LIFEHEALTH / CTI AFRICA

Rethinking Informed Consent for the Digital Age FOR STRATEGIC LEADERSHIP

A Dynamic Consent Assurance Framework (DCAF)
for research, public health, and clinical trials

CTI-Africa | LifeHealth | Proprietary

THE CHALLENGE

Traditional consent was built for a paper world

TRADITIONAL CONSENT

- Long, legalistic documents
- One-time signature only
- No participant visibility after signing
- Limited multilingual support
- Poor auditability of understanding

DYNAMIC CONSENT (DCAF)

- Interactive, visual, animated explainers
- Ongoing, updateable consent
- Participant consent dashboard
- Multilingual by design
- Full audit trail with comprehension checks

THE CORE QUESTION

A fundamental shift in what consent means

OLD QUESTION

"Did the participant sign the form?"

NEW QUESTION

"Did the participant understand the information and make an informed choice?"

This distinction is fundamental to everything that follows.

FRAMEWORK DESIGN

Four dimensions determine consent requirements

01
Risk

Potential harm to the participant from the activity or data use

Minimal · Low · Moderate · Significant · High

02
Intrusiveness

How much the activity affects the participant's daily life

Questionnaire · Record review · Follow-up · Drug admin · Surgery

03
Sensitivity

How sensitive is the data being collected or used

Public stats · Medical history · Genetic info · Mental health

04
Reversibility

Can the consequences of participation be undone?

Anonymous survey · Research contact · Drug admin · Gene therapy

Dynamic Consent Assurance Levels — overview

LEVEL	USE CASES	RISK	REQUIREMENTS	LIFEHEALTH DELIVERY
A1 Informational	Health education, awareness, anonymous surveillance	Minimal	Plain language info · Simple acknowledgement	Animated explainer · Tap-through ack · Vima AI
A2 Observational	Disease registries, pharmacovigilance, public health monitoring	Low	Educational explanation · Digital consent · Participant review	Consent dashboard · Visual explainer · Audit trail
A3 Enhanced observational	Longitudinal cohorts, historical records, future contact	Moderate	Interactive explanation · Comprehension checks · Digital signature	LifeHealth Passport · Nexus · Comprehension quiz
A4 Interventional	Clinical trials, novel diagnostics, device evaluations	Significant	Risk-benefit explanation · Understanding verification · Investigator	MedWand · Vima AI · MatchRite · Enhanced audit
A5 High-risk intervention	Gene therapy, experimental surgery, first-in-human	High	Enhanced education pathway · Multiple checks · Witness validation	Dynamic Consent Framework · Witness module · Oversight layer

Consent delivered through the platform

Dynamic Consent is not a standalone product. It is a layer within LifeHealth's patient-owned health infrastructure — already built and operational.

LifeHealth Passport

Portable, citizen-controlled digital health identity. Consent records travel with the participant across institutions and borders.

A2 · A3 · A4 · A5

Vima (AI layer)

Animated healthcare professionals, plain-language explanations, comprehension-level adaptation — available in local languages.

A1 · A2 · A3 · A4 · A5

Dynamic Consent Framework

The full consent engine: tiered flows, comprehension quizzes, digital signatures, real-time dashboards for participants and researchers.

A3 · A4 · A5

Nexus

Research network integration layer. Connects clinical sites, registries, and ethics systems — enabling federated consent across multi-country studies.

A2 · A3 · A4

Consent delivered through the platform

Every consent interaction is independently validated at the point of occurrence — creating an immutable, auditable record of who, when, where, and what was agreed.

New: XValidator

XValidator — event-level verification

Every consent event, every investigator interaction, every patient touchpoint — independently validated and timestamped

PERSON	TIME	DATE	LOCATION	EVENT
Identity verified — patient, investigator	Exact timestamp of every consent event	Immutable date record tied to participant	Clinical site or geolocation at consent	Consent, review, withdrawal, or visit

VALIDATED EVENT CHAIN — EXAMPLE: CLINICAL TRIAL ENROLMENT

Patient ID Verified → **Investigator** Confirmed → **Site & time** Logged → **Consent given** Sealed → **Audit trail** Immutable

- **Proof of identity**
  Participants are who they say they are — every time, every site
- **Regulatory confidence**
  Ethics committees and sponsors get verifiable, immutable audit records
- **Research integrity**
  Investigators can prove every interaction happened as documented

Dynamic Consent does not replace sovereignty — it operationalizes it.

NATIONAL SOVEREIGNTY

Where is data governed?

- National laws and regulations
- Ministry of Health oversight

INSTITUTIONAL SOVEREIGNTY

Who may access and use data?

- Ethics approvals and consortium agreements
- Research, sponsor & institutional governance

PARTICIPANT SOVEREIGNTY

What has the participant agreed to?

- Consent permissions and participant choices
- Ongoing participant control and transparency

ALL THREE MUST ALIGN

Trusted Research | **Public Health** | **Clinical Trials** | **Pandemic Preparedness**

Dynamic Consent: the transparent governance layer connecting all three

National sovereignty determines where data is governed

Institutional sovereignty determines who may access data

Participant sovereignty determines what may be done with it

THE DEMONSTRATOR

A guided digital learning journey — not a consent form

Built on sickle cell disease. Applicable across registries, trials, genomics, and public health programmes.

1 Quick Overview

Concise summary for participants who prefer a short explanation

2 Standard Overview

Balanced explanation with key concepts — suitable for most participants

3 Detailed Overview

Comprehensive explanation with full context for those wanting deeper understanding

Animated healthcare professional

Serves as narrator — explains purpose, data use, participant choices in simple language

Clean, mobile-friendly interface

Progress indicator shows participants where they are and how much remains

Comprehension over compliance

Designed to ensure understanding — not just to satisfy a regulatory checkbox

Progressive information delivery

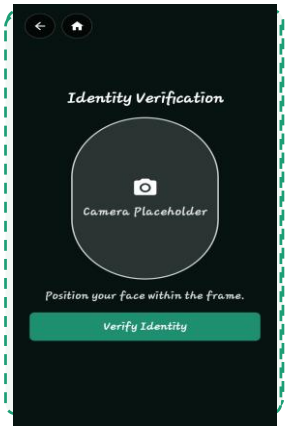
Participant navigates at their own pace; information reveals layer by layer

THE DEMONSTRATOR — IN PRACTICE

See it in action

[ADD VIDEO LINK HERE]

5-minute animated consent walkthrough · Sickle Cell Disease demonstrator



Current state: Interactive education · Animated explainer · Layered depth · Digital engagement

Next phase: Registry decisions · Trial notifications · Consent dashboard · Withdrawal

STAKEHOLDER VALUE

Benefits across the research ecosystem

FOR PARTICIPANTS

- Genuinely understand what they are agreeing to
- Real-time visibility into their consent status
- Ability to update or withdraw consent digitally

FOR ETHICS COMMITTEES

- Verifiable audit trail of participant understanding
- Tiered standards matched to activity risk
- Consistent, comparable consent quality

FOR CLINICAL RESEARCHERS

- Higher quality participant recruitment
- Improved longitudinal retention
- Faster, scalable consent processes

FOR PUBLIC HEALTH AND MOH

- Greater community trust in programmes
- Higher participation in surveillance and registries
- Infrastructure ready for pandemic preparedness

INVITATION TO COLLABORATE

This is a discussion, not a finished product.

01

Review the framework

Critique the A1–A5 levels and four dimensions with STRATEGIC

02

Pilot with sickle cell

Test interactive consent flows across all five assurance levels

03

Connect to SINCEP-Africa

Deploy DCAF as consent infrastructure across 19 clinical sites

04

Scale to preparedness

Build rapid, trusted consent infrastructure for outbreak response

STRATEGIC · Ethics Committees · Research Networks · Ministries of Health · Africa CDC · Clinical Researchers · Patient Advocates