INFORMED CONSENT
SECONDARY USE OF BIOLOGICAL SAMPLES

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.

Written informed consent form for adults participating as volunteers in the study.

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

I, _____, identified with ID number _____

1. Authorization for secondary use of biological samples.

I declare that during my voluntary participation in the clinical study entitled "*Determination of the protective efficacy of the PvCS.2/M-51 vaccine formulation against controlled infection with Plasmodium vivax sporozoites,"* blood samples were taken from me and analyzed for the study.

I hereby authorize the remaining quantity of these samples to be stored for up to **twenty (20) years** and used in **research related to malaria, specifically the immune response to the parasite**, i.e., studies that seek to further the knowledge, treatment, prevention, or diagnosis of malaria. Therefore, my samples **may not be used** for unrelated research, commercial or reproductive purposes, or in another genetic research.

2. Storage and custody

The samples will be stored under secure and controlled conditions **in the biobank** at the headquarters of **CENTRO DE ESTUDIOS CLINICOS ASOCLINIC LTDA - IPS or the CENTRO INTERNACIONAL DE VACUNAS**, the study sponsor, for a period of up to twenty (20) years, after which the samples will be destroyed using established biosafety standards.

The samples will be subject to strict confidentiality and personal data protection measures.

3. Confidentiality

All personal and clinical information associated with the samples will be handled confidentially, in accordance with **Law 1581 of 2012** and other regulations governing the protection of personal data in Colombia. My data will be coded or anonymized as appropriate to prevent me from being directly identified.

4. Participant rights

- I have been informed that my decision to authorize or not authorize this secondary use **does not affect my participation** in the original clinical study or my access to related medical services.
- I may **withdraw this authorization at any time** by submitting a written request to the principal investigator or the relevant ethics committee, without this causing me any harm.
- I understand that if the samples have already been used prior to the withdrawal of consent, **it will not be possible to reverse such use**.

6. Contact and questions

I have been informed that, for any concerns, complaints, or to exercise my rights, I may contact the principal investigator, the coordinator, or the Research Ethics Committee at **CENTRO DE ESTUDIOS CLINICOS ASOCLINIC LTDA – IPS**, Calle 21a - Cra 23. Zona Minera -La Virginia, Quibdó, Choco.

7. Contact details

Sócrates Herrera Valencia. Principal Investigator
Email: sherrera@inmuno.org
Telephone: (57) 317 517 0552

Myriam Arévalo Ramírez. Study Coordinator.
Email:marevalo@inmuno.org .
Phone: (57) 317 517 055

Ignacio Alberto Concha Eastman, MD, MSc. Chair of the Ethics Committee

for Research
Email:alberto.conchaeastman@gmail.com
Tel: (57) 310 465 9004

PARTICIPANT STATEMENT

I have read (or had read to me) the contents of this document and have had the opportunity to ask questions, which have been answered clearly and satisfactorily. I understand the purpose of the secondary use of my biological samples and authorize such use as set forth herein.

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

Witness signature (if applicable):

Witness signature: _____
Date**:**

Signature of the investigator or authorized delegate:

Date**:**