

H3Africa Ethics and Community Engagement WG

Meeting Notes

Thursday, June 20, 2019

Agenda

1. The Study Coordinators proposed manuscript (concept note attached)
2. Update on any consent forms approved at various research groups
3. Community and Public Engagement (CPE) Work plan and time lines e.g. for 6 months
4. Comments/reactions on papers sent by Jennifer related the positive and negative effects of releasing aggregate data results
5. Decision on forming a mini-journal club to get a deeper understanding of GSR (Genomics Summary Results)
6. Request the Genome Analysis Working Group to join the E&CEWG call to help clarify technical issues on GSR
7. Update/brief on the Tunis meeting CPE presentations/discussions

Meeting Notes

1. Sophie Osawe, the study coordinator for the BEAMING study, was present to represent the Study Coordinators WG. The group would like to perform an additional study and were looking to the E&CE WG for guidance regarding the necessary approvals for this study.
 - a. The group would like to explore patient adherence in completed H3Africa studies, collecting data such as missed visits, community engagement activities, and, among others, strategies to increase patient adherence. They've assembled a database to compile this data that they plan to use to determine connections between these data, if any.
 - b. The E&CE WG gave the following recommendations:
 - i. While the proposed study *could* be IRB exempt, it sounds like a new, secondary analysis, which does require IRB approval.
 - ii. The SC WG should put together a proposal to capture all possible data and any related procedure of analysis.
 - iii. The SC WG should identify the studies in their network that have follow up visits and reach out to the PIs.
 - iv. The SC WG should ask permission from the PIs to review the consent forms and IRB approvals and verify if the study mentioned secondary data analysis or something similar.
 - v. The group *may* not need to re-consent participants; however, they need to submit to the IRB for approval in the country IRBs were mentioned.
 - vi. A suggestion was made to reach out to the PIs on the possibility of having them submit to their IRB this proposal.
2. There were no new updates to the consent forms reported.
 - a. **Action: Pius** will send a Google doc to the various research networks to determine which countries have been approved.
3. In addition to the list of unresolved topics that Mary has compiled, the group discussed goals for the next six months.
 - a. Kofi suggested that the group revisit previous H3Africa guidelines (Community Engagement, Informed Consent, etc.) to see if any of these need to be updated.

- b. Jennifer suggested that the group form dedicated task forces to come to a conclusion on the issues of a.) Genomic Summary Results (GSR) and b.) Commercial benefit sharing. She added that once these are complete, the group could then write a white-paper to state its conclusions.
 - c. **Action: Pius** will add these considerations to the list that Mary previously developed, with the goal of streamlining the objectives via email by the second week of July.
- 4. As little progress has been made since the last E&CE WG meeting, Pius suggested that the group condense agenda topics 4-7 to one discussion about genomic summary results (GSR).
 - a. The group is supportive of the formation of a journal club to discuss papers focused on GSR. It was agreed that the group would benefit from the inclusion of interested members of the Genome Analysis WG and the consortium as a whole.
 - i. **Action: Harry** will connect Mary and Pius to the chairs of the GA WG (Debo and Zane).
 - b. There was discussion of a plan to present the group's findings on GSR to the Steering Committee on July 7, but Mary is hesitant as she believes that the group is not near a conclusion on the issue. However, Jennifer suggested that the group could present an overview of the discussion to date while highlighting the outstanding issues that still need to be resolved in the next six months. Additionally, the group could advertise the journal club in the same presentation.
- 5. AOB
 - a. **Action: Mary** will resend the Tunis meeting report to collect additional comments from the WG.