



Informed Consent and Community Engagement *Guidelines and Recommendations*

H3Africa Working Group on
Ethics

Accra, 17th May 2013

Key Ethical Issues in H3A

- Consent:
 - How to explain genomics
 - broad consent/consent to different components of studies (main study, sample sharing limitations)
- Feedback of findings (individual/group)
- Sample sharing and local RECs' authority
- Ownership over samples and genomic sovereignty

How can the WG Ethics best support H3A?

- Identify ethical issues & provide guidance on how these could best be addressed
 - e.g. materials on how genomics can be explained in different African contexts
- Training and education for RECs
- Clear lines of communication with all the projects
 - Every project has a presence on the WG
 - Membership to provide input but also to tell the WG of challenges encountered, feedback from the RECs etc.
 - But how to make sure members are engaged?

H3 Africa Projects

Value of Community Engagement

- **Intrinsic Value**
 - **Respect** the community's values, culture, traditions, and social practices
 - Recognition that *communities* themselves might suffer **collective harm**
 - To ensure the **relevance** of research
 - **Protective** measure to limit harm to *individuals*
- **Instrumental value**
 - Support consent process by providing information over time
 - Ensure that research and consent processes are culturally appropriate, identify appropriate terminologies and analogies
 - Maximize opportunities for stewardship/ownership/control by community
 - Provide ongoing channels of communication between communities and researchers
 - Address local fears, anxieties and rumours about blood sampling
 - Establish relationships, build trust, seek commitments from formal and informal authorities
 - Feedback of findings

Some methods of Community Engagement

- Community consultation/approval
 - Satisfy local protocol and then proceed to obtain informed consent from individual
 - Permission by community representatives (opinion leaders, elders, religious representatives)
- Community meetings
- Radio programmes, songs, theatre
- Community advisory boards

The Navrongo Model of Community Engagement



**Community
Entry**

**Community
Durbars**

**Compound and
Household
Meetings**

**INDIVIDUAL
CONSENT**

FEEDBACK TO THE COMMUNITY!!!!

H3Africa Community Engagement Questionnaire

Key Findings

- Around ½ groups have some experience using CE for genomics studies
- Almost all groups planning CE activities for H3Africa project (many in planning stages)
- CE most commonly used to:
 - Facilitate recruitment, empower communities, provide transparency, be respectful to communities & identify concerns
 - Education
- Wide diversity of audiences targeted but most grants consulted with community/tribal leaders
- Methods proposed include:
 - CABs, community meetings, workshops, Q&A sessions, radio, TV, newsletters & theatre

H3Africa Community Engagement Questionnaire

Specific Challenges to CE

- Difficulties in communication
 - Finding appropriate language to interpret technical concepts
- Engaging with community leaders
 - Highlighted as necessary gateway to access communities
- Managing expectations
 - Speed & availability of feedback, returning research results & dissemination of findings
 - Being clear about lack of immediate benefit
- Uncertainty about best CE tools for H3Africa
 - Complicated by fact studies across countries, areas (rural vs urban)

H3A Consent Forms - analysis

Key Similarities

- All forms mentioned the following:
 - Purpose
 - Risks & benefits of participation
 - Confidentiality
 - Voluntariness
 - Right to withdraw
 - Sample storage & usage
 - Consent needs to be witnessed
 - Contact information

H3A Consent Forms - analysis

Key differences

- Commercial Usage
- Incentives & compensation
- Feedback of results
- Mention of H3Africa consortium
- How genetics or genetic terms are described
- Details on whether and how data will be shared
- Length & level of detail of forms

H3A Consent Forms - analysis

Key Points of Interest

- Lack of mentioning H3Africa Consortium
 - Do we feel this is an issue given proposed governance of access/sample usage may be by consortium
- How clearly genetics is explained
 - Withdrawal and once shared withdrawal is no longer possible
 - Nuances of confidentiality
- Feedback of results
- Broad consent versus specific

Informed Consent (IC) Content – Recommendations 1

- Keep it simple!
- Find the way people talk about ‘heredity’ and use this to explain the study
 - E.g. isiXhosa ‘unombo wosapho wegazi’ – the family tree that is in the blood
- Use analogies to talk about difficult concepts, e.g.:
 - Explain ‘genetics’ through familial inheritance (facial features, particular diseases)
 - Explain unique features of genetic material through fingerprint analogy

IC Content – Recommendations 2

- Difference between written & spoken language – what is written may need to be explained differently orally
- Important to train fieldworkers and support staff who will be obtaining consent
- Importance of trust in the consent process

IC Guidelines – Purpose

- Guidelines to help researchers develop consent forms for H3A studies
- Informative and considerations, not prescriptive
- Relevant for all projects, but if consent forms already approved then no need to go back to REC (unless 2 key issues are not included)

IC Content – Required Components

- Data sharing
- Sample Sharing:
 - Mandatory for NIH H3A studies, recommended for WT H3A studies
 - Possibility for layered consent
 - Primary study
 - Sample sharing (perhaps even in a tick box)
 - But controversial for RECs and Participants?
 - How best to explain to these stakeholders?
 - Addressing any local concerns about sample sharing?

IC Content – Recommended Components

- Feedback of results
 - Something ought to be said about this
 - But: what kind of results can/should be fed back?
 - Aggregate
 - Individual? ('medically actionable' – what does that mean in the African context?)

IC Content – Other Components

- Foreseeable benefits and risks
 - Immediate benefits to individual
 - Benefits to community
 - Physical risks (e.g., risks associated with blood draw) and non-physical harms
- A statement that participation is voluntary and right to withdraw

Issues for debate & research

- Feedback of results
 - is it appropriate to feed back any individual genomic research results?
 - If so, how?
- Commercialisation
 - Should this be mentioned in the IC forms?
 - ‘Mild’ language, e.g. ‘could lead to the development of drugs’
- Ownership of samples/data
 - Should this be mentioned?

Issues for debate & research

- Cell line creation
 - Envisaged for all samples in the future
 - But what are the issues?
 - For participants and communities?
 - For RECs and governance?
 - How best to explain this?
- Cell lines just another way of storing DNA?
- Layered consent acceptable?

Ways forward – IC guidelines

- Process of consultation for the guidelines:
 1. Circulate doc to all H3A PIs for input/comment
 2. Finalise guidelines for consultation
 3. Publish guidelines on H3ABioNet website for comments from public, e.g.:
 - Ethics committees and National Research Ethics Councils
 - Bioethics centres & bioethicists across the world
 - Non-H3A (African) investigators with experience in genomic studies
 - Patient organisations
 4. Final guidelines released end of July 2013
- Make all the H3A consent forms publicly available?

Ways forward - WG

- Future issues to investigate & address:
 - Biobank governance (ethics): sample sharing, cell lines, relations with RECs, ethics approval
 - Access to & ownership of data and samples
 - Returning results
 - H3ABioNet Ethics pages
 - Engagement and education with RECs across Africa
 - How best to do this?
 - Funding?