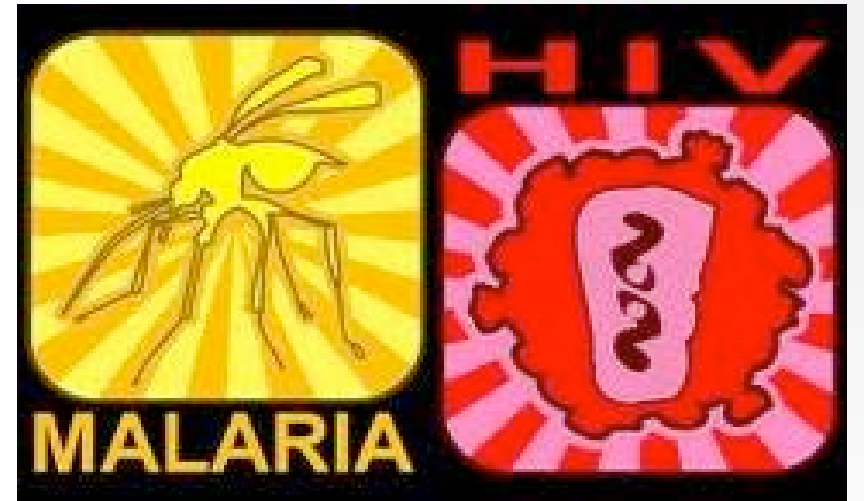


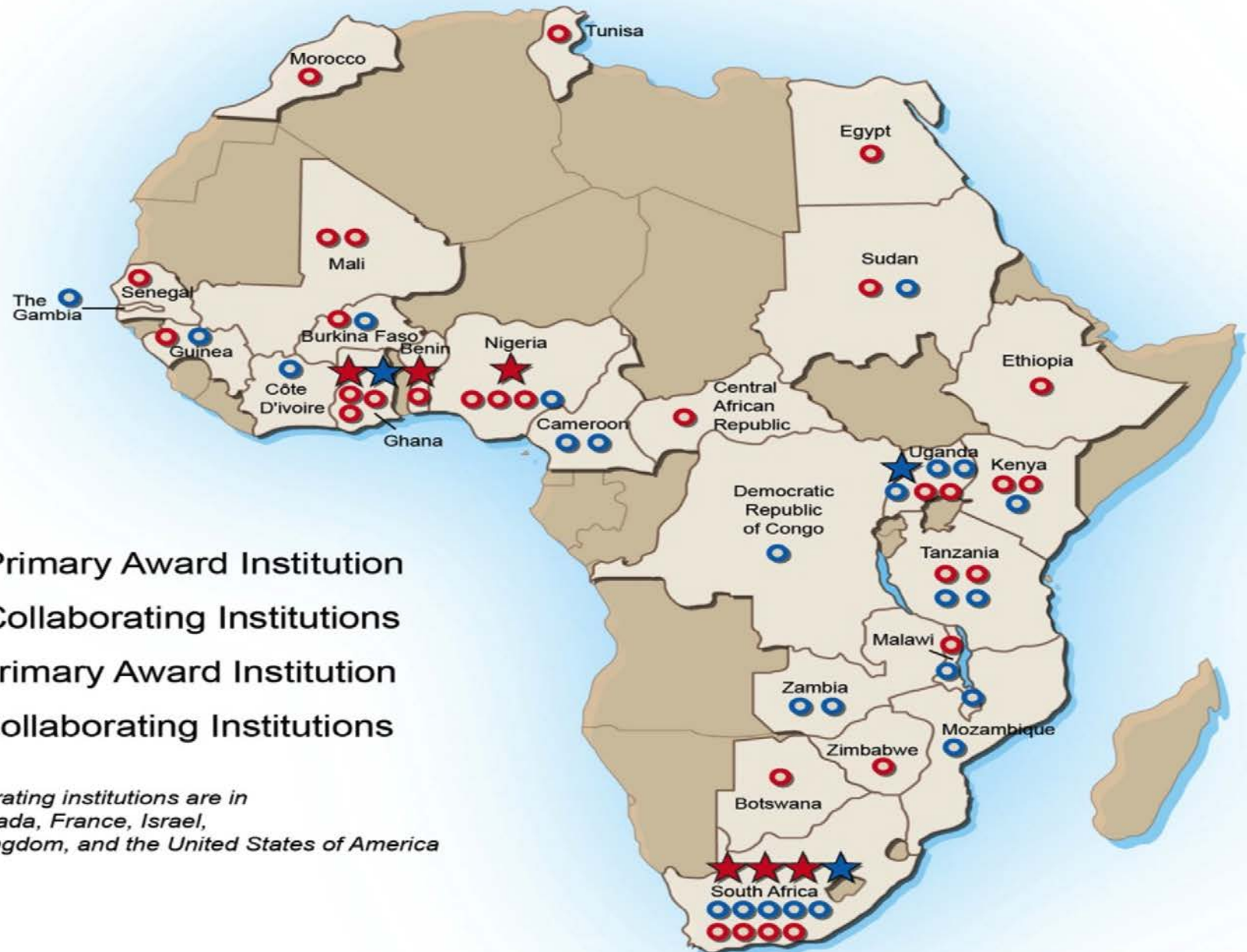
H3AFRICA - IN AFRICA, FOR AFRICA, BY AFRICANS

- But (partly) with American taxpayers' money?
 - What are the strings attached?
- What does it mean to be "African"?
 - All PIs and majority of co-applicants need to have their *primary* affiliation with a research institution in Africa
 - >50% of funds needed to be spent in Africa
- Focus of the projects is on:
 - Poverty-related infectious diseases like RHD, Trypanosomiasis, HIV/AIDS, TB
 - Chronic diseases like Obesity, Diabetes, kidney disease
 - Mental illness – schizophrenia



H3AFRICA RESEARCH NETWORK

- 21 projects are funded,
- About 15 scientific research consortia
- Involves researchers in 27 countries (out of 54)



KEY ETHICAL ISSUES

- Fair collaboration: how to optimise benefit whilst empowering African scientists
- Scientific and ethical review: different regulatory structures and experiences across countries
- Consent: broad consent for biobanking is novel in Africa
- Sample collection, storage
- Regulation of sample and data sharing
- Community engagement
- strategies for promoting African research capacity

HOW DOES H3A STRIVE TO PROMOTE EQUITABLE COLLABORATION?

1. African Leadership
 - All PIs and a majority of co-applicants based in Africa
 - All PIs together form the H3A Steering Committee
 - Ultimately, leadership is therefore African
2. African ownership
 - a. Data Sharing Policy
 - b. Sample Sharing Policy
 - c. DBAC composition
3. Stakeholder consultation
 - a. Community engagement
 - b. Consultation meeting with REC members
4. Using technology to reduce disparities in capacity and infrastructure

“AFRICAN OWNERSHIP”

- H3A research takes place in a context of historical exploitation
- There are many suspicions regarding international collaboration, data and sample export and sharing
- In order to allay concerns, H3A has had to develop a **credible** and **trustworthy** governance framework
- An essential component of that framework has been to ensure that African people have *exclusive access* to samples and data:
 - 3 years in the case of samples
 - 2 years in the case of data
- In the case of samples, for 3 **years** access will only be given to:
 - a. Investigators based in Africa
 - b. Investigators outside of Africa collaborating with African researchers who will aim to build African research capacity

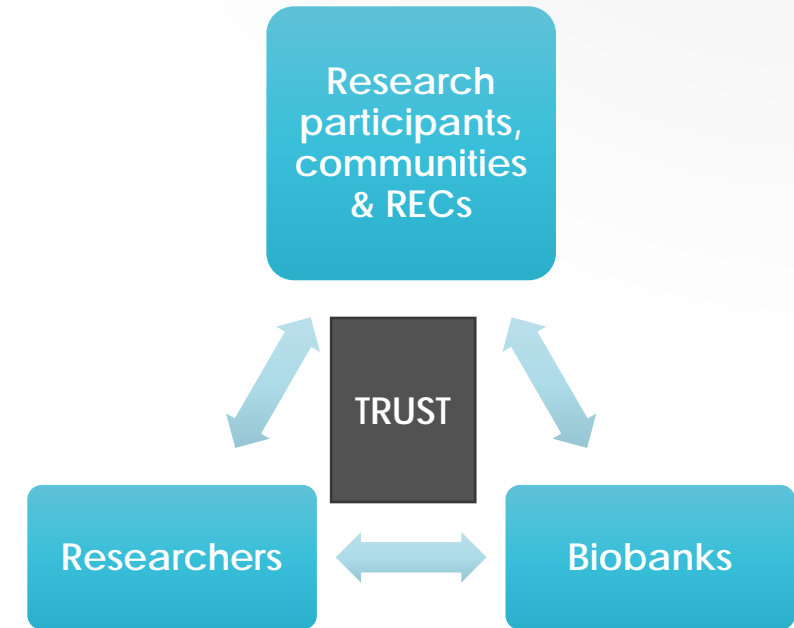
H3AFRICA ETHICS CONSULTATION MEETING

- Aim: to discuss ethical challenges in H3Africa research
- Members from 40 RECs (institutional and national) in 18 countries in attendance
- Also H3Africa PIs, members of the H3Africa Working Group on Ethics, and representatives Wellcome Trust and NIH.

- **Prima facie ethical concerns**
- Equity concerns - while important for global health research, H3A must firstly provide opportunity to significantly improve the capacity of individuals and institutions in Africa to engage more and contribute to the global health research agenda
 - ownership of the intellectual capability to understand the information contained in samples among African scientists
- ethical imperialism vs ethical relativism

GOVERNANCE FRAMEWORK

- There were real concerns around broad consent and sample sharing across Africa
- Key to dealing with these challenges is the development of *trust* and of a governance framework that can inspire it
- Participants question whether 3 year protection is sufficient to allow for significant capacity building
 - But is it ethically desirable to reduce access and sharing?
- Critical question is whether and how local IRBs should be involved in 2dary access decisions



SOME OTHER IMPORTANT SUGGESTIONS FOR IMPROVING THE GOVERNANCE FRAMEWORK

- Restricted vs indefinite storage of samples – when is it ethical to destroy stored samples
- Further considerations in implementation of broad consent – process should provide the option to refuse *broad* consent, while allowing participation in the primary research project.
 - people often give consent on the basis of trust, not knowledge.
- Guidance on how to manage changing relationships over time:
 - children who reach the age of maturity or people who pass away
 - decisions to withdraw samples from biobanks after donation
- Ensure that community engagement is made an integral component of building trust, promotion of fairsharing of risk and benefit; application of broad consent
- Appropriate capacity building for RECs involved in the governance of H3A projects

LESSONS FROM H3A PRACTICES

- “expert’ groups help foster in-depth discussion and facilitate development of commonly agreed guidance on specific topics – e.g. ethics
- Periodic and on-going engagements to monitor progress and discuss emerging issues
- Efforts at identifying ways to foster community engagement would help improve ownership, social value and promote fair distribution of risks and benefits
- Engagement with African RECs is important in shared learning and identification of opportunities for capacity building – promote application of global best ethical practices while respecting country laws and guidance
- Involving African professionals and others with expertise in doing research in Africa in shaping the project – has helped in fostering

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LESSONS FROM H3A PRACTICES

- The engagement processes at the consortium level, level of different consortia, between the consortium and RECs makes the H3A a good model for:
 - Harmonising ethics both in the research process and in the review
 - Good working model for fostering capacity of African research scientists and aligning ethical and scientific learning and practises

RESEARCH AGENDA

- This is not clear yet, but there is consensus on the need to foster empirical research to further understand how ethical issues in genomics and biobanking research should best be addressed in the African setting. Some initial thoughts include:
 - Models of community engagement and their potential roles in promoting biobanking research in Africa
 - Knowledge and perceptions of African stakeholders in health research on the meaning and criteria for application of the principle of 'broad consent' in medical research in Africa.

CONCLUSION

- Although it poses a number of ethical issues, the H3Africa initiative has the ability to make African researchers true partners in global health research;
- The lack of regulatory infrastructure in relation to the ethical issues that the project raises, gives a wonderful opportunity for science and ethics (and law) to co-evolve in this region and in a way that would impact significantly in the way ethical research is undertaken globally;
- Ongoing discussion and consultation with and between stakeholders is essential for this to happen effectively.

ACKNOWLEDGEMENTS

- All H3Africa Ethics WG members
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- Jantina De Vries shared initial slides which were adapted for this presentation
- Katherine Littler and Clement Adebamowo provided suggestions on issues to be highlighted
- Image on 'cradle of modern humanity' from Prof. Charles Rotimi
- 'hands around the globe' sharing image:
<http://www.realviewdigital.com/track-sharing-content-online-digital-brochure/>
- My participation was sponsored by a travel award from NIH Fogarty and the Wellcome Trust through the GBFR Interim Steering Committee