

Social Behavioral Science Core

IMPAACT Annual Meeting

June 10 -14, 2019

**Rivet Amico (chair), Jessica Haberer,
Renee Heffron, Rachel Kidman, Kenneth Ngunjiri,
Jennifer Libous, Nicole Montañez**

impaact.sbscore@fstrf.org



BACKGROUND

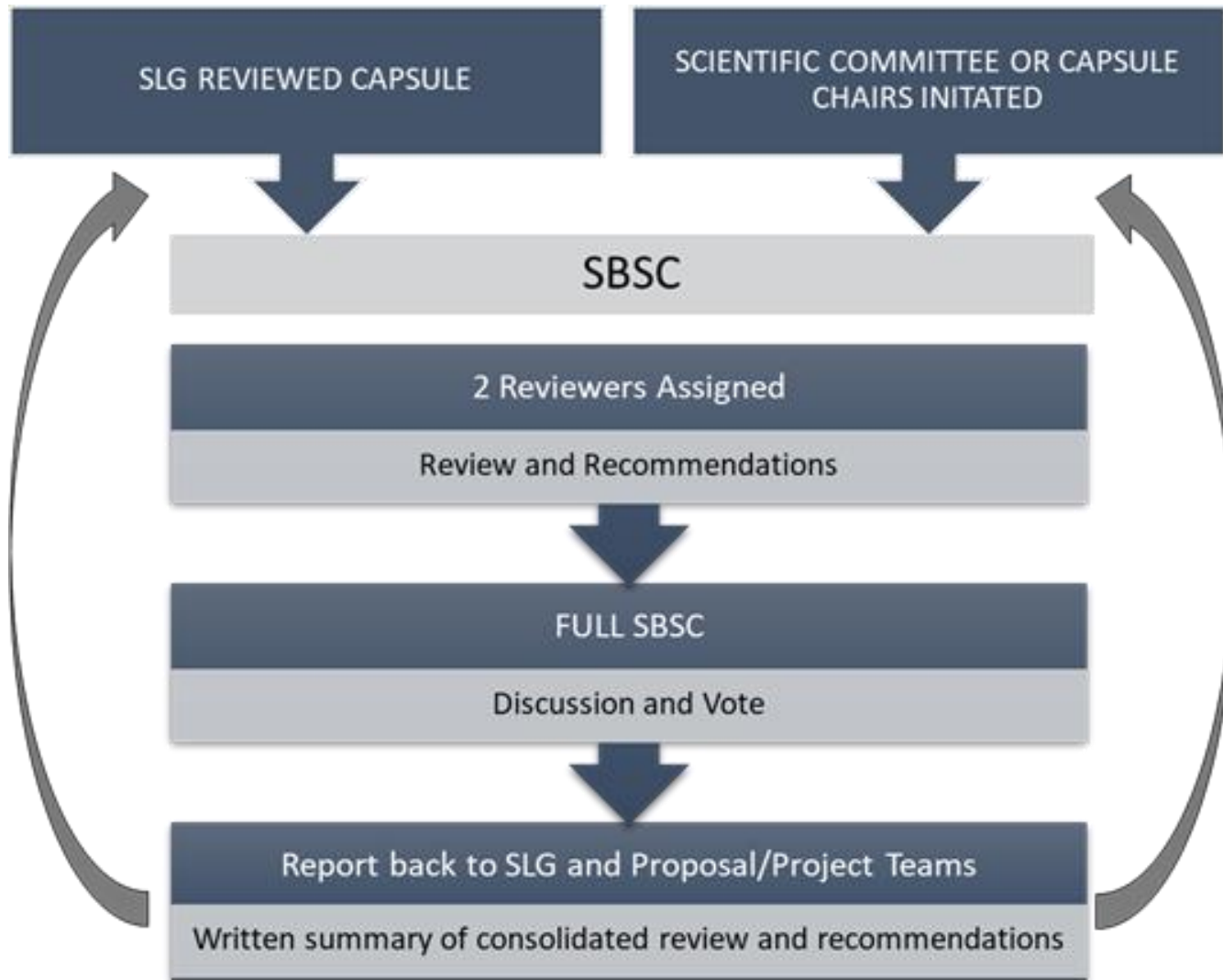
Formed in January 2019 and charged with providing additional social behavioral science focused review of proposals after capsule review from the IMPAACT Scientific Leadership Group (SLG), or as requested by leadership or a protocol team.

- **Role of social behavioral factors** in successful implementation of a wide range of clinical trials is increasingly well recognized.
- **Non-adherence** to study regimens limit confidence in findings generated by all phases of trials.
- **Measuring and optimizing adherence** is a robust area of inquiry with great evidence emerging.
- **Multi- and transdisciplinary teams** with a strong representation in social behavioral science can more rapidly ensure factors are identified and address.

Core Members

- Experts in HIV care, HIV prevention, retention, adherence, and other aspects of social behavioral determinants of study product and open-label drug use, support and measurement.
- Experienced in the conduct of multi-site clinical trials and review of proposals and protocol.
- Available to the Network:
 - **Reviews of proposals including capsules, concept sheets and protocols**
 - **Information and guidance to protocol teams and IMPAACT members**
 - **Collaborations with scientific committees in social behavioral science focused efforts to prevent and treat HIV, TB and other HIV co-infections and complications**
 - **Ad hoc consultation and project support to all scientific committees and leadership**

Review Process



Types of Recommendations

- Objective Measurements of Adherence
- Self-Reported Adherence harmonization across studies
- Assessments of Acceptability and Palatability
- Measurements of Social Determinants, Mediators and Moderators to Advance Understanding of Adherence
 - Structural barriers (e.g. transportation and access to care)
 - Individual barriers (e.g. mental and physical well-being, behavioral tendencies)
 - Social barriers (e.g. stigma)
 - Interpersonal barriers (e.g. disapproval from partner or other important people or community)

GOAL

Ensure proposals/studies within the IMPAACT network have the opportunity to consider social-behavioral factors in design, implementation and measurement that may influence outcomes of interest or success of the study

Review Outcomes To Date

- **CAP 543 (CS 5019), TB SC:** Phase I/II Dose Finding and Safety Study of Isoniazid and Rifapentine daily for one month (1HP) for treatment of latent tuberculosis (LTBI) in HIV-infected and uninfected children
- **CAP 544 (CS 5021), TB SC:** Trial of the safety, tolerability, and pharmacokinetics of 1 month of daily (1HP) vs. 3 months of weekly (3HP) isoniazid and rifapentine in HIV-infected and HIV-uninfected pregnant and postpartum women
- **CAP 545 (CS 5020), Complications SC:** Low Dose Aspirin For Prevention Of Preterm Birth In Women Living With HIV
- **IMPAACT 2020, TB SC:** Phase II Study of Shortened Oral Treatment for Multidrug-Resistant Tuberculosis in Children (SMaRT Kids)

THANK YOU

**Rivet Amico (chair), Jessica Haberer,
Renee Heffron, Rachel Kidman, Kenneth Ngunjiri,
Jennifer Libous, Nicole Montañez**

impaact.sbscore@fstrf.org