From Global Standards to Local Implementation: Applying REWS' Model Consent Clauses in African Research Settings

Work Stream / Subgroup:

REWS

Date (Day/Month)**: October 8th, 2025**
Time (UTC)**: 11:30 am-1pm**
Session chair(s):

- Mercury Shitindo, PhD (in person)
- Diya Uberoi, PhD (in person)

Zoom meeting recording: link
Pass code: F=C28KG^
Link to slides: slides

Session description:

Institutions and organizations have long developed data sharing policies to promote the responsible sharing and use of genomic data. GA4GH has led this effort through its Framework on Responsible Sharing of Genomic and Health Data and tools such as the REWS Consent Policy and Toolkit. Despite this leadership, however, the extent to which these tools and standards—particularly those related to informed consent—have been adopted by researchers in LMICs remains unclear. The REWS Global ELSI group works to identify and address barriers to cross-border data sharing, by developing resources that researchers in LMICs can use to ensure equitable exchange of genomic data.

This session integrates existing GA4GH frameworks with the equity-focused priorities of the REWS Global ELSI group to address implementation challenges of GA4GH's *Model Consent Clauses for Genomic Research* in Africa. Specifically, it will explore how traditional ethical frameworks and principles in Africa, including Ubuntu, reciprocity, and communal responsibility, can be leveraged to facilitate the implementation of GA4GH policy tools.

Meeting aims:

- To identify barriers and opportunities to the adoption of the REWS' Model Consent Clauses for genomic research in Africa
- To discuss potential solutions to facilitate the implementation of the consent clauses in the region

We envision that the discussion from this session will lead to the development of a set of clauses that can be used to draft informed consent templates that are contextualized for research in Africa.

Agenda:

	Agenda item	Presented by	Time
1.0	Introduction & Welcome	Diya Uberoi, PhD	5 mins
1.1	Background to Global ELSI Group	Diya Uberoi, PhD	5 mins
2.0	Introduction to African perspectives on implementing REWS policies	Mercury Shitindo, PhD	5-7 mins
2.1	Identified barriers to implementation	Mercury Shitindo, PhD	10 mins
	Discussion ● What are your perspectives on these barriers? ● Can you identify other barriers to implementation for researchers in Africa? In LMICs?	Everyone	20 mins
3.0	Proposed solutions	Mercury Shitindo, PhD	10 mins
3.1	Discussion & Next Steps ● What do you think of some of these tangible solutions?	Everyone	15 mins
4.0	Wrap Up	Diya Uberoi, PhD	5 mins

Resources and links:

- Model consent clauses for genomic research
- African Bioethics Network

Attendees:

1. Liane Hughes
2. Anja Bedeker
11. Keelan Jordan
12. Lauren Maxwell
21. Mayumi Kusunose
22. Olla Walleman

3. Melissa Basford
4. Paula Medina-Perez
5. Desley Pitcher
6. Monica Munoz Torres
7. Sarion Bowers
8. Minjeong Kwon
9. Yann Joly
10. Arman Ardalan
13. Jaclyn Estrin
14. Ofonime Ebong
15. Chinyere Anyika
16. Ma'n Zawati
17. Mercury Shitindo
18. Diya Uberoi
19. Gemma Brown
20. Deborah Ekusai Sebatta
23. Femanda Bittar
24. Yoshihiko Izumida
25. Dianne Nicol
26. Matilda Haas
27. Dawn Chen
28. Rukia Mohamed Haji
29. Vasiliki Rahimzadeh
30. Jumi Popoola

Meeting Introduction

Diya Uberoi **(DU)** opened the session "From Global Standards to Local Implementation," introducing the Global ELSI Group's mission to ensure GA4GH's 43+ standards work equitably across diverse contexts. She emphasized that standards developed primarily in high-income settings can inadvertently disadvantage Global South researchers, making contextual adaptation essential for true global applicability.

Highlighting the need for this work, she introduced Mercury Shitindo (**MS**), Director of the Africa Bioethics Network (ABN), to present on the African research landscape and initial consultation findings regarding REWS consent clauses. **MS** explained that ABN brings together over 1,200 members across 42 African countries, including bioethics experts, early-career researchers, and policymakers, and focuses on advancing bioethics dialogue, capacity building, and collaboration across the continent.

MS went on to provide critical context about Africa's paradoxical position in genomic research. Despite comprising 19% of the global population across 55 countries and harboring the highest human genetic diversity, Africa represents less than 3% of genomic research participation. She explained that this disparity persists despite expanding initiatives like H3Africa and Africa CDC, with research infrastructure ranging from world-class facilities to minimally resourced centers.

Africa's 55 national systems each blend international standards with local customs, creating unique ethical landscapes shaped by community engagement, benefit sharing, data sovereignty, and traditional leadership. While bodies like the African Union work toward harmonization, the continent's ethical foundation remains siloed.

Given Africa's distinct cultural traditions, she highlighted the importance of traditional philosophies like Ubuntu and Utu, which emphasize collective responsibility over individual autonomy. These principles shape how African communities understand consent, trust, and

reciprocity, making them crucial for shaping how genomic research must be approached across the continent.

Project Aim and Approach

To consider how REWS products are fairing in Africa, **DU** explained the first project's aim, **which** assesses how the REWS Consent Toolkit (approved in 2020), particularly its Consent Clauses for Genomic Research, is understood and applied in African research contexts. The group's initial focus was to gather early feedback to inform the potential development of model clauses tailored for African contexts. **DU** emphasized that this is an early-stage initiative and invited feedback to help shape the work as part of a broader, ongoing collaboration.

Methodology

MS added that the initial consultation was conducted over two months with 9 experts from Kenya, Tanzania, Rwanda, Zimbabwe, and two UK-based researchers working in Sub-Saharan Africa. Participants represented genomics, clinical research, ethics committees, law, and policy. Data collection included document annotation, written responses to structured questions, and semi-structured interviews. Analysis identified 46 distinct implementation challenges clustered into 7 barrier categories: (1) Language and Comprehension, (2) Cultural and Community Dynamics, (3) Practical Infrastructure Limitations, (4) Benefit Sharing and Reciprocity, (5) Privacy and Data Governance, (6) Assumptions and Knowledge Gaps, and (7) Usability and Adaptation Burden.

Key Findings

She chose to highlight the four main findings.

1. Cultural and Community Dynamics

5 Experts highlighted tensions between individual-based consent frameworks and Africa's relational ethics. Frameworks such as Ubuntu, reciprocity, and collective decision-making shape how consent is understood. Traditional authority consultation is often required but rarely formalized. Biological samples carry spiritual meaning, linking individuals to ancestors and future generations. The key ethical challenge is balancing community involvement without undermining individual autonomy.

2. Language and Comprehension-Testing

In many communities, "DNA" is equated with paternity testing, creating mistrust. Technical terms lack clear local equivalents, and Western metaphors assume literacy levels that may not exist.

Effective consent requires linguistic and cultural accuracy, ensuring participants fully understand what genomic research entails.

3. Benefit Sharing and Reciprocity
Participants noted that research participants often expect immediate clinical benefits, though genomic research results may take years and rarely impact direct care. Phrasing such as “you will not receive profits” was seen as extractive. Within African relational ethics, reciprocity is viewed as obligation, not charity, underscoring the need for fair benefit frameworks.

4. Practical Implementation Realities
Experts called for consent options allowing participants to choose specific uses rather than provide “wholesale consent.” Some commitments—like long-term storage or digital data systems—exceed local capacity. Adapting global tools to local settings often requires significant, unfunded effort, raising questions about sustainability and equity in implementation.

Proposed Solutions

MS went on to present four solutions that relate to each of the findings: 1) the need to integrate relational consent integration to address concerns around cultural & community dynamics; 2) culturally grounded communication to address language & comprehension barriers; 3) visible reciprocity commitments to better account for benefit-sharing & reciprocity; and 4) modular consent to meet practical implementation realities.

Beyond technical solutions, **MS** highlighted the importance of addressing the broader systemic issue. Currently, tools designed in high-income contexts reflect only their infrastructure, leaving 55 African countries to individually adapt them. This creates an unsustainable burden, when resources are limited. She explained that even this initial consultation required two months despite ABN's established network. To address this challenge, **MS** proposed a paradigm shift: **From "global development → local adaptation" to "co-development globally from diverse starting points."** Key principles: (1) Include LMIC voices during tool design, not after; (2) Integrate diverse ethical frameworks from inception; (3) Produce tools that work globally without heavy retrofitting; (4) Build equity into the process, not as a later fix.

Discussion

DU then opened the floor for discussion. Yann Joly (**YJ**) praised the group’s progress and stressed the importance of creating standards that function globally and locally, and raised questions about H3Africa's current status. **MS** responded that global funding cuts are affecting everyone and have made sustainability and adaptable tools more critical than ever.

Monica Munoz (**MM**) called this "an important wake-up call" and drew parallels to her work on family health history standards, which face similar challenges representing kinship across cultures. She urged that REWS become integrated across all GA4GH standards, including Phenopackets and exposure data, and presented this as a “no longer business as usual—be disruptive” moment.

Dianne Nicol (**DN**) strongly agreed and raised concerns about overburdening communities, based on reflections from Australia. **MS** responded: "The best way to find out if you're taking too much is to ask them, to walk with them, to include them. The reason it seems like we're asking too much now is that communities weren't included in the first instance. When communities are part of the design, they define what’s acceptable."

Lauren Maxwell (**LM**) suggested that consent should be conversational and dynamic, suggesting AI tools could help scale and localize consent interactions. DU concurred, while Deborah Sebatta (**DS**) underscored widespread genomic illiteracy, even among health workers and REC members. **MS** responded by emphasizing the need for ongoing training and capacity building.

Ma’n Zawati (**MZ**) noted that tools are “living documents” needing feedback loops and suggested formal/informal local GA4GH nodes. He emphasized that translation is critical and capacity building means making local principles like Ubuntu visible and integrating them, not just external experts teaching.

Jumi Popoola (**JP**) echoed similar West African findings and noted public–private partnerships and correcting misconceptions about expertise, noting Africa’s strong genomic leadership. **MS** added that translation must go beyond language to cultural and contextual relevance, noting that ABN training is 98% African-led but often fragmented by silos.

Anja Bedeker (**AB**) warned against producing more tools without implementation, citing H3Africa’s 40-page consent form that even leaders rarely use. **MS** agreed that many guidelines didn't include relevant people during development, noting: “A 40-page document is too much—no one will use it. We need experts and communicators who can make it digestible for high school students.”

MM suggested crowdsourcing translations, referencing the Human Phenotype Ontology’s success across 10+ languages.

DU closed the session by thanking participants and inviting continued collaboration with the Global ELSI Group through the REWS coordinator.

Key Takeaways

1. Genomic standards and consent tools must account for cultural, ethical, and infrastructural diversity, particularly in LMICs, to ensure global applicability. Current frameworks often reflect high-income contexts, creating adaptation burdens and potential inequities.
2. African research emphasizes collective decision-making, traditional authority, and relational frameworks such as Ubuntu and Utu, which must be integrated alongside individual consent to ensure ethical and culturally appropriate practices.
3. Language, comprehension, and practicality are critical. Technical terminology, Western metaphors, and assumptions about literacy or infrastructure can hinder trust and
4. Training, translation, iterative feedback, and support for local GA4GH nodes are necessary to make standards usable and sustainable across diverse research environments.
5. REWS should be embedded across all standards and technical workstreams, ensuring that ethical, legal, and social considerations inform every aspect of genomic data sharing.

Next Steps

- The group will expand its consultations with more countries in the continent (account for regional differences)
- Finalize the Findings & possible solutions
- Based on today's session & ongoing feedback, develop draft adapted clauses