External Advisory Panel Charter
Roles and Responsibilities

Study Title: Adolescent Transition To Adult Care for adolescents living with HIV in Kenya (ATTACH)

Protocol Co-Chairs: Dr. Grace John-Stewart, MD, PhD and Dr. Dalton Wamalwa MBChB, MMed, MPH
Site: Kenya

The External Advisory Panel (EAP) will act in an advisory capacity to the University of Washington, and the University of Nairobi, to monitor recruitment, enrollment, and potential social harms of the intervention. Dr. Grace John-Stewart and Dr. Dalton Wamalwa (Principal Investigators), are conducting a clinical trial entitled "Adolescent Transition To Adult Care for HIV-infected Adolescents in Kenya (ATTACH)".

This cluster randomized controlled trial will evaluate the effectiveness of an Adolescent Transition Package of care (ATP) to improve time to disclosure of HIV status and readiness to transition to adult care among adolescents living with HIV (ALHIV) ages 10-24 enrolled in HIV care clinics in Kenya. Twenty HIV clinics in Nairobi, Kajiado, Nakuru and Homabay counties will be randomized and ten will receive the ATP intervention and ten will receive standard of care practices. The intervention will be administered at the clinic level to all eligible adolescents. The primary outcomes are: 1) Time to full disclosure among adolescents who do not know their HIV status at baseline and 2) Transition readiness among adolescents who know their HIV status. We will also collect data on overall adolescent clinic retention and viral suppression in addition to the implementation outcomes of acceptability, feasibility, fidelity, adoption, penetration and costs of the intervention. If effective, we will conduct cost-effectiveness analysis. The trial is expected to last approximately two years, with enrollment beginning in October 2019.

The responsibility of the EAP will be to review recruitment, enrollment, and potential social harms at periodic intervals (annually) during the course of the trial. Specific responsibilities are:

- Review summaries of recruitment, enrollment, and retention data during the trial
- Review of the research protocol and data collection schedule
- Discuss study progress, including adherence to protocol, data quality, and any scientific or policy developments that may have an impact on the study
- Review any reported study-related social harms to participants
- Offer suggestions to improve study implementation and/or reporting

The EAP can recommend suspension or termination of the study due to serious concerns about subject's safety, inadequate performance, scientific or policy developments that impact the study, or inadequate enrollment rates.

Confidentiality will be maintained during all phases of EAP review and discussions. EAP members must maintain strict confidentiality concerning all privileged trial results ever provided to them. The EAP will review data only by masked study arm unless these groupings are necessary for their decision-making.

Membership

The Chair of the EAP is the contact person for the EAP and is responsible for overseeing the meetings and developing the meeting agenda in consultation with the Principal Investigator (PI). Members of the EAP include statisticians, pediatrician/adolescent medicine specialists, HIV specialists; the National Institutes of Health Program Officer will attend as a non-voting observer (Appendix 1). Members are completely independent of the investigators and have no financial, scientific, or other conflict of interest with the trial.

Meetings

The first meeting will take place shortly after study initiation to discuss the protocol, triggers for data review, define a quorum, and establish guidelines to review the study and procedures for business. The appointed Chair of the EAP and the PI will prepare the agenda for the meetings.

The EAP will convene every 12 months to review enrollment and retention data, social harms, study progress and discuss other factors (internal or external to the study) that might impact trial implementation. The University of Washington will provide the logistical management and support of the EAP meetings. The meetings will be convened by teleconference/skype. Meetings will require a quorum of at least 3 voting members. Additional meetings may be scheduled as requested by the team.

Meeting Format

The sessions may be attended by the PI and should always include the study biostatistician (Dr. Barbra Richardson). Members will discuss recruitment, enrollment, and retention data (provided in a brief report before the meeting), protocol compliance, and any problems encountered. No identifiable data will be presented. The discussions at these sessions are completely confidential.

Report

The Chair of the EAP will submit a written report within three weeks of each meeting. Each report will include with a summary of the main discussion points and suggestions. The report will not include un-blinded data, or any discussion of the un-blinded data. Once approved by the EAP, the Chair will forward the approved report to NICHD and the PI within 4 weeks of each meeting. The PI will submit these meeting reports to the UW Institutional Review Board (IRB), as appropriate.

Confidentiality

All materials, discussions and proceedings of the EAP are completely confidential. Members and other participants in EAP meetings are expected to maintain confidentiality.