# Cultural Implications of Signed Informed Consent Form

**Balancing Ethical Standards with Local Traditions**

By

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# Declarations.

**I do not have any conflicts** in this presentation, but I would like to declare that I was sponsored by the organisers to make this presentation.

Moreso, **the views expressed do not represent those of the organisers, my institutions or any institution or person mentioned in the cause of the presentation**, except for reference purposes.

# The Purpose of the Presentation

- To **inspire** some conversations about the ethics  written and signed informed consent in culturally diverse society.
- To **create** an opportunity for the reconsideration of the Nigeria's RECs requirements and the research ethics community practice of informed consent documentation in research.
- To **suggest** a need for more research and training on the cultural acceptability of the written and signed consent in Nigeria context.

# PART ONE

**ENTER STORY ONE!**

De no wan meddle with de law

- This is based on a True life story experienced and told by the presenter and his wife, both alumni (Diploma) of the Center for Bioethics and Research (CBR), Ibadan

# What is your story when you bring out the form for your participant to sign?

- Please share with us?
- In your understanding, from the history and purpose of the informed consent, who was the process supposed to protect (primarily)? But who does it, In reality,  protect?
- (The Dad Must Know and My Research Student's Story)

# PART TWO: The Ethics Standard- The Informed Consent Requirement

Enter Video Two

# What is Informed Consent?

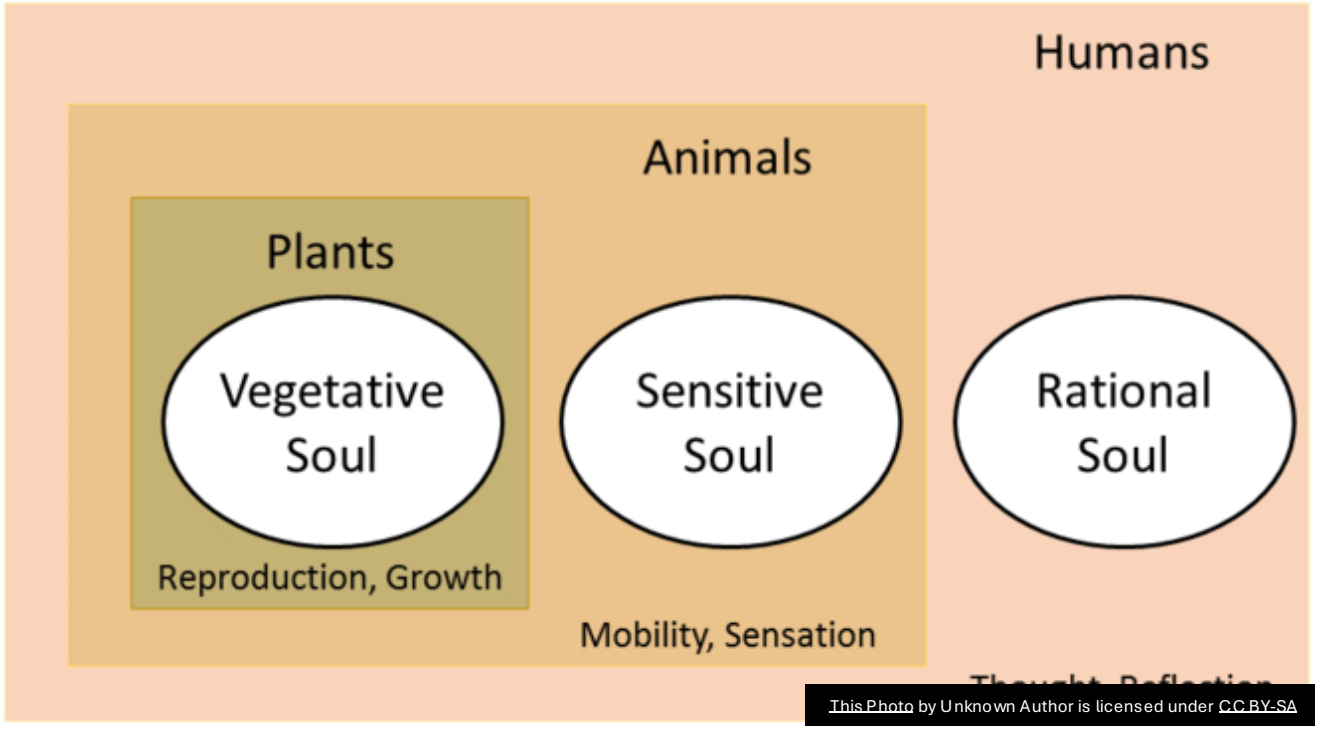
- An informed consent could have several definitions as long as it contains the key elements and serves the purpose, which is the respect for the autonomy of an individual.
- *It could mean an agreement or an autonomous decision by a competent person who has received adequate information about a procedure, including its risk and benefits, in a manner he/ she understands and has been given adequate time to consider participating in the procedure voluntarily.*


# Some Ethical Standards

- 1. Nuremberg Code – requires a voluntary consent (1)
- 2. Declaration  of Helsinki- freely-given informed consent (ref)
- 3. ICH-GCP Guidelines- informed consent
- 4. The NCHRE- informed consent
- 5. Others (see OHRP, International Compilation of Human Research Standards, 2024 Edition)

# Philosphical Justification of Informed Consent in Research

- Except for some requirements for waivng the requirements for informed consent, it's a settled ethical and legal principle (1-7)
- The informed consent is based on the belief that humans possess the capacity to reflect on what kinds of beings they want to be, what kind of activities they want to pursue, what kind of life they want to live.
- Persons have the capacity to form and comply with their values and them conception of a good life.  Humans have purpose, values that should be respected.
- To be able to make significant decisions freely without interference is the basis for the respect for autonomy
- So, for those who can make such decisions about participating in a research, their autonomy should be respected by obtaining the informed consent.





# Philosophical Justification of Informed Consent in Research

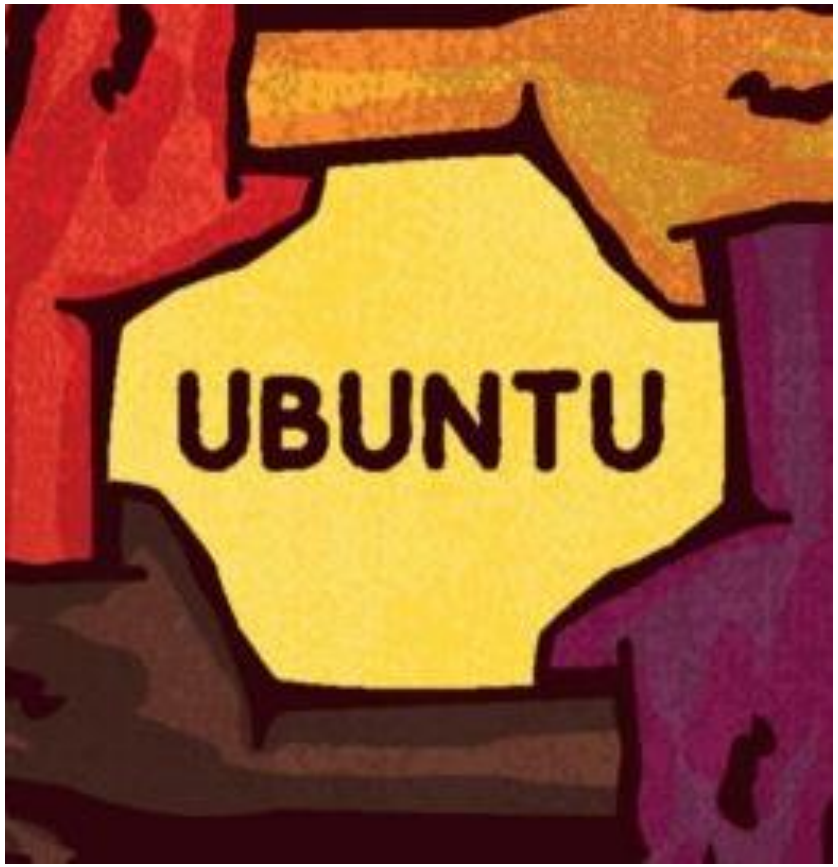
There may be other considerations:

1. individuals are generally the best judges of their own interests and so, on their own, can participate in a research if it serves their interests and values.

2, Public support for medical research rests on the belief that it is being conducted ethically.

# The African Philosophy and the Informed Consent

- Nigeria, like many African countries is a multicultural society. The rich unity in diversity in Nigeria is because of the value placed on her communitarian/collective consciousness, not only of Nigerians but of all Africans who practice the Ubuntu ethics. (I am because you are).
- To gain meaning, the society in which an individual lives is important. (Coeztee & Roux, 2001)
- Truly, there is no true liberal individualistic view without the help from the community. There is always a community. So, Western or non-western, the community is part of our personhood and can only be enhanced by our relationship (reciprocity) with the community. (Eckmecki &Arda, 2017)




# The Element of a Valid Informed Consent

- There are three distinct components, and these are where the consideration of balance between ethical standards (of respect for autonomy) and traditional (for example, African Ethics of Ubuntu comes in).
- A careful dissection of the elements and the requirements for documentation in consideration of how it affects the African value of Ubuntu/ reciprocity, is important in understanding the cultural implication of a signed informed consent.

# The Element of a Valid Informed Consent

Information

Voluntariness

Competence

# The Element of a Valid Informed Consent

1. **Information**

- Requires (**appropriate**) in an **understandable form** to **each** potential participant
- Goal- enable a participant to make an informed decision. (note the African/traditional way of decision-making which has pro's and cons)
- The challenge- What is adequate (details) information? (as long as you don't mindlessly dump the truth, the following are considered adequate)- there are standards which have been considered such as reasonable persons and standard professional practice (ref)

# The Element of a Valid Informed Consent

1. **Information**

a. A statement that the project is research (not therapy).

b. The purpose of the research

c. The description of the research-what will happen to the participants.

d. A description of the foreseeable risks and disomforts, as well as the benefits

e. Appropriate alternatives, if any.

f. The extent of confidentiality that can be expected

# The Element of a Valid Informed Consent

**1. Information**

g. An explanation of any medical treatment available for injury and/ or compensation for disability .

h. A pledge that the participation is entirely voluntary, and participants can withdraw at any time without loss of benefits to which they are otherwise entitled and

i. Whom they to contact for answers to questions. (15)

ii. There may other research-specific requirements (which may also include research with cultural implications).

# PART Three: The Local Tradition and The Informed Consent Requirement

- Let's begin with the question: What are the implications if we tilt to one end? The Ethics Standard or the Local Tradition?

# Q: In the African Context, what Information would a Reasonable (mature) African want?

- And how do you think a reasonable (mature) African would go about obtaining or trusting the adequacy of the information he/she is being given?
- For example, would a reasonable person always want to know that a research possess the risk of death?

- Q2: How would a traditional African person avoid the risk of therapeutic misconception about the research (the belief of a cure or of benefits)

# Q: In the African Context, what Information would a Reasonable (mature) African want?

- Q3: How does a reasonable traditional African expect the interaction between him/her and the researcher concerning the research process be in order to make an informed choice?
- Q4: Should an ongoing process necessarily require a one time signature, every time signature or none or at the end? What would a reasonable African man want? A single signing event may not be adequate (21, 22)
- Q4: is complete understanding required to make a valid consent

# The issue of Disclosure and the Traditional Person

- For consent to be informed, there must be disclosure and comprehension.
- Required by the CODE, international guidelines such as the ICH-GCP, the US Common Rule, the FDA, etc.

**National Code of Health Research Ethics**

**FEDERAL MINISTRY OF HEALTH**

**August 2007**

(f) **Informed consent** is a *sine qua non* for ethical conduct of research. In order for consent to be valid, it must have the following components

(1) Adequate information must be provided at the educational level no higher than that of individuals with at most 9 years of education in Nigeria.

(2) The design of the consent process must be appropriate for the type of research, expected participants, risks anticipated and the research context.

(3) Consent forms shall not be longer than 8 pages in order to ensure comprehensibility and enhance recall of pertinent information. Unnecessary verbiage, legalisms, jargons and truth-dumping are to be avoided. The recommended format for each page of the consent form is as follows:

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# The Element of a Valid Informed Consent

1. Voluntariness

Consent can be made involuntary in more than one way.

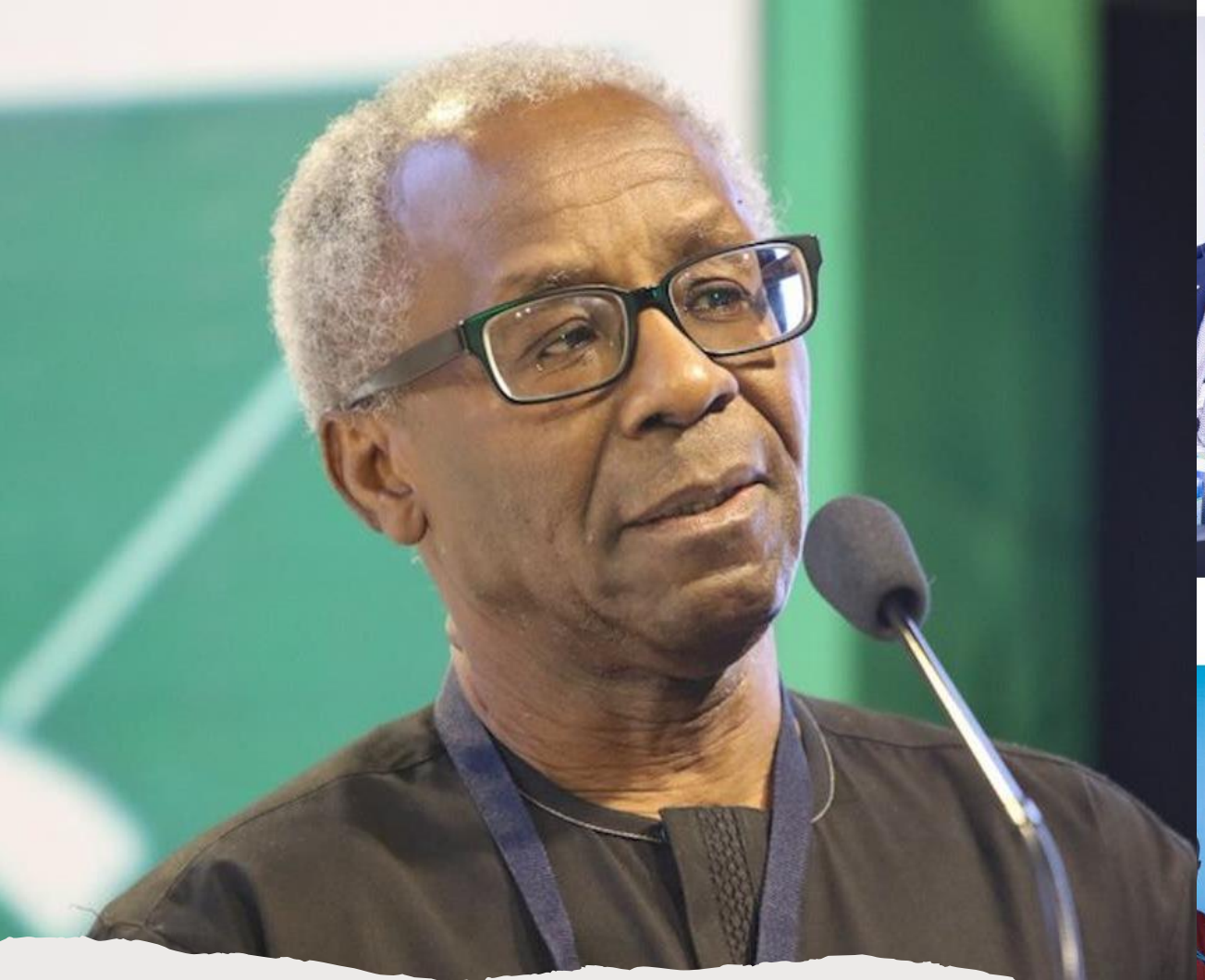
a. By coercion (one of the cons of the African collectivitst approach to consent) remember the reciprocity of care in the African context. This is more common from family members than from invstigators. (Ref. pg 609)

b. Coercion can also come from social institutions (30)

c. Manipulation and excessive incentives can be coercive.

# Imagine Research in a Multicultural Society


# Africa’s Rich Cultural Heritage




EXCEL RITE CONFERENCE DAY 2


# What is the Worth of  Humans (a Person?) (or an African person?)

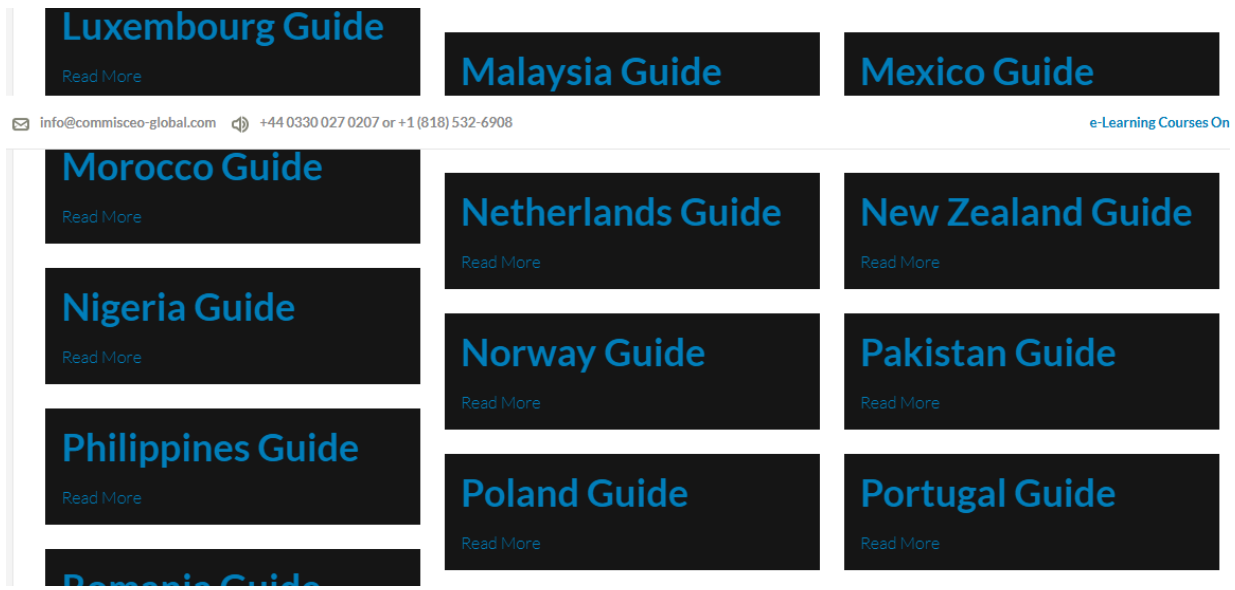
# The Worth of The African man


The Western View of Person-Subject/ case and the Slave trade

# No more colon-re-invade. Africa needs an effective cultural protocol in (STEAMS).

1. They are set of guidelines
2. They give directions
3. They protect the culture
4. Community is at the gate
5. Paraachute research is prevented.

# Do countries (even Nigeria) have cultural protocol? Yes. But is research included??


https://www.commisceo-global.com/resources/country-guides

## Trovan case, Nigeria, 1996

Kano, was struck by an epidemic meningitis.

While thousands of children were treated in an ill-equipped hospital, Pfizer came in to a test a new antibiotics drug Trovafloxacin.

Trovan had never before been administered to kids orally. Parents not aware that children were included in a clinical trial. No permission was asked to test the drug. Pfizer argued that IC could not be obtained from parents, because they were illiterate.

11 children died, 200 permanently disabled

in 2002 families sued Pfizer, (USD 75 million compensation in 2011)

Prof.Dr. Berna Arda



# What is the Informed Consent and why is it required?

# The Element of a Valid Informed Consent

1. **Competence**

This is part of what is necessary for autonomous choices.

Adults are presumed to be competent unlike children whose parents decide for. Older children, in addition to their parental consent, give their assent.

Capacity can vary according to the complexity of the research and over time (for those whose medical conditions affect their capacity)

# The Element of a Valid Informed Consent

1. **Competence**

Decision-making capacities needed for competence:

a. Capacity for understanding and communication.

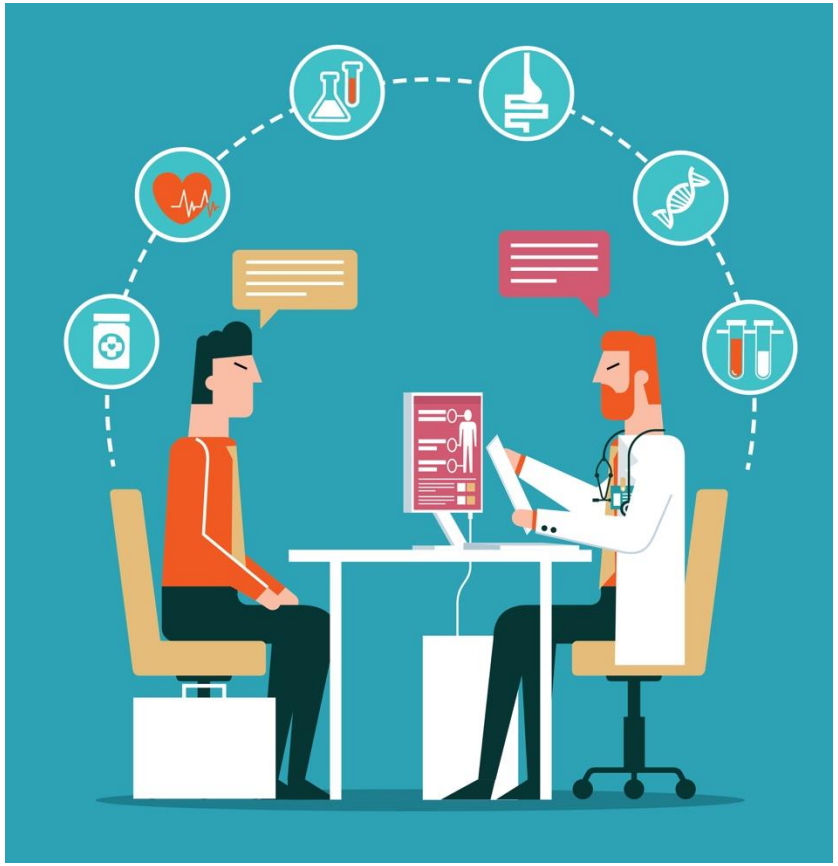
b. Capacity for reasoning and deliberation.

c. Possession of aims and values that can be used as the basis of selecting from among alternative courses of actions.

Competence evaluation focus on the above three areas.

# The **Process** of the Informed Consent

- Although it is not required that consent be written and signed, it is commonly agreed or accepted that consent is evident when the participant signs the form.
- It should be noted that participants may feel the seriousness of the participation when signing the form (this may not be favourable for some types of research/settings).
- Note, **consent is not the paper, nor the signature**; it is the process.
- Consenters usually believe that consent is a form (have you obtained consent is the usual question)
- The documentation (written and signed) originates from the US/ western society ( 45 CFR 46. 117(b) (2). The focus is on the form and not on the process. Most REC know/care about the form and not about the process.



# Waiving the requirement for a consent

- **The requirement of a signed consent may be waived under two circumstances:**
- 1. the research in which the principal risk would be the potential harm resulting from a breach of confidentiality and the only record linking the subject to the research would be the form itself.
- 2. not more than minimal risk research  and involving only procedures for which written consent is not normally required outside of research.
- Written consent is not required where it is not culturally acceptable (38). When written documents are used to forfeit rights or where it implies a distrust.

# The Signed Informed Consent and cultural implication

- It could mean a lack of trust to just put a signature on a paper.
- In some cultures, the decision-maker is designated by the group; a signature on a piece of paper, as opposed to verbal consent, may convey a lack of trust; illegal immigrants may be reluctant to sign for fear of deportation.
- It ignores the African value for the community or the African ethics of Ubuntu.
- It also (when coercion is involved) means that the individual has agreed where, in the genuine sense, there was coercion.

# Ethical Imperialism and the Written signed informed consent

- Ethical imperialist believes that there is one universal truth or one pathway to the truth.
- The western thinker believes that a signed document is a valid form of agreement and that is an ‘absolute’ truth.
- 1. However, there is evidence that the documentation and signature has been regarded by non-western thinkers as fetish and even unethical. (Wynn and Israel, 2018)
- Because it did not reflect the nature of ethnographic research methods.

# Argument against the documentation of the consent process.

Ethnographers argued that written consent turned ethical, collaborative relationships into bureaucratically mediated formalities:

*"I feel the trust I've built as a member of the community I work with has been the major strength of my research; I really don't like having to introduce written consent forms as it overly formalizes research based on creative collaboration." (Wynn and Israel, 2018)*

*We can argue that the socio-cultural relationship between a researcher and his participants changes once a formal is presented for signature (personal experience).*

# Argument against the documentation of the consent process

Because of ethical abuses requiring evidence of informed consent, it does not imply that the same reason applies in every situation and for that, a consent form must be written and signed (except for two/three reasons).

According to Wynn and Isreal (2018), ethnographers believe that signing the form evokes  colonial histories, land appropriation by mining companies, surveillance regimes, and different cultural meanings of paper and signing.

# The functions of signatures

it authenticates and assures identity between people who were not known through ex isting relationships (Mihm 2007)

it documents data integrity, “the assurance that the contents of a signed docu ment or file have remained unaltered” (Hawkins 2011, 8)

ensure nonrepudiation; they are evidence that the signer participated in the signing.

# The Meaning of signature on the consent form

1. That the research participants has agreed to participate in the research following the requirements for informed consent.

It implies that it is a one-time process and that the participants understood the research process and his/her role.

It means that the researcher, not the participant is protected by the written contract (so, to whom does the consent protect)?

It means that the entire research was or will be conducted as stated in the information sheet and having signed, it confirms that there was trust in that claim (and maybe, the claim did not change throughout the duration of the research).

# The Meaning of Signature on the consent form

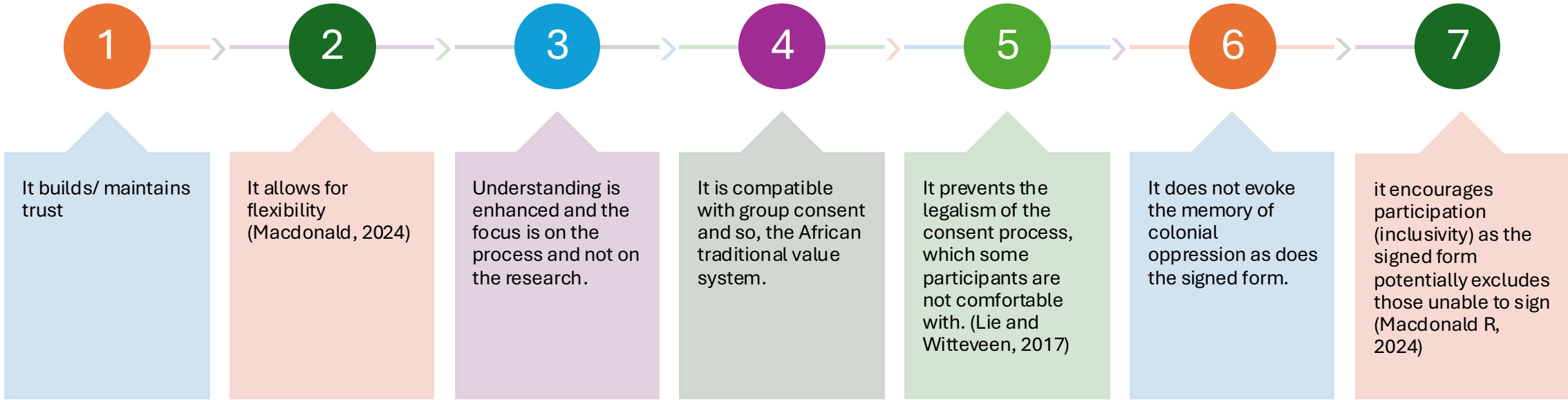
1. According to *Kuner and Anja* (1999, p.144)

***'signing makes it clear to all that the signatory has committed to a final transaction and cautions the signatory that she is entering a binding transaction.'***

Q: Doesn't this meaning contradicts the purpose of the informed consent which is the respect of autonomy?

*' the very existence of the signed document is predicated on the possibility that the relationship will fail.'*

# Some benefits of the oral consent process



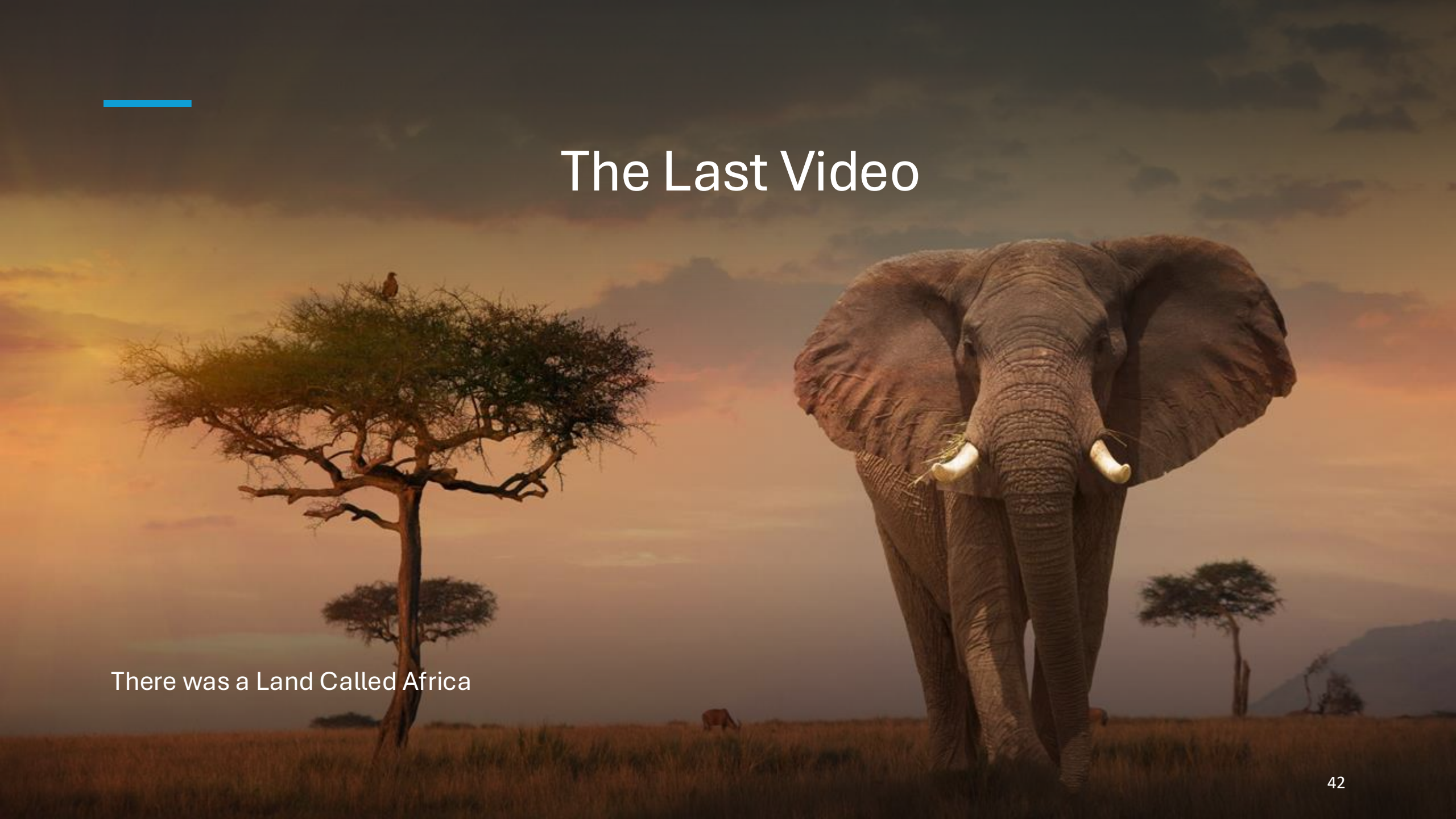
# STRIKING A BALANCE

1. While respecting the autonomy of a research participant by requiring his/her permission/ consent, be sensitive to the acceptable approach of gaining that consent.

2. There are situation where a participant (vulnerable participant) may be at risk of coercion from the family or the community, take extra step to engage the community, respecting their traditional values while ensuring that the participant agrees to participate freely and without fear of repercussion.

3. To be able to strike a balance between the ethics standards and traditional standard, the researcher should learn or be trained in the cultural implication of conducting research in a culturally-sensitive environment.

# The Last Video



There was a Land Called Africa

# Conclusion and Recommendation

History of research abuses such as the Nazi experiment led to formal requirements for informed consent although this could be dated earlier than the development of the Nuremberg code.

Nigerian and other African countries apply the western approach to consent such as documenting and signing the form.

However, there are empirical evidence that African values do not support, not just an individualistic approach, but approaches that tend to ignore cultural values of trust, communitarianism and respect which a mere paper and signature comes into conflict.

# Conclusion and Recommendation

Although studies in Africa suggest the abolishment of the written and signed informed consent, in addition to ethics guidelines that also suggest there may be traditions that would not accept a signature on a written document, there is yet an empirical study on the subject in Nigeria.

Researchers should train in the culture of the environment where they plan to conduct research to ensure a balance of ethical standards and the site's tradition.

There is, therefore, the need for more conversation on the subject to ensure the practice of autonomy as currently advised does not disrespect the national culture and tradition.

There should be a cultural protocol to strike a balance between the ethics and the local traditions. Any extreme should be avoided.

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