**Tentative agenda Research Ethics workshop**

**June 18&19, 2015, Bergen, Norway**

**Ethics and Clinical Research**

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. Two controversial issues in research ethics have direct relevance for these two developments, the ethics of risk judgments and the ethics of international collaborative research. This workshop will examine both issues.

**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

**Current status of debates in the ethics of international collaborative research**.

International research, in particular in resource poor settings, have raised some of the most controversial debates in recent research ethics. There are issues of standard of care, and obligations to provide interventions at the end of the study. These were also at the heart of the controversy over recent revision of the Declaration of Helsinki. The workshop will summarize some of these debates as well as suggest what are the important unresolved issues

**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 Norway, Singapore, US and Japan.

The workshop will feature the world’s leading experts in research ethics, from the Department of Bioethics, at the US National Institutes of Health. 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 Alan Wertheimer. Rethinking informed consent

16:30 Discussion

17:00 End of day one

**Friday, June 19**

9:00 **Ethics of international collaborative research**

 9:00 Reidar Lie. Introduction

9:15 Joseph Millum. Ethics of international research

10:00 Questions and discussion

10:30 Break

11:00 Kenji Matsui, Calvin Ho, Shimon Tashiro. Developing research ethics expertise in Japan and Singapore

12:30 Lunch

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

15:00 End of day two

**BIOS**

**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.

**Alan Wertheimer** is Senior Research Scholar in the Department of Bioethics at the National Institutes of Health. He is Professor Emeritus of Political Science at the University of Vermont, where he taught from 1968 to 2005. Before retiring, he was John G. McCullough Professor of Political Science. He is the author of Coercion (Princeton University Press, 1987), Exploitation (Princeton University Press, 1996), Consent to Sexual Relations (Cambridge University Press, 2003) and Rethinking the Ethics of Clinical Research: Widening the Lens (Oxford University Press, 2011). He has held fellowships at the Institute of Advanced Study, Princeton (1984-85) and the Program in Ethics and the Professions, Harvard University (1989-90). His current research focuses on the ethics of clinical research with particular reference to issues of coercion, exploitation, and consent.