Research Ethics workshop

June 18&19, 2015, Bergen, Norway
Ethics and Clinical Research
Venue: Sydnesplassen 12/13 – 1st floor
Department of Philosophy, University of Bergen

Many institutions and countries have recently given higher priority to the development of clinical research centers. For some countries it is seen as a strategy to attract foreign investment. For other countries it is seen as essential to develop cost-effective interventions for health systems that are under pressure financially. This workshop will examine a recent case that is important for how one conducts comparative effectiveness research. We will also explore strategies for building capacity in clinical research ethics.

The controversy over the Ethics of Risk Judgments in Clinical Research
In 2013 the US Office of Human Research Protection (OHRP) notified those responsible for the conduct and review of the Surfactant, Positive Pressure, Oxygenation Randomized Trial (SUPPORT) that it was in violation of the US research ethics regulations. This judgment by the US regulatory agency made this one of the most controversial trials in recent research ethics. It was clear that the controversial issues raised by this case affect how one should conduct comparative effectiveness research in general: that is research where two interventions already in general use are compared for their comparative advantages. The controversy also exposes uncertainties about how to make risk judgments appropriately in clinical research in general. The identification and assessment of the risks of research is particularly important in research on subjects who cannot give consent, such as pediatric research and Alzheimer research. The workshop will summarize current views on this topic and attempt to develop a structure for the ethics of risk judgments in clinical research

Development of ethics competency in a clinical research setting
Competence in research ethics is essential for leading clinical research centers. The workshop will discuss how different institutions have built ethics expertise, with examples from various countries.

The workshop will feature the world's leading experts in research ethics, from the Department of Bioethics, at the US National Institutes of Health, in addition to leading experts from Hong Kong and Beijing, Japan and Singapore. It will enable participants to receive information about the latest developments in research ethics. It should be of interest to clinical researchers and those interested in research policy.

Agenda

Thursday, June 18

9:00 Reidar Lie. Welcome and Introduction

9:15 Risk/benefit assessments in clinical research

9:15 Reidar Lie. Risk benefit assessments. Norwegian and International Regulations

9:45 Questions and Discussion

10:00 David Wendler. Risk benefit judgments in clinical research. Components analysis. Net risk test

11:00 Coffee

11:30 Discussion

12:30 Lunch

13:30 Reidar Lie. The SUPPORT trial. OHRPs proposal for comparative effectiveness studies. Brief introduction to controversy

13:45 Christine Grady. Risk judgments and comparative effectiveness studies

14:45 Discussion

15:15 Break

15:45 Panel: Possible research projects?

16:30 End of day one

Friday, June 19

9:00 **Development of ethics competency in a clinical research setting**

9:00 Reidar Lie. Introduction

9:15 Joseph Millum. Ethics competency internationally: The Fogarty program

10:00 Questions and discussion

10:30 Break

11:00 Xiaomei Zhai: Developing Research Expertise in Beijing

11:30 Francis Chan: Developing Research Expertise in Hong Kong

12:00 Kenji Matsui, Shimon Tashiro: Developing research ethics expertise in Japan

12:30 Calvin Ho: Developing Research Expertise in Singapore

13:00 Lunch

13:30 Christine Grady, Joseph Millum, David Wendler. Research ethics expertise at NIH. Best practices

15:00 End of day two

BIOS

Professor Chan Ka Leung, Francis is the Dean of Faculty of Medicine and the Choh-Ming Li Professor of Medicine and Therapeutics of The Chinese University of Hong Kong (CUHK). He is a member of the Board of the Hong Kong Hospital Authority. As an internationally renowned clinician-scientist in peptic ulcer bleeding, helicobacter pylori, endoscopic therapy, and colorectal cancer, Professor Chan has published over 400 full scientific articles in high impact international journals and his h-index is 50. He is the only researcher in academic history who has published 7 first-author original research articles in the top two prestigious medical journals, namely The New England Journal of Medicine and The Lancet. Besides, his contributions to medical research have been recognized worldwide with many national and international awards. Professor Chan is the first scholar in China to be selected by The Lancet to exemplify his academic profile. In recognition of his outstanding academic achievement, he received the degree of Doctor of Science from the Chinese University of Hong Kong in December 2011. Besides serving the medical and academic profession, he also actively participates in community service. During the SARS outbreak, Professor Chan organized a large-scale screening test to detect silent SARS infection for over 12,000 Hong Kong citizens. In recognition of his contributions to the society, he received the honour of the Justice of Peace in 2010.

ZHAI, Xiaomei, MD, Ph.D., is the Executive Director, Centre for Bioethics, Chinese Academy of Medical Sciences and the Dean of the School of Social Sciences and Humanities, Peking Union Medical College, Beijing. She has been Research Fellow at Harvard School of Public Health, USA, and visiting scholar at Visiting Scholar at Johns Hopkins University. She was Vice President of the Asian Bioethics Association from 2002-2006. She is a member of the Ethics Committee at China's Ministry of Health and the Expert Committee on Organ Transplantation at the Ministry of Health. She has served as consultants for WHO and the European Commission. She has published several textbooks in Bioethics in Chinese.

Christine Grady is Chief of the Department of Bioethics at the National Institutes of Health Clinical Center. Her research focuses on the ethics of clinical research, especially subject recruitment, incentives, vulnerability, informed consent, and international research ethics. She is currently a member of the Presidential Commission for the Study of Bioethical Issues; and also a senior research fellow at the Kennedy Institute of Ethics and an elected fellow at the American Academy of Nursing and at the Hastings Center. Dr. Grady has authored more than 125 papers, authored or edited several books, and has lectured widely on ethical issues in clinical research and clinical care, HIV disease, and nursing. She is an attending on the Bioethics Consultation service, an IRB and DSMB member, and a member of several editorial boards. She 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.

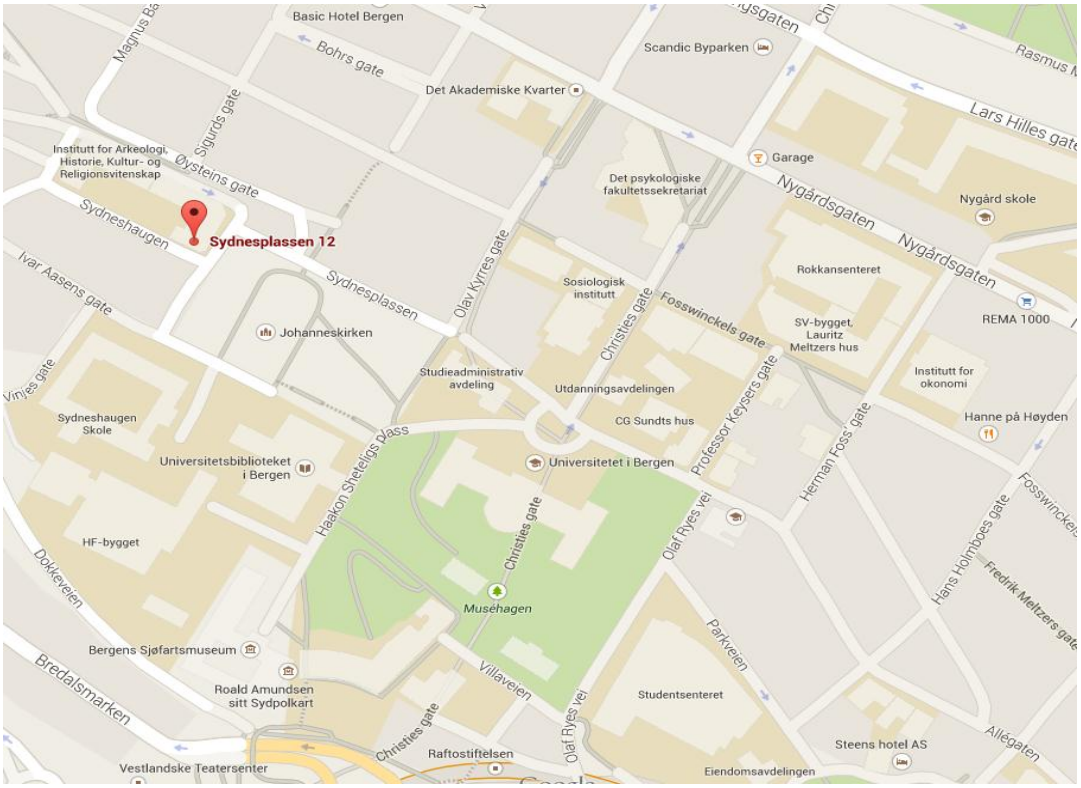
Joseph Millum serves as a liaison between the Clinical Center Department of Bioethics and the Division of International Science Policy, Planning, and Evaluation at the Fogarty International Center, where he provides ethics consultation and educational support. Dr. Millum received his undergraduate degree from Edinburgh University and his Ph.D. in philosophy from the University of Toronto. He completed a post-doctoral fellowship at the Clinical Center Department of Bioethics before taking up his present position. His current research focuses on the rights and responsibilities of parents, global justice and bioethics, priority setting for global health, and international research ethics.

David Wendler is a senior investigator and Head of the Section on Research Ethics in the Department of Bioethics at the NIH Clinical Center. He is a philosopher trained in the philosophy of science, and metaphysics and epistemology. Dr. Wendler is an attending on the Bioethics Consultation service and has served as a consultant to numerous organizations, including the Institute of Medicine, the World Health Organization, and the World Medical Association. His current research focuses on clinical trials and clinical care with individuals who are unable to give informed consent.

Kenji Matsui is Head of the Office for Research Ethics & Bioethics at the National Cerebral and Cardiovascular Center of Japan. Dr. Matsui was trained as a physician and holds a Ph.D. in medicine from Shiga University of Medical Science. His current research focuses on the ethics of clinical research, research ethics education, and health research policy. He also gives consultation services on research ethics and clinical ethics and has serves as an expert member of several IRBs and governmental committees on health research.

Calvin WL Ho is Assistant Professor at the Centre for Biomedical Ethics in the Yong Loo Lin School of Medicine, National University of Singapore (NUS). He is also Co-Head of the Collaborating Centre for Bioethics of the World Health Organization, and a Research Associate with The Ethox Centre, University of Oxford. In addition, he serves as an Assistant Director with the Legal Aid Bureau (Ministry of Law), and a member of two national advisory committees on genetics and organ transplantation with the Ministry of Health in Singapore. Calvin holds a doctorate degree from Cornell University, and was also trained in law at NUS and University of Cambridge. In addition, he holds degrees in sociology and economics from LSE and SOAS (London). His research interests include research governance and policy, and health policy and systems.

Shimon Tashiro is Head of the Section on Bioethics in the Center for Research Administration and Support at the National Cancer Center, Tokyo, Japan. Dr. Tashiro received his undergraduate degree and his Ph.D. in sociology from the Tohoku University. His research interests focus primarily on research ethics, such as issues on the distinction between research and practice, the ethics of innovative therapy and the ethics of RCTs. He is also interested in the end-of-life care, professional ethics, and history of bioethics.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Scandic Byparken
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Garage
Det psykologiske fakultetssekretariat
Nygård skole
Rokkansenteret
REMA 1000
Institutt for Arkeologi, Historie, Kultur- og Religionsvitenskap
Sigurds gate
Øysteins gate
Sydneshaugen
Sydnesplassen
Ivar Aasens gate
Johanneskirken
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Sosiologisk institutt
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