

# INDIGENE

Indigenous linguistic and cultural concepts of  
heritability and comprehension of genomics  
research in Nigeria

By

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# Outline

- Background
- Research Aims
- Theoretical framework
- Method
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- Changes in timeline
- Challenges to date

# Background

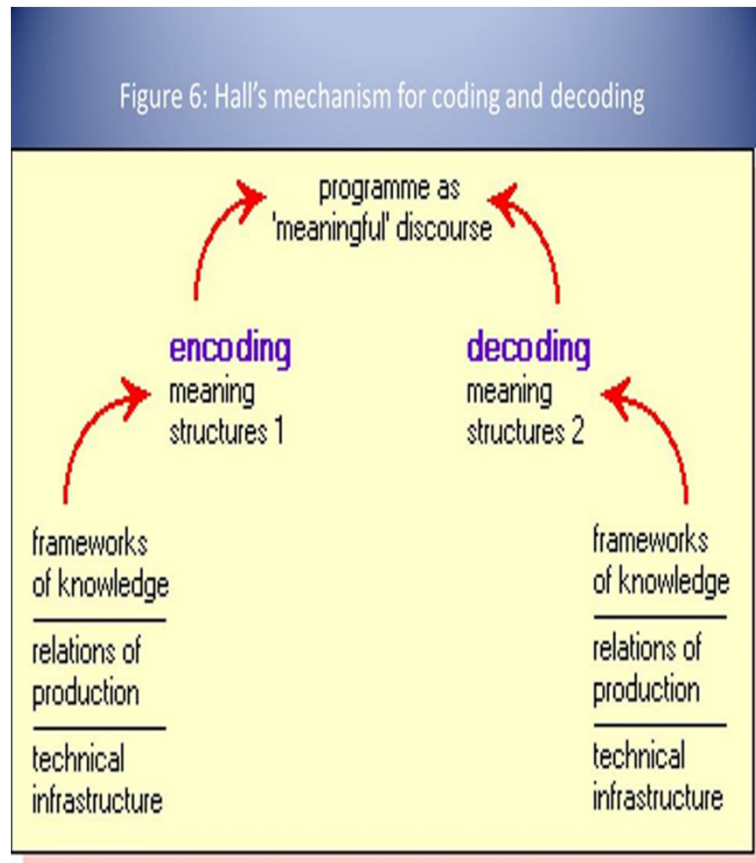
- Level of general health education in Africa is lower than in the rest of the world with about 38% lacking basic literacy
- **Adequate** comprehension is required before participants can give informed consent

# Steps for comprehension of informed consent

- i. There is evidence that a potential participant has integrated current knowledge that he/she has, with the new information provided during the consent process
- ii. This evidence is seen at the time the participant decides whether or not to take part in the research.
- iii. At a minimum, the integrated information includes the key components of the proposed research and of informed consent as stipulated by national and international ethics regulations (Buccini, 2009)

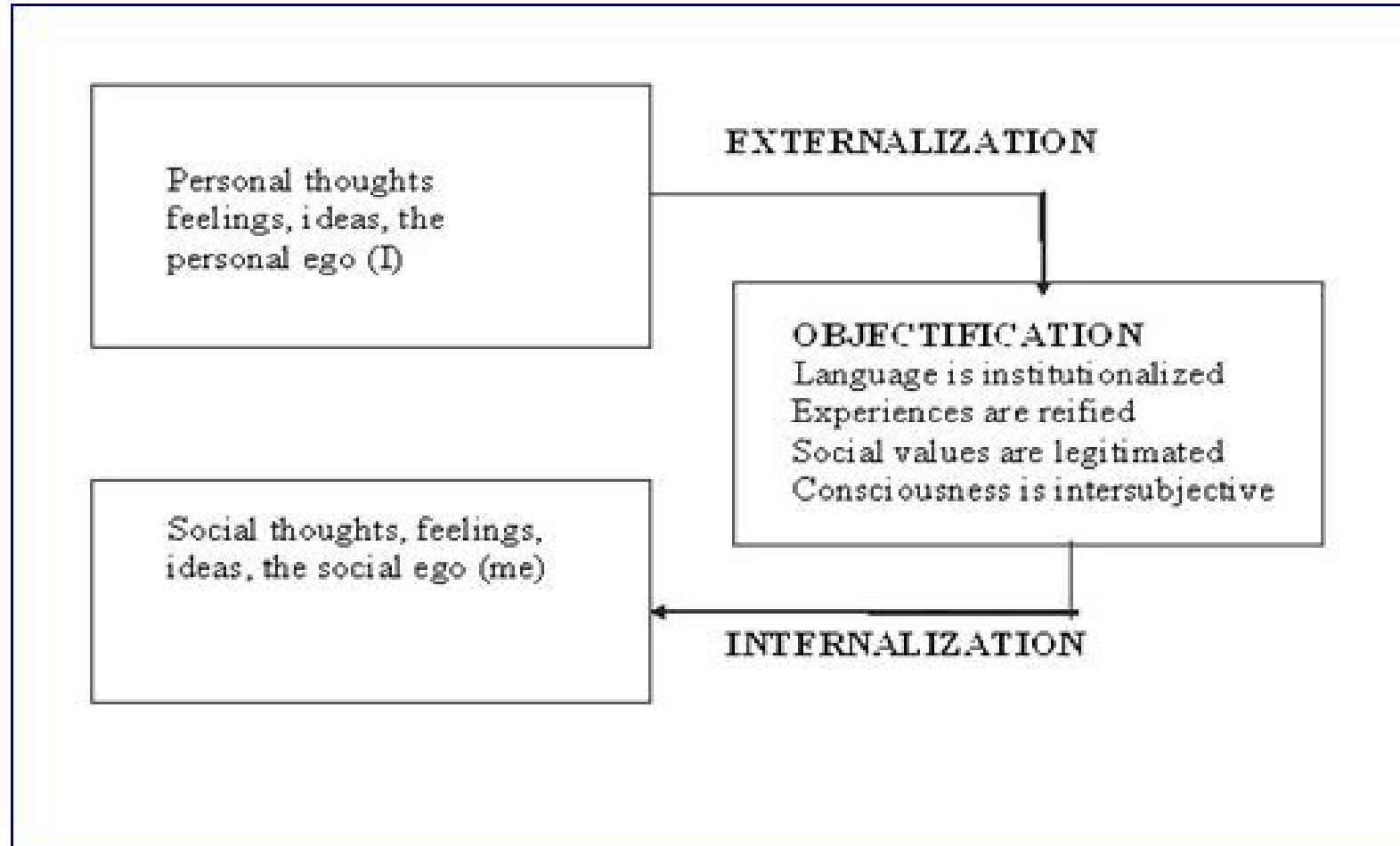
# Theoretical framework

Figure 6: Hall's mechanism for coding and decoding



- Communication theory: Hall's Coding and Decoding
- Social Epistemology

# Epistemology and Ontology



# Ethics in genomics research in Africa

- Genomics research poses specific challenges related to informed consent
- Evidence suggests that there is a 'general understanding' and familiarity with concepts related to genomics among different communities in Africa, irrespective of levels of literacy

# Research Aims

- Aim 1: Study existing linguistic and cultural concepts of genomics including heritability and their relationship to non-communicable diseases in indigenous communities in Nigeria



# Research aims

- Aim 2: Evaluation of the impact of incorporation of cultural and linguistic concepts of heritability on the comprehension of informed consent in genomics research of cervical cancer in indigenous Nigerian population.

# Methods

- Phase 1: Identify existing linguistic and cultural concepts on genomics and heritability.
- Focus group Discussions and Key informant interviews
- Focus on genomics transmissibility of disease risk as an “inheritance” rather than “heritability”

# Methods

- Sample population: 100 people randomly sampled from the National Electoral Register for the FDGs
- 50 community leaders for KIIs (local government officials, administrators, religious leaders, local chiefs, head teachers, community and opinion leaders)

# Methods

- Phase 2 (Pilot) : Evaluate the extension of linguistic and cultural concepts of genomics and heritability to comprehension of genomics of heritable traits
- Study population: 400 randomly selected individuals from the general population and randomised into two groups (A and B)

# Methods

- Group A: Administer enhanced information sheet on cervical cancer
- Group B: Administer standard information sheet used for study on cervical cancer

# Methods

- Phase 3: Evaluation of the impact of incorporation of cultural and linguistic concepts of heritability on the comprehension of informed consent of cervical cancer
- Study population: 400 individuals randomly sampled from the 6,000 individuals participating in the NIH cervical cancer research in Nigeria.

# Methods

- Rapid assessment test on health literacy (modified S-TOFHLA)
- 400 participants will be randomly sampled into Group A (administered enhanced informed consent sheet), and Group B (standard informed consent sheet)
- Assessment of comprehension and attitudes and perceptions of the informed consent process

# Analyses

- Sample size for qualitative research is typically based on the research hypothesis and the previous publications in the field and we have used that approach here
- For survey research of KAP where there is no hypothesis testing, the sample size is usually determined by the precision with which population values can be estimated and examples from published literature.



For comparison of dichotomous outcome variables,  
sample size considerations were based on 2 sample test  
for equality of proportions

- Based on the normal approximation with continuity correction

$$n_1 = \frac{n'}{4} \left[ 1 + \left\{ 1 + \frac{2(r+1)}{n' r |p_1 - p_2|} \right\}^{1/2} \right]^2$$

- $n_2 = r n_1$  where  $n'$

$$n' = \frac{\left[ z_{1-\alpha/2} \left\{ (r+1) \overline{p} \overline{q} \right\}^{1/2} + z_{1-\beta} (r p_1 q_1 + p_2 q_2)^{1/2} \right]^2}{r (p_1 - p_2)^2}$$

$$\overline{p} = (p_1 + r p_2) / (r + 1)$$

$$\overline{q} = 1 - \overline{p}$$

# Analyses

- We will analyze the different qualitative data using methods based in grounded theory and content and reconstructive analysis.
- An interdisciplinary team of researchers will triangulate between the transcripts of people's shared narratives, interviews and research observations, and will then use cluster analysis and open coding to identify emerging themes from the data using the Atlas.ti qualitative analysis software.
- Subsequently, data analysis workshops will be held to discuss and refine the most prominent themes, capturing narratives, local knowledge, terminology that embodies concepts related to health, and applicable examples from the field.

# Analyses

- Differences in means will be tested using Fisher's exact test and chi-squared tests will be used to detect differences in proportions.
- Composite scores will be developed from the questionnaire used to measure knowledge of survey participants and the results categorized.
- Univariate logistic regression analysis will be done to identify significant predictors at p-value 0.20. These variables will be included in multivariable logistic regression models and used to identify predictors of knowledge of survey participants according to this model of predicting the odds of experiencing an event -  $\frac{p}{1-p} = \frac{e^{\alpha + \beta_1 x_1} / (1 + e^{\alpha + \beta_1 x_1})}{1 / (1 + e^{\alpha + \beta_1 x_1})} = e^{\alpha + \beta_1 x_1}$  and taking the natural logarithm of each side of the equation  $\ln \left[ \frac{p}{1-p} \right] = \alpha + \beta_1 x_1$

# Sample size

Sample size calculations			
No	Cases – proportion administered enhanced consent form	Controls – proportion administered standard consent form	Sample size (n)
1	0.50	0.39	445
2	0.59	0.39	140
3	0.78	0.39	37

- Based on the assumption that intervention increases the proportion of those who comprehend the research goals to 50%, by at least 20% or double to 78%, and the formula for equality of proportions above

# Progress and Benchmarks

- Recruitment for the cervical cancer study has started
- Survey instruments and protocol have been submitted for ethical approval
- Research staff recruitment has started

# Acknowledgment

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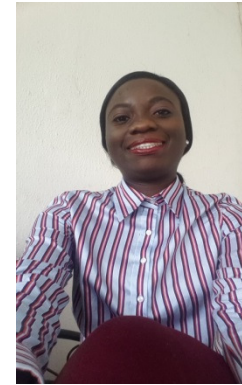
# Research team



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# Conclusions

