INFORMED CONSENT FOR HIV TESTING

Protocol title: Determination of the protective efficacy of the *Pv*CS/Montanide ISA-51 (*Pv*CS.2/M-51) vaccine formulation against controlled infection with *Plasmodium vivax* sporozoites.

Study location:	Quibdó (Chocó)
Principal Investigator:	Sócrates Herrera Valencia, MD
Institution:	CENTRO DE ESTUDIOS CLÍNICOS ASOCLINIC LTDA – IPS
Description of the study population:	Adult individuals with and without previous malaria (naïve and semi-immune groups)
Name of study participant:	
Code assigned in the study:	

Study code: 2201-3

1. Purpose of this consent

You have been invited to undergo **testing for Human Immunodeficiency Virus (HIV) infection** as part of the screening/follow-up examinations for the indicated clinical trial. This test is requested **to protect your safety and** ensure that the study results are interpreted correctly. **Your decision is voluntary and does not affect** your health care or your participation in the main study (except when, according to the protocol criteria, the result is an inclusion/exclusion criterion or requires procedures to be deferred for your safety).

2. What the test involves

- A **venous blood sample** (approx. 5–10 mL) will be taken or, if approved by the protocol, a **rapid** capillary/venous blood **test** will be performed.
- If the screening result is **reactive**, the **confirmatory algorithm** will be performed immediately with supplementary tests validated by the Colombian Ministry of Health.
- The estimated time for delivery of the result and the method of delivery (in person/secure online) will be communicated to you by the study team.

3. Expected benefits

- Know your HIV status and, if necessary, **access counseling** and **timely referral** to your insurer/IPS for comprehensive care.
- Contribute to **safety** during the clinical trial.

There are no financial benefits for taking this test.

4. Risks and discomforts

- **Physical**: mild pain, bruising, or dizziness associated with venipuncture.
- **Emotional/psychosocial**: anxiety or concern while waiting for or receiving the result.
- **Confidentiality**: minimal risk of unauthorized disclosure, mitigated by strict data protection measures.

You will be offered **support and counseling before and after the test**.

5. Confidentiality and data protection

- Your data will be treated with **strict confidentiality**, using **codes** instead of your name.
- Access to the information will be restricted to **authorized** study **personnel**, **regulatory authorities**, and the **ethics committee** when required, preserving your identity.
- The results **will not be shared** with third parties (employers, family members, insurance companies) without your authorization, except where legally required.
- The information will be kept for the time required by the protocol and regulations, in secure repositories.

6. Voluntariness and right to withdraw consent

- **You may** refuse the test or **withdraw your consent at any time**, without penalty or loss of benefits to which you are entitled.
- If you decide not to undergo the test and the protocol requires it for safety or scientific reasons, the team will explain the **alternatives** (e.g., deferring procedures, exclusion from the study) and their implications.

7. Handling of results

- **Negative/Non-reactive**: You will be informed of the result, and preventive measures will be maintained. You will be reminded of **the "immunological window"** (the period during which a recent infection may not be detected) and, if applicable, a repeat test will be scheduled.
- **Reactive/Positive**: The **confirmatory algorithm** will be activated. If HIV infection is confirmed:
    - You will receive individual **post-test counseling**.

  - You will be **referred** to your insurer/IPS to begin comprehensive care (including medical evaluation and antiretroviral treatment).
  - If the result affects your continued participation in the study due to safety criteria, this will be explained to you, and the appropriate **clinical follow-up** will be guaranteed.
- You may indicate with whom you wish **to share** your result (optional). By default, only you and the study staff who need to use that information for in justified reasons will know it.

8. Costs and compensation

- The test **is free of charge** for you.
- No payments are made for taking the test, except for reimbursements/compensation allowed by the protocol (e.g., transportation), when applicable.

9. Alternatives to participation

You can get tested for HIV **outside of the study** at your IPS or through public health programs without affecting your relationship with the research center.

10. Questions, concerns, or complaints

If you have concerns about this consent form, wish **to withdraw your authorization**, exercise your **habeas data rights**, or file a **complaint**, please contact:

- **Principal Investigator:** Sócrates Herrera Valencia, MD
- **Study Coordinator:** Myriam Arévalo Ramírez, PhD
- **Chair of the Ethics Committee:** Ignacio Alberto Concha Eastman, MSc
- **Address:** Cll 21a - Cra 23, Zona Minera, La Virginia, Quibdó, Chocó
- **Telephone numbers:** (57) 317 517 0552 – (57) 317 517 0557 - 310 465 9004.
- **Email:**sherrera@inmuno.org / marevalo@inmuno.org/
- cei-asoclinic@inmuno.org /alberto.conchaeastman@gmail.com .

11. Statements and signatures

I have read (or had read to me) this HIV testing consent form. I have had the opportunity to ask questions and all of them have been answered clearly. I understand the purpose, risks, benefits, confidentiality, and my rights. **I** voluntarily **authorize** the HIV test to be performed as described.

I authorize my results to be shared with (optional):

[ ] No one (only me)
[ ] My treating physician for the study
[ ] My IPS/insurer
[ ] Other: _____

I authorize the study team to contact me to deliver the results by:

[ ] In person
[ ] Phone call
[ ] Secure email/patient portal

Do I authorize the retention of a sample aliquot exclusively for the repetition/confirmation of this test, in accordance with current regulations?

[ ] Yes [ ] No

Participant's name: _____
Identification document: _____
Participant's signature: _____
Date: _____

Witness signature (if applicable):

Witness signature: _____
Date**:**

Signature of the investigator or authorized delegate:

Date**:**