



Progress Report

September 20, 2016

Subcommittee: Ethics and Regulatory
Chair: Stephen Olufemi Sodeke, PhD, MA
Co-Chairs: Junko Nishitani, PhD;
John C. Smith, MSW, CIM, CIP

Sub-Committee Responsibilities

- Ensure that RTRN activities meet and exceed standards for regulatory compliance, placing particular emphasis upon meeting federal requirements and addressing privacy issues for health and research-related electronic records at the clinical sites.
- Ensure compliance with HIPAA and that there are adequate securities and privacy.

Major Activities and Milestones (1 of 2)

- August 19, 2016: RCCI coordinated the Discussion of IRB Harmonization Documents meeting (Dr. Foreman and Ms. Baker were very helpful)
- Ad Hoc Committee designed a TEMPLATE to enable IRB Directors contacted to supply Institution-Specific language for the design of a Standard RTRN Adaptable Informed Consent Form.
- Ad Hoc Committee produced “Acknowledgement Letter” for Relying IRBs
- Ad Hoc Committee produced “RTRN Protocol Registration Application”
- Reviewing all the above-named documents for presentation and ratification by the RTRN Steering Committee when ready.

Major Activities and Milestones (2 of 2)

- August 24, 2016: Dr. Sodeke attended the Western IRB Group's Seminar on "Operationalizing the NIH Single IRB Mandate for Multi-Site Studies"—an informative session!
- September 2, 2016: RCCI Workspace Webinar for Ad Hoc Committee Members.
- Ethics and Regulatory Sub-committee now has RCCI Workspace on the RTRN.net site to do its work.
- Westney's multisite proposal that includes Morehouse, Howard, and Meharry may be used to pilot-test the RTRN IRB Harmonization Agreement.

Challenges and Actions to Resolve Them

- FWA Data for “Checked” or “Unchecked the box” are not complete
- IRB Directors or Personnel Contact List need updating. Personnel in certain institutions have changed (For example: UTSA; TSU).
- Ad Hoc Committee to be formed to ascertain that current procedures are consistent with new NIH Policy being concluded: **Volunteers still needed**
- Planning for Webinar on **NIH policy on Rigor and Reproducibility: Volunteers still needed**