

Institutional review board review variation in bioethics health research and central IRB

This seminar will cover local IRB review variation and practical tools for its standardization. The speakers will address central IRB advantages and drawbacks and discuss the Meharry Regulatory Affairs Unit.

Topics will include:

- Research: Definition and importance.
- Research Bioethics.
- History of Research Bioethical aspects.
- Response to unethical research and legislation.
- An Introduction to the Moral Ethic theories and Human Subject protection developments
- Ethical theories
- Clinical research – Unethical research and federal regulation developments

About Abdul Sawas, Ph.D.

Dr. Sawas is a human subject protection administrator at Meharry Medical College. He has been an academic mentor and research for more than 15 years at multiple universities. Previously, he was CRA at CTCSCRO and an IRB senior administrator at NGHHA. He holds a BPharm from Cairo university, a Ph.D. in biochemical pharmacology from Heriot-Watt University and an environmental health associate degree from Cook College of Rutgers University.

He has completed a CRA license, ICH/GCP certification courses from accredited centers including UNESCO. In addition, he is extensively specialized in clinical pharmacokinetics population determination, dosage prediction and therapeutic managements.

Overall, he is an expert in ICH/GCP review for both clinical research protocol and adverse events for regulatory enforcements. He pursues oxidative stress clinical research and its application for health care management.

Dr. Sawas has received the following awards for his scientific achievements:

- British council overseas student of researcher distinguishing candidate.
- Abha cultural club for best drug abuse ward for his book entitle “Cocaine from Coca Cola to dependence.

About Rajbir Singh MBBS

Dr. Rajbir Singh is Executive Director for Precision Medicine and Health Equity Trials Design at Meharry Medical College. He also serves as one of the directors of the Clinical and Translation Research Center of Excellence (CTRCOE) and co-director for the Center for Women's Health Research (CWHR). He is the chair of IRB at Meharry. His core mission is to increase the participation of under-represented or underserved communities impacted by health disparities in clinical research for building health equity.

He serves as the principal investigator (PI) of multiple genomics trials:

- Implementing Genomics in Practice (IGNITE) Consortium trials,
- Genomic Testing to Understand and Address Renal Disease Disparities In US (GAURDD-US),
- testing participants for APOL1 gene, and
- A Depression and Opioid Pragmatic Trials in PGX (ADOPT PGX),
- testing for CYP2C19 and CYP2D6 genes for targeted therapy recommendations.

He is the Meharry site PI of the Phase-III of PCORI for STAR CRN. He is also associated with the Electronic Medical Records and Genomics (EMERGE) trial to have genomics implemented via EMR. Working closely with the community engagement core at Meharry, Dr. Singh has led and coordinated more than 50 clinical trials, including oncology clinical trials, pharmaceutical trials, and the recent Novavax clinical trial for the COVID-19 vaccine. As the lead on these trials, he oversaw the ongoing trial activities across the project life cycle. His participant-centered strategies have led to the highest rate of enrolment of minority communities at Meharry.