H3Africa Working Group Ethics Consortium update

9th November, 2014
H3Africa Ethics Consultation Meeting
June 2014, Cape Town

• Attended by ±80 people including 60 members of 40 ethics committees from 18 African countries (out of 21 countries where H3Africa projects located)

• Identified need for more critical thinking around informed consent, and the need to develop training in the review of genomics research proposals for REC members
Community Engagement Project

Phase 1: Systematic review of community engagement in African settings completed and manuscript currently under review at *BMC Medical Ethics*

Phase 2: Mapping exercise of community engagement activities within H3A

- 10 out of 14 projects involved in some CE activities
- Definition of community and CE methods consistent with findings of literature review; methods ranged from CABs to community meetings including the use of social media.
Community Engagement Project

Key insights from Mapping Exercise

- Communicating genomics to participants and community remains a major challenge
- Need for communication tools to keep the target communities informed
- Need to address community’s expectations of obtaining research results
- More research needed to evaluate the effectiveness of CE strategies to facilitate ongoing engagement.
Informed Consent and National Ethics Guidelines Project

- Analysing H3A informed consent documents and national ethics guidelines to examine
  - Which consent models are currently used in H3A research
  - Whether there are regulatory obstacles to using broad consent
- Analysis of 37 consent forms from 12 projects
- Received 13 national research ethics guidelines; waiting to receive more guidelines
Informed Consent Project

• 6 out of 12 projects use some form of *tiered consent*

• 7 out of 12 use *broad consent* for aspects of the genomic research

• Explaining genetics: a) comparison with inheritance of physical traits; b) comparative perspective used; c) some explanations scientific—“molecular units of heredity” and other explanations more basic—“things in the blood”
Informed Consent Project
Feedback of Results

• 7 out of 12 projects say something about feedback of results
  – Most share non-genetic research data, e.g. blood pressure, blood sugar
  – Most share ‘generic study results’ after study termination

• 3 projects specifically mention the possibility that some genetic results will be fed back
  – 1 project indicates that genetic results can be shared ‘upon request’
  – 2 projects speak about potential genetic findings that could be relevant to health, which may be fed back
REC Training Activity

• Working with the West African Bioethics Network (Clement Adebamowo) to develop an online/interactive training module for REC members

• West African Bioethics Network has experience and platforms for online training of REC members

• Funding provided by NIH Common Fund via NHGRI for development of the course

• Project runs Aug 2014 - Aug 2015
Second H3A Ethics Consultation Meeting, May 2015

• Topic of this meeting will likely be Informed Consent
• Responding to a needs identified during 1st Ethics Consultation Meeting, June 2014
• Explore how informed consent relates to governance models for genomics and biobanking
• Invited participants will be members of RECs and individuals from the African academic bioethics community
Future Work

• Continue our work on Informed Consent and Training of RECs
• Continue our analysis of national ethics guidelines to assess issues relevant to genomic research
• Develop guidance on return of research results