book in Hebrew on medical ethics. But his major publications are in ethical theory, on the subjects of toleration, supererogation, and future generations. He is the winner of EMET Prize in philosophy.



Prof. Ephrat Levy-Lahad Director, Medical Genetics Institute, Shaare Zedek Medical Center, Jerusalem

Ephrat Levy-Lahad is Professor of Medical Genetics and Internal Medicine at the Hebrew University of Jerusalem and Director of the Genetics Institute at Shaare Zedek

Medical Center (SZMC) in Jerusalem, Israel. Prof. Levy-Lahad's clinical laboratory includes a large pre-implantation diagnosis service, and cancer genetics diagnostics. Her research focuses on population genetics of breast/ovarian cancer and on the genetic basis of rare diseases. Her work on population genetics of breast cancer has led to the recent adoption of population screening for BRCA among Ashkenazi Jews in Israel.

Prof. Levy-Lahad is also active in bioethical aspects of genetic research. She was co-Chair of Israel's National Bioethics Council and was a member of the USA National Academy of Sciences Committee on gene editing. In 2018 she was awarded the EMET Prize in Life Sciences prize. She currently serves as Vice President of the Israel National Academy for Science in Medicine.

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### **Participants**



### Dr. Sharon Alroy Preis

Israel Ministry of Health, head of public health services

Dr. Alroy Preis graduated Medical School with honors, from the Technion, Israel institution for Technology in 2000. She completed Internship with honors at Rambam Medical Center and continued to Internal Medicine Residency at Carmel

Medical Center in 2002. Following the completion of her residency, she relocated with her family to New Hampshire, USA, for an Infectious Disease Fellowship at Dartmouth Hitchcock Medical Center. During her fellowship training, she was chosen for the prestige program of Leadership in Preventive Medicine Residency (LPMR), combing her clinical fellowship with Preventive Medicine Residency and MPH studies at Dartmouth College. During the second year of her residency she served as chief resident. Upon successful completion of her training, Dr. Alroy Preis was chosen at 2010 to be New Hampshire State Epidemiologist, at the Division of Public Health Services. Alroy Preis served in this role for 3 years during which she was the Incident Commander for two major multistate outbreak investigations, in charge of strategic planning for the Ministry of Health and developed web-based platform for sharing public health data. In 2013 she returned to Israel with her family, Joined the Infectious Disease team at Carmel Medical Center, and was recognized as Public Health specialist in Israel. At 2015 Alroy-Preis was asked to build the Quality Improvement Division at the hospital. In 2018 she was chosen as hospital deputy CEO. Between 2017-2019 Dr. Alroy Preis took part in the esteemed leadership program INBAR, during which she completed with honors MBA at Tel-Aviv University, and Health Administration fellowship. Since August 2020 she is serving as the Director of Public Health Services at Israel Ministry of Health. In her role she is the most senior public health professional at the office, advising the government in areas pertaining to her specialty. She has been part of the leading team in charge of Israel's COVID-19 response and the data analysis that aided policy decisions, both locally and internationally. For her role in the pandemic she received several awards and repeatedly chosen as one of the most influential people in Israel.



Prof. Allan Brandt Amalie Moses Kass Professor of the History of Medicine Professor of the History of Science Department of the History of Science Department of Global Health and Social Medicine Harvard University, USA

Allan M. Brandt is the Amalie Moses Kass Professor of the History of Medicine and Professor of the History of Science at Harvard University, where he holds a joint appointment between the Faculty of Arts and Sciences and Harvard Medical School. Brandt is the author of No Magic Bullet: A Social History of Venereal Disease in the United States since 1880 (1987, 2020); and co-editor of Morality and Health (1997). His book on the social and cultural history of cigarette smoking in the U.S., The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product that Defined America, was published by Basic Books in 2007 (paperback, 2009). He has written on the social history of epidemic disease; the history of public health and health policy; and the history of human experimentation among other topics. Brandt is currently serving as the interim chair of the Department of Global Health and Social Medicine at Harvard Medical School.

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# Prof. Yehiel Michael Barilan Sackler Faculty of Medicine, Tel Aviv University

Y. Michael Barilan is a practicing physician, expert in internal medicine and a professor at Tel Aviv University's school of medicine. His focus of research is the intersection between social history of medicine and medical ethics. His books

include Human Dignity, Human Rights and Responsibility (MIT Press) and Jewish Bioethics (Cambridge University Press). He co-edited a book on ethics in personalized medicine, (Oxford University Press).



Prof. Avraham Shlomo Berliner Chair, IRB Committee, Tel Aviv Sourasky Medical Center (Ichilov)

A.S. Berliner M.D., Ph.D.

Dr. Berliner has received his M.D. from the Tel-Aviv University Sackler Faculty of Medicine and his Ph.D. in cell biology from

the same university. The post Ph.D. fellowship was performed at the Scripps Clinic in La Jolla, San Diego California and focused on the role of Von Willebrand Fctor and other adhesion molecules in the etiopathogenesis of Thromboinflammation. Dr. Berliner is a specialist in Internal Medicine and is a researcher in the fields of coagulation and inflammation. During the years, 1995-2021 served as the head of the department of Internal Medicine at the Tel-Aviv Medical center and is currently an emeritus full Professor of medicine. Has published more than 330 scientific papers and is currently the head of the IRB committee at the Tel-Aviv Medical Center.

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### Prof. Ilan Cohen

Chair, IRB Committee, Meir Medical Center

Ilan Cohen M.D. graduated Sackler School pf Medicine, Tel Aviv University, and he is a full professor of Obstetrics and Gynecology in this Medical School He graduated residency in Obstetrics and Gynecology in Meir Hospital. In 1988-

1989 he worked and trained as a fellow in the Department of Reproductive Biology, Case University, Cleveland, Ohio, USA. Professor Ilan cohen was mostly involved in Fertility Preservation and in Gynecological Survey and prevention of Breast cancer patients, in the Department of Obstetrics and Gynecology at Meir Hospital. He published or was a co – author in 100 original articles in peer- reviewed journals ,mostly on several aspects, follow up and prevention of Gynecological pathologies among pre and postmenopausal breast cancer patients, and thus, established the protocol of gynecological follow-up of breast cancer patients.



Dr. Catherine Ela Director, Department of Clinical Trials, Israel Ministry of Health

Catherine Ela, Ph.D., is currently the Director of the clinical trials department at the Ministry of Health. Prior to that she held the position of the head of the clinical trials medical

devices and advanced therapies unit and was a pharmacist at the Pharmaceutical Department at the Ministry of Health. She was a lecturer at the Bar Ilan and the Ben Gurion universities in the field of GCP. She was born in France where she graduated from the Faculty of Sciences Nice Sophia Antipolis and received her Master's Degree in Biochemistry. After arriving in Israel in 1985 she completed a Master's degree in Microbiology and a Ph.D. at the Hebrew University Medical School. She is also a registered pharmacist graduate of the Hebrew University School of Pharmacy.



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# **Prof. Daniel Filc** Department of Politics and Government, Ben Gurion University of the Negev

Dani Filc, MD, PhD. is a Professor at the Department of Politics and Government, Ben-Gurion University. Among his fields of research, Israeli politics, populism and the health

care system. Among his publications the books Circles of Exclusion: *The Politics* of Health-Care in Israel and The Political Right in Israel: The Many Faces of Israeli Populism and Comics and Politics.

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Prof. Eitan Friedman Professor , MD. PhD. Tel Aviv University Head of the Helsinki Committee Israel Ministry of Health

Dr. Eitan Friedman is the founder of the Oncogenetics unit, Sheba Medical Center (SMC), and its director from 1995-

2021. Since his retirement from the SMC, he has been involved in establishing a genetics service (personal and public) at tehn Dr. Friedman graduated in 1979 from the Sackler School of Medicine, Tel-Aviv University, and served as the Divisional field physician of the Israeli paratrooper unit. From 1982-1987, he specialized in Internal Medicine at SMC. From 1987 to 1992, he worked as a post-doctoral fellow at the Molecular Pathophysiology Branch, at the NIH, in Bethesda, MD. Between 1992-1994 at the Department of Clinical Genetics, Karolinska Institute, Stockholm Sweden, he was a visiting scientist, and earned his molecular biology PhD. Upon returning to Israel in 1994 he finished his genetics residency and established the oncogenetics service at SMC, and the Meirav high risk clinic in the same medical center. After retiring from Sheba in March 2021, he is currently the head of the personalized preventive medicine initiative at Assuta Medical center, Tel Aviv. Since April 2020 he is the head of the Ministry of Health Helsinki committee for genetic studies. Dr. Friedman is a tenure track full professor, Department of Genetics and Biochemistry, Sackler School of Medicine, Tel Aviv University. He has trained 15 Ph.D. and 32 Masters students, and ~40 physicians on 6-month rotations. He has published or was a co-author of more than 440 original articles in peer-reviewed journals, and contributed 10 book chapters. Dr Friedman is involved in medical education at several levels: organizing courses for students and physicians in Israel, Brazil, and Uruguay, hosting medically oriented TV shows, and publishing three medically oriented children's books. Last but not least, Dr. Friedman is the first Israeli to complete a solo swim across the English Channel (1993) and swim around Manhattan (1989).



Dr. Lee Goldstein Chair of IRB, Head of Internal Medicine C, Haemek Medical Center, Afula

Born in South Africa and made Aliya with her family in 1977. Trained in medicine at the Medical School of the Hebrew University of Jerusalem, and qualified in 1993. Specialized

in internal medicine at the Bnei Zion Medical Center in Haifa, and in clinical pharmacology at the Shamir Medical Center in Zerrifin. Currently Head of Internal Medicine Department C, at Haemek Medical Center in Afula, Israel.

Dr. Goldstein is Head of the Israel Society of Clinical Pharmacology and the Israeli delegate in the European Association of Clinical Pharmacology and and Therapeutics in the European Coalition for Reducing Bureaucracy in Clinical Trials. She is a member of the Israel Medical Associations ethics committee and has been Chair of the Haemek Medical Center IRB for the past 8 years.



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### **Dr. Christine Grady**

Chief, Clinical Center Department of Bioethics, US National Institutes of Health, USA

Christine Grady is a nurse-bioethicist, senior investigator, and Chief of the Department of Bioethics at the National Institutes of Health Clinical Center. Her research focuses on

clinical research ethics, including informed consent, vulnerability, study design, and recruitment, international research ethics and on ethical issues faced by nurses and other healthcare providers. Dr. Grady has authored more than 200 papers in the biomedical and bioethics literature and authored or edited several books, including The Oxford Textbook of Clinical Research Ethics. She is an elected fellow of the Hastings Center and the American Academy of Nursing, a research fellow at Kennedy Institute of Ethics and an elected member of the National Academy of Medicine. Dr. Grady holds a B.S. in nursing and biology from Georgetown University, a M.S.N. in community health nursing from Boston College, and a Ph.D. in philosophy from Georgetown University. Dr. Grady has authored more than 200 papers in the biomedical and bioethics literature and authored or edited several books, including The Oxford Textbook of Clinical Research Ethics. She is an elected fellow of the Hastings Center and the American Academy of Nursing, a research fellow at Kennedy Institute of Ethics and an elected member of the National Academy of Medicine. Dr. Grady holds a B.S. in nursing and biology from Georgetown University, a M.S.N. in community health nursing from Boston College, and a Ph.D. in philosophy from Georgetown University.

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### Prof. Dror Harats

Tel Aviv University; Sheba Medical Center, Tel-Hashomer

Prof. Harats is currently a professor of medicine in the department of biochemistry at the Sackler Faculty of Medicine, Tel-Aviv University, Israel. At The Sheba Medical Center, Tel-Hashomer, Israel he is the VP of Research and

Development, Chairman of the IRB committee and President of the Bert Strassburger Lipid Center. Prof. Harats is a graduate of the Hadassah Medical School at the Hebrew University, Jerusalem. He completed his residency in Internal Medicine at Hadassah and fellowship in Pulmonary and molecular biology at the University of California, San Francisco (UCSF).

For the past 25 years Prof. Harats has been involved in "cutting edge" Research in Lipid Metabolism, Atherosclerosis and Vascular Biology. He was one of the pioneers who discovered the role of the immune system in atherosclerosis and invented a new genetic tool for the treatment of angiogenesis, a process that plays a major role in cancer and cardiovascular disorders. His research was published in more than 212 papers and chapters in books, and rewarded him with numerous prizes and grants in the field of atherosclerosis and cancer.



**Prof. Søren Holm** Professor of Bioethics, Centre for Social Ethics and Policy, Department of Law, University of Manchester, UK

Søren Holm is a Danish medical doctor and philosopher. He is Professor of Bioethics at the University of Manchester and Professor of Medical Ethics (part-time) at the University of Oslo.

He holds degrees in Medicine and in Philosophy and Religious Studies, a master's degree in health care Ethics and Law; and a PhD and a higher Danish doctorate in Medical Ethics. He is a former President of the International Association of Bioethics and of the European Society for the Philosophy of Medicine and Healthcare. He is currently coordinating the EU funded project HYBRIDA on the ethics and regulation of organoid technologies.

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Prof. Jonathan Kimmelman James McGill Professor, STREAM Research Group Director, Biomedical Ethics / Interim Co-Director, Dept. of Equity, Ethics and Policy School of Population and Global Health, McGill University, Canada

Jonathan Kimmelman, PhD, is James McGill Professor of

Biomedical Ethics at McGill University, and directs the Biomedical Ethics Unit as well as his own research group, STREAM (Studies in Translation, Ethics and Medicine). Kimmelman's research centers on ethical, policy, and scientific dimensions of clinical development. Kimmelman received the Maud Menten New Investigator Prize (2006), a CIHR New Investigator Award (2008), a Humboldt Bessel Award (2014), and was elected a Hastings Center Fellow (2018). He has sat on various advisory bodies within the U.S. NHLBI and NIAID, served for four tours of duty on U.S. National Academies of Medicine committees, and chaired the International Society of Stem Cell Research *Guidelines for Stem Cell Research and Clinical Translation* revision task force 2015-16. His research has been covered in major media outlets, including NPR's *All Things Considered, STATNews*, and Nature. Kimmelman is deputy editor at *Clinical Trials*, and associate editor at *Cell Med*.



### Prof. Sandra Soo-Jin Lee

Professor of Medical Humanities and Ethics, Chief of the Division of Ethics, Columbia University, USA Chief of the Division of Ethics and tenured faculty, Department of Medical Humanities and Ethics, Columbia University, NY, USA

Sandra Soo-Jin Lee, PhD, is Professor of Medical Humanities and Ethics and Chief of the Division of Ethics at Columbia University. Trained as a medical anthropologist, Dr. Lee has extensive experience leading multi-disciplinary research on equity and the use of categories of race and ancestry in genomics, precision medicine and artificial intelligence, the ethical governance of biorepositories and commercialization of biotechnology. Dr. Lee publishes broadly in the genomics, medical, bioethics, and social science literatures, and co-edited Revisiting Race in a Genomic Age (2008). Her NIH funded studies include the Ethics of Inclusion: Diversity in Precision Medicine Research; Beyond Consent: Patient Preferences for Governance of Use of Clinical Samples and Data; and Social Networking and Personal Genomics: Implications for Health Research. Dr. Lee is Co-Director of the Center for ELSI Resources and Analysis and the Biennial International ELSI Congress. She currently serves as President of the Association of Bioethics Program Directors, and on the US Health and Human Services Secretary's Advisory Committee on Human Research Protections, the Scientific Advisory Board of the Human Pangenome Research Consortium and the editorial boards of the American Journal of Bioethics and Narrative Inquiry in Bioethics. Dr. Lee is a member of the National Academies of Science, Engineering and Medicine's Committee on the Use of Race, Ethnicity, and Ancestry as Population Descriptors in Genomics Research and is a Hastings Center Fellow. Dr. Lee received her doctorate from the UC Berkeley/UCSF joint program in Medical Anthropology and her undergraduate degree in Human Biology from Stanford University.



Prof. Jonathan M. Metzl MD, PhD; Director, Department of Medicine, Health, and Society, Vanderbilt University, USA

Jonathan M. Metzl is the Frederick B. Rentschler II Professor of Sociology and Psychiatry, and the director of the Department of Medicine, Health, and Society, at Vanderbilt

University. His books include *The Protest Psychosis: How Schizophrenia Became a Black Disease, Prozac on the Couch: Prescribing Gender in the Era of Wonder Drugs, Against Health: How Health Became the New Morality, and Dying of Whiteness: How the Politics of Racial Resentment is Killing America's Heartland, which won the 2020 Robert F. Kennedy Human Rights Book Award.* 

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# Prof. Dror Mevorach Hadassah Medical Center, Jerusalem

Dror Mevorach, MD, is a professor of Medicine at Hadassah Medical Center and the Faculty of Medicine, the Hebrew University. He directed the Department of Internal Medicine between 2009-2022 and COVID-19 wards during the

pandemia. Currently he is the Chairman of Immunology-Rheumatology-Allergology Institute. Professor Mevorach was the first to report about mRNA vaccine myocarditis to the Ministry of Health and the WHO, summarized in three New England Journal of Medicine papers and one in Circulation (2021-2022).

Professor Mevorach directed all medical studies at the faculty of Medicine for 8 years, was the Vice Dean for Teaching, and conducted the swear of the doctor's oath of over 1000 new doctors at the Faculty of Medicine. He developed at Hadassah a novel cellular therapy using apoptotic cells that was used and is used today by Enlivex Therapeutics (Founder Dror Mevorach), in bone marrow transplantations, cancer, sepsis, and COVID-19.

His general research goal is to understand the molecular mechanisms of autoimmune and autoinflammatory diseases via innate immunity associated alteration and relevance to phagocytosis of dying cells and resolution of inflammation, and to develop therapeutic modalities based on these mechanisms. He leads a research group with the help over the years of 15 PhD students that he mentored, many fellows and other students.

His group now studies the mechanism of myocarditis, COVID-19 and long Covid, but also focuses in deciphering the mechanism of innate immunity in cancer and in monogenic diseases. This led to identification of novelle autoimmune, autoinflammatory, and immune deficient diseases including VPS 45 deficiency in neutrophils, CD59, and CD55 deficiencies, Calcium Sensing Receptor mutations, LACC1, and many more.

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**Prof. Jonathan D. Moreno** David and Lyn Silfen University Professor University of Pennsylvania, USA

Jonathan D. Moreno is the David and Lyn Silfen University Professor at the University of Pennsylvania where he is a Penn Integrates Knowledge (PIK) professor. At Penn he

is also Professor of Medical Ethics and Health Policy, of History and Sociology of Science, and of Philosophy. Moreno is an elected member of the National Academy of Medicine and a recipient of the American Society for Bioethics and Humanities Lifetime Achievement Award.

He has served as staff member or adviser to many governmental and nongovernmental organizations, including three U.S. presidential commissions, the Howard Hughes Medical Institute, the Bill and Melinda Gates Foundation, and the UNESCO International Bioethics Committee. Moreno is currently a member of the Bayer Bioethics Council. He was named an official "Mad Scientist" by the U.S. Army's Training and Doctrine Command. In 2008-09 he was a member of President Barack Obama's transition team. Currently he is an investigator on a \$1.1 million Department of Defense project on artificial intelligence-enabled neurotechnologies and warfighters. He is senior consultant to a six-year, 10 million-euro project on cold war medical science on both sides of the iron curtain, funded by the European Research Council.

His most recent books are *Everybody Wants to Go to Heaven but Nobody Wants to Die: Bioethics and the Transformation of Healthcare in America*, co-authored with former Penn president and currently US ambassador to Germany Amy Gutmann; and *The Brain in Context: A Pragmatic Guide to Neuroscience*, written with neuroscientist Jay Schulkin.

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Prof. Dorit Nitzan Professor, MD, MPH, RD Director, Health Emergencies Program, School of Public Health, and Chair, Food Systems, One Health and Resilience (BGU-FOR) Initiative, Ben Gurion University of the Negev

Prof Dorit Nitzan is a physician, specialized in pediatric gastroenterology and nutrition, she is also a clinical dietitian and has MPH and experience in in public health and emergencies. She served in various senior roles in the World Health Organization (WHO) for 17 years. From 2005 to 2012 she was the WHO Representative and Head of Country Office in Serbia and Montenegro and a Manager of Public Health Services for South-East Europe. From 2012 to 2016, Dorit served as the WHO Representative and Head of Country Office in Ukraine. She was subsequently appointed WHO Regional Emergencies Director in the WHO European Region and was based in Copenhagen, Denmark. She retired in February 2022. At the start of the war in Ukraine, Dorit joined NATAN Disaster Relief NGO and headed, together with a logistics and operations colleague, the first humanitarian medical aid team for the Ukrainian refugees on the Polish-Ukrainian border. A few weeks later she was recalled to WHO as the Emergencies' Incident Manager of the WHO humanitarian response in Ukraine. Before joining WHO, Dr Nitzan was the Director of the Food and Nutrition Administration in the Israeli Ministry of Health. She was active in global health work through the Israeli Ministries of Health and Foreign Affairs, World Health Organization, World Food Program, JDC, Physicians for Human Rights and was a consultant and on relief operations to Thailand, Ethiopia, China, Moldova and the Russian Federation.

Dorit has a degree in clinical nutrition from the Hebrew University. She then pursued her medical degree Tel Aviv University Faculty of Medicine. She completed her pediatric residency in Morristown Memorial Hospital in New Jersey, USA, and her fellowship in pediatric gastroenterology and nutrition at the Columbia Presbyterian Medical Center/Babies Hospital, New York. At the same time she gained her MPH in epidemiology and biostatics, at the School of Public Health, Columbia University, New York, USA. Prof Nitzan has joined Ben Gurion University of the Negev, Israel, as the Director of the Emergency Medicine Department in the School of Public Health, and Head of the new Ben Gurion University Food Systems, One Health and Resilience Initiative (BGU-FOR).

Dorit has received awards and recognitions from the Israeli Ministry of Foreign Affairs, UN, WHO and during her clinic work.

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Prof. Vardit Ravitsky

Professor, Bioethics Program, Department of Social and Preventive Medicine, School of Public Health, University of Montreal, Canada Senior Lecturer on Global Health and Social Medicine, Harvard Medical School

Vardit Ravitsky is a Full Professor at the Bioethics Program, School of Public Health, University of Montreal and Senior Lecturer on Global Health and Social Medicine at Harvard Medical School. She is Past-President and currently Vice-President of the International Association of Bioethics. She is the Director of Ethics and Health at the Center for Research on Ethics and holds a Research-Creation Chair on the Reappropriation of Maternity. She is a 2020 Fellow of the Pierre Elliott Trudeau Foundation and chaired the Foundation's COVID-19 Impact Committee. She is also a Fellow of the Canadian Academy of Health Sciences and of the Hastings Center. She was member of the CIHR Standing Committee on Ethics for over 6 years and is currently member of the Institute Advisory Board of CIHR's Institute of Genetics.

Ravitsky's research focuses on the ethics of genomics and reproduction and is funded by Canada's leading funding agencies. She published over 190 articles and commentaries on bioethical issues. Her research covers a variety of topics such as: public funding of In-Vitro Fertilization (IVF); the use of surplus frozen embryos; posthumous reproduction; pre-implantation genetic testing (PGT); gamete donation; epigenetics; prenatal testing, in particular the ethical, social, and legal aspects of Non-Invasive Prenatal Testing (NIPT); germline and somatic gene editing; and mitochondrial replacement. More recently, she has been involved in research and policy regarding pandemic ethics and was heavily involved in public outreach during COVID-19.

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Prof. Michal Rozen-Zvi Director, Al in Healthcare, IBM Israel; Faculty of Medicine, The Hebrew University of Jerusalem

Professor Rosen-Zvi is the Director for AI in Healthcare at IBM Research and an Adjunct Professor of Computational Medicine at the Faculty of Medicine, the Hebrew University.

She is also heading the AI for Healthcare Department at IBM Research, Israel. In addition, she is a member of the board of the Israeli Society of Health Tech and the Head of Digital Health section of the fellowship in health tech for expert physicians. Michal published more than 50 peer-reviewed papers, has h-index 22 and 5500+ citations according google scholar. More information can be found at https://en.wikipedia.org/wiki/Michal\_Rosen-Zvi.

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# Prof. Varda Shalev

Management Partner Team8, VP; School of Public Health, Sackler Faculty of Medicine, Tel Aviv University

Prof. Varda Shalev, MD MPH, is a management partner at Team8. Prior to that she was a Co-Founder and CMO of a startup called Alike – a social network of patients. She was

the founder and CEO of KSM - Maccabi Research & Innovation Institute, and serves as faculty member at the Tel-Aviv University School of Public Health (TAU SPH) where she teaches areas of big-data and medical informatics. Prof. Shalev is an active primary care physician in Maccabi Healthcare Services (MHS) sick fund.

With an MD degree from Ben-Gurion University Medical School, she completed her residency in family medicine and earned an MPA in Health Public Administration at Clark University. After a two-year fellowship in medical informatics at the Johns Hopkins University Hospital, Prof. Shalev established the Medical Informatics Department at Maccabi and was responsible for planning and developing its computerized systems encompassing data from two million members and 9000 care providers. She has pioneered the development of multiple disease registries to support chronic disease management. Prof. Shalev has served as the director of Primary Care Division at MHS and implemented several structural reforms in the provision of care. Prof. Shalev's research interests are epidemiology, medical informatics and predictive analytics. She has authored or co-authored over 250 publications in peer-reviewed journals.

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### Dr. Adv. Sivan Tamir

Policy Counsel and Senior Research Fellow, Israel Tech Policy Institute; Research Fellow, The International Center for Health, Law and Ethics, the University of Haifa

Dr. Sivan Tamir is a Senior Researcher and Policy Counsel at the Israel Tech Policy Institute. She is also a Research Fellow

at the International Center for Health, Law, and Ethics, and a Teaching Fellow in the Faculty of Law, at the University of Haifa. She is a former Coordinator of the National Helsinki Committee for Human Medical Research (Ministry of Health), and a researcher in the Genetic Policy & Bioethics Unit, at the Gertner Institute for Epidemiology & Health Policy Research, Sheba Medical Centre. Dr. Tamir is a member of the Advisory Committee on Bioethics of the Israel Academy of Sciences and Humanities, and a member of the Israel Fertility Association (IFA) Ethics Committee.

Dr. Tamir's principal research interests lie in the fields of medical law and bioethics, genetics, clinical research ethics, reproductive ethics, health data ethics, and ethics of emerging technologies. Her previous research includes ethical and legal considerations of postnatal human genetic enhancement; the ethico-legal and practical implications of direct-to-consumer (DTC) genetic testing; sperm donors' ethical obligation to disclose personal genetic information; the precision medicine (health) data environment in Israel; and artificial intelligence in government – the case of implementing algorithmic decision-making systems in welfare services.



Prof. Jeroen van den Hoven University Professor Professor of Ethics and Technology Delft University of Technology, The Netherlands

Jeroen van den Hoven is University Professor and Professor of Ethics and Technology at Delft University of Technology. He

is Founding Editor in Chief of Ethics and Information Technology (Springer Nature) and permanent member of the European Group on Ethics (EGE) to the President of the European Commission. He has published widely on Ethics of Digital Technology, e.g. Design.

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Prof. Effy Vayena Professor of Bioethics, ETH Zürich Vice-chair of the Institute of Translational Medicine, ETH Zürich Chair of the Greek National Bioethics and Technoethics Commission

Dr. Effy Vayena is Professor of Bioethics at the Swiss Federal Institute of Technology Zürich (ETH Zürich). In her work, she investigates how advances in science and technology can be ethically applied for best outcomes in public and personal health. Vayena completed her education as a social historian with a PhD in Medical History from the University of Minnesota and a habilitation on Bioethics and Health Policy at the University of Zurich. A keen interest in health policy led her to work for the World Health Organization where she served as a technical officer for several years. Upon her return to academia, Vayena was awarded a Swiss National Science Foundation professorship and founded the Health Ethics and Policy Lab. The lab's purpose is to tackle ethical questions that arise at the cutting edge of biotech research, in areas such as genomic technologies and big data analytics for healthcare. The lab moved to ETH Zurich in 2017. Vayena has been appointed Faculty Associate at the Berkman Klein Center for Internet & Society at Harvard University, where she was previously a Fellow. She has published over a hundred peer-reviewed articles and book chapters and co-edited several books. Vayena is also an elected member of the Swiss Academy of Medical Sciences. She chairs the Ethical, Legal and Societal Implications advisory group for the Swiss Personalized Health Network, a national infrastructure and research program which aims to advance personalized healthcare in Switzerland. She is a member of the World Economic Forum's advisory board for the Global Risks Report. She co-chaired the WHO's expert advisory group on Artificial Intelligence health ethics and governance. In 2021 she was named chair of the Greek National Bioethics and Technoethics Commission. Professor Vayena is renowned for her expertise, and frequently advises governments and public policy organizations on matters of digitization and ethics.

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