

### ● **Crossing Borders: Review of Transnational Human Subjects Research**

While there are challenges to human subjects oversight of intra-national research collaborations, they pale in comparison to those faced when participating in transnational research collaborations including, but not limited to, those arising from different cultural, regulatory, and institutional contexts. But then, so do the opportunities.

This session is designed to explore the various challenges that institutions, IRBs/ECs and researchers face when conducting transnational research. Panelists will address a variety of issues that may arise regarding transnational research and how they have addressed them including, but not limited to:

What regulations to consider and how to approach unregulated transnational research

The expertise needed for review and conduct of the research

Types of approvals that may be required related to the collaboration

Factors that may affect risks assessment

On-going oversight of research, including communication plans, should researchers need to change their study

Consent and consent process including assent age limit

Research involving collection of specimens for biobanking

Post-trial benefits sharing

Ethics dumping

Speakers from different continents will discuss how they would address and use case studies to explore a variety of issues that may arise regarding protections of human subjects in transnational research. This session considers the principles of transnational research regardless of where the researchers are based.

During this session, speakers and attendees will: 1. Identify the various challenges in human subjects protections in transnational research collaborations 2. Discuss various approaches for the elimination or mitigation of challenges to human subjects oversight in transnational research collaborations 3. Examine policy and process best practices for IRBs/ECs in the review of transnational human subjects research.

### **Presenters:**

- Dr John Baumann, Indiana University (United States)

John R. Baumann, Ph.D. is the Associate Vice President for Research Compliance at Indiana University, including both Bloomington and Indianapolis campuses as well as the five regional campuses and affiliated hospitals. He earned his Ph.D. in Sociology from the Graduate Center of the City University of New York.

Dr. Baumann has over 30 years of experience in research, research administration, responsible conduct of research and research compliance. In these positions, he has had direct line responsibility for research development, coordination and submission of grant and contract applications, management of funded research as well as compliance with regulations and ethical standards for human subjects research, research with animals, conflict of interest, and radiation and biological safety. He has, therefore, been directly involved in the administration of research at all levels.

In addition to his position at IU, he provides consulting services and serves as a site visitor – and former member of Council of Accreditation -- for AAHRPP and other organizations, universities, and hospitals and chairs the social behavioural IRBs of National Development and Research Institutes and American Academy of Family Physicians. Prior to joining IU, Dr. Baumann was Vice Provost for Research at University of Missouri – Kansas City and, before that, Deputy Executive Director of National Development and Research Institutes (NDRI), a private not-for-profit behavioural science research institute in New York City with a primary focus on substance abuse, HIV/AIDS, and related social problems.

- Dr Jepchirchir Kiplagat, Moi University (Kenya)

Jepchirchir Kiplagat holds a PhD in Public Health from the University of the Witwatersrand in South Africa, Masters Degree in Public Health and an undergraduate Degree in Environmental Health from Moi University (MU). Dr Kiplagat serves as an Ethics Review Committee member for Moi and the Director for the AMPATH Research Program. She provides oversight in the coordination of all research activities within the AMPATH catchment area. She manages the Kenyan functions of the AMPATH Research Program Office and works with a North American counterpart to provide administrative and infrastructure support for partner institutions engaged in research at AMPATH. Dr Kiplagat was a co-investigator in an NIH-funded project that developed a Research Integrity Office at MU.



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