

Institutional Endorsement
Research Project
REG-R03.000.0000-006

CTIN Code (##-YYYY): 26-2016

Project Title

Zika en Embarazadas y Niños en Colombia (ZEN Colombia)

City and Date: Bogota D.C., December 12, 2016

Directed to: Diana Valencia, MS, MS - NCBDDD/DCDD

Group: Deputy Directorate of Scientific and Technological Research

Entity: CDC - National Institute of Health

Email address of the sender: ile9@cdc.gov

Mailing address of the sender: Deputy Directorate of Scientific and Technological Research

Name of responsible investigator at INS: Claudia Marcela Castro

The present has as its purpose to inform that the National Institute of Health (INS) awards institutional endorsement of the research project titled CTIN Num. 26-2016 "Zika in Pregnant Women and Children in Colombia (ZEN Colombia)". This project has technical and ethical endorsement from the respective committees at INS.

The following are the approved line items to execute with counterpart resources from INS*:

INS line items	Cash value	In Kind Value
Permanent staff		52,949,000
Use of equipment		480,000,000
Total value		532,949,000
Total		532,949,000

*counterparts subject to institutional budget assignment

The time of execution is 24 months.

Name of general directorate: Jorge Martin Rodriguez Hernandez

Position: General Director (E.)

Note: This document authorizes the principal investigator to begin the management of the research project with the approval of INS.

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Directed to: Diana Valencia, MS, MS - NCBDDD/DCDD

Research group: Deputy Directorate of Scientific and Technological Research

Email address of principal investigator: ile9@cdc.gov

Mailing address of the principal investigator: CDC and INS General Directorate

Name of responsible investigator at INS: Marcela Mercado, May Bibiana Osorio

The Technical Committee for Research (CTIN) of the National Institute of Health (INS), created under Resolution 1528 of September 29th, 2008 and modified under Resolution 481 of April 15, 2015; considers that the project "CTIN Num. 26-2016 Zika in Pregnant Women and Children in Colombia (ZEN Colombia)" fulfills the technical requisites so that it is granted technical endorsement as communicated electronically with the last technical revision of the project December 12th, 2016.

If technical aspects of the approved version of the project are made during its execution, we ask that these be reported to CTIN in order to make the respective revision.

Name of the person who carries out duties: Yamileth Ortiz Gomez

Position: Executive Secretary

Notes:

1. This document should be saved in the project folder of the Research Technical Committee.
2. This document does not authorize the principal investigator to begin the execution of the research project approved by CTIN.

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City and Date: Bogota D.C., December 12, 2016

Directed to: Diana Valencia, MS, MS - NCBDDD/DCDD

Research group: Deputy Directorate of Scientific and Technological Research

Email address of principal investigator: ile9@cdc.gov

Mailing address of the principal investigator: CDC and INS General Directorate

Name of responsible investigator at INS: Marcela Mercado, May Bibiana Osorio

The Ethical Committee for Research (CEIN) of the National Institute of Health (INS) created under Resolution Num. 0594 of July 11, 1996 and modified under Resolution Num. 0836 of July 1, 2015; considers that the project "CTIN Num. 26-2016 Zika in Pregnant Women and Children in Colombia (ZEN Colombia)", fulfills the ethical requisites for its approval so that it is granted ethical endorsement under Record Num. 9 of October 13, 2016.

Decision: Keeping in mind the content of the document, it is established that there does not exist any ethical dilemma and it is recognized that the principal investigator described complete information in the project, so that the members in consensus recommend giving ethical endorsement. In accordance with Article 11 of the Ministry of Health Resolution 008430 of 1993, "it is research with minimal risk."

If the approved version of the projected is modified in regards to its ethical component, or in the case that there exists other aspects that can affect the ethical component of the project during its execution, we ask for your collaboration in reporting these to CEIN to make the respective revision.

Level of risk of the project (see Article 11 Ministry of Health Resolution 8430 of 2003)	Research without risk	Research with minimal risk X	Research with greater than minimum risk
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Name of the person who carries out duties: Yamileth Ortiz Gomez

Position: Executive Secretary

Notes:

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This document does not authorize the principal investigator to begin the execution of the research project approved by CEIN.