INFORMED CONSENT IN H3AFRICA
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 – 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

- Compensation

- A statement that participation is voluntary and right to withdraw
IC CONTENT – COMPONENTS

• Data and 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)
IC CONTENT – RECOMMENDED COMPONENTS

• Feedback of results
  • What kind of results can/should be fed back?
    • Aggregate
    • Individual? (‘medically actionable’ – what does that mean in the African context?)
INFORMED CONSENT RECOMMENDATIONS

• Keep it simple!
• Find the way people talk about ‘heredity’ and use this to explain the study
• 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 RECOMMENDATIONS

• 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
ISSUES FOR DEBATE & RESEARCH

• Feedback of results
  • Is it appropriate to feed back any individual genomic research results?
  • If so, how?
• Commercialization
  • 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?
• Informed consent cannot do all the work:
  • Needs to be embedded in Community Engagement activities
  • And in governance structures (e.g. Data Access Committee and Sharing Policy) that protect the interests of research participants
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
THANK YOU

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