H3Africa Ethics and CE WG Call _20 December 2018

Present:

Aseffa Affiliation
Yemisrach Zewdie
Ashaye Affiliation
John Imaledo
De Vries Affiliation
Mary Kasule
Patrick Okonta
Matovu Affiliation
Vincent Pius Alibu
Matshaba Affiliation
Keofentse Mathba

Thato Regonamanye
Thembela Mavuso,
Bheki Ntshangase
Mulder Affiliation
Nicki Tiffin
Ngwa Affiliation
Paulina Tindana
NIH Affiliation
Barbara Sina
Ebony Madden
Gabriel Batzli

Harry Wedel
Jennifer Troyer
Robin Mason
Other
Patrick Okonta
H3ACC / Skelton Affiliation
Confidence Mothiba
Linda Dywili

Nominations for the Chair of the committee – Paulina Tindana

Vincent Pius Alibu and Mary Kasule were appointed as the new Co-Chairs for the Ethics and CE Working Group.

WG comments on NIH policy - Jennifer Troyer

The NIH Policy focuses on Data Sharing and Privacy Issues. The decision was made that NIH funded projects, in addition to making genomics data accessible through controlled access, summary statistics would be shared openly. What summary statistics are in the context of genomics are real frequencies, if you view chips, GWAS, on a population of 10,000 people and you see a SNP at 5% you report that, so this is aggregate data, it is summary statistics.

One of the reasons to share that publicly is that very often when someone is doing a genomic study what they want is to validate or to replicate their SNPS. The policy facilitates fast and easy access to the summary data. It is a fast way to get the data at individual level, but data does not get released, individual data stays private. There is less opportunity for people to put other data at risk as a person will receive the most wanted pieces of information. The policy went through a lot of assessment and valuation on its potential for risk with regards to data sharing and privacy issues, the results showed that there is less risk and the benefits outweigh the risk.

The NIH has left an ability to request an exception if a person is working with a small unique isolated population and they are worried of the sigma risk that somebody will be able to identify individuals that participated in the study.

The policy was launched on the **1st November, 2018.** It states that all NIH funded projects should share their summary statistics, both retrospective and prospective should be shared openly. However, the H3Africa PI's have this 6-month period, which would end on the **1 May 2019**, to put on paper if they want an exception.

The policy changed and when it changed it was brought forward at the Steering Committee Meeting, with the following questions posed:

H3Africa Ethics and CE WG Call _20 December 2019

- *Do we want to have a policy that H3Africa is happy to share summary statistics?*
- *Do we want to have a policy that H3Africa wants to share summary statics except in these few rare cases? And what are those rare case?*
- *Do H3Africa investigators want to do the same thing? Do they want to work individually depending on the circumstances of the project*

The Steering Committee responded that there needs to be guidelines like we have with informed consent. The request was Jantina should draft something that can be discussed in the next Ethics and CE WG.

Comments from Nicki Tiffin: Bioinformatics Network is looking at beacons, there is a concern that if we release the information people have the potential to reconstruct things. Most people may want to look at SNPs and something like a web server could be used, a person could type in their SNPs of interest, operating like a web portal. This would allow for data not to leave the EGA, in a piece mail way. Proposed that we should use a beacon system as there is a complexity in categorising certain populations in South Africa and other regions. We should also speak about benefit sharing.

Suggestion from Vincent Pius: Jantina's paper should be used as a framework that the smaller committee work and develop on.

Action Item:
- Laura Rodriguez will be requested to join the next meeting to assist in answering some of the policy questions.
- WG members are requested to make suggestions on what are the issues that need to be taken into consideration.
- Nicki Tiffin, Laura Rodriguez, Nicky Mulder were nominated to be part of the task team. Others may forward their names if interested to join to the H3Africa Coordinating Centre.