IRB Authorization Agreement

Outside institution relying on a CDC IRB

This IRB authorization agreement is suitable for documenting a formal agreement between the Centers for Disease Control and Prevention (CDC) and an institution that relies on a CDC IRB for review of the research activities specified below. This agreement is permitted by human research regulations at 45 CFR 46.114 and 21 CFR 56.114.

1 Institution providing IRB review (Institution A)

Centers for Disease Control and Prevention (CDC)
IRB Registration #: 00000183 Registration expiration date: 9/16/2019
Federalwide Assurance (FWA) #: FWA00001413 FWA expiration date: 9/30/2020

2 Institution relying on designated IRB (Institution B)

Name of Institution B: Vysnova Partners, Inc.
FWA #:00023351 FWA expiration date: 8/07/2020

3 Scope of authorization agreement

The officials signing below agree that the Vysnova Partners, Inc. may rely on the CDC IRB both for review under 45 CFR part 46 (and 21 CFR parts 50 and 56, if applicable) and for continuing oversight of the involvement of human subjects in the research described below:

	Institution A: CDC	**Institution B**: **Vysnova Partners, Inc.**
Title of research protocol	Zika en Embarazadas y Ninos en Colombia (ZEN Colombia)	Zika en Embarazadas y Ninos en Colombia (ZEN Colombia)
Protocol reference ID	6921	not yet assigned
Principal investigator (name, phone, fax, e-mail)	Margaret Honein, PhD, MPH 404-498-3921 Mrh7@cdc.gov	William Bertrand, PhD 504-975-3369 wbertrand@vysnova.com
Primary contact (name, phone, fax, e-mail)	Denise Jamieson, MD , MPH 770-488-6377 djj0@cdc.gov	Carlos Rivera 301-830-8875 crivera@vysnova.com

Sponsor or funding agency: USAID Award number, if any:

Additional comments:

The review and continuing oversight performed by the CDC IRB will meet the human subjects protection requirements of the HHS regulations (and FDA regulations, if applicable) for the protection of human subjects, as well as the requirements of the OHRP-approved FWA at the Vysnova Partners, Inc.. The CDC IRB will follow written procedures for reporting its findings and actions to appropriate officials. CDC will make relevant minutes of IRB meetings and related records available to the Vysnova Partners, Inc. upon request. The Vysnova Partners, Inc. remains responsible for ensuring compliance with the IRB's determinations and with the terms of its FWA. This document must be kept on file at both institutions and provided to OHRP upon request.

4 Signatures

Institution A: CDC

Lashonda J. Roberson -S3

Digitally signed by Lashonda J. Roberson -S3
DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000463851, cn=Lashonda J. Roberson -S3
Date: 2016.09.26 10:44:39 -04'00'

Signature Date

LaShonda Roberson
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Institution B: Vysnova Partners, Inc.

9/23/16

Signature Date

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