Form Approved
OMB No. 0920-XXXX
Exp. Date xx/xx/20xx

Pregnant Woman Eligibility

Note: Before enrolling a woman, make sure you have enough supplies (study kits, blood and urine collection materials, paper forms, etc.)

Name of Person Completing the Form: _____

Cedula of Pregnant Woman: _____

Today's date: _____/_____/_____ (DD/MMM/YYYY)

IPS Information

Clinic name: _____

City: ☐ Barranquilla ☐ Bucaramanga ☐ Tuluá

Pregnant Woman Information

Last names: _____

First name(s): _____

Pregnant woman date of birth _____/_____/_____ (DD/MMM/YYYY)
If under 18, date of pregnant woman 18th birthday _____/_____/_____ (DD/MMM/YYYY)

Expected delivery date (EDD): _____/_____/_____ (DD/MMM/YYYY) ☐ Unsure

How determined: ____ by LMP ____ by ultrasound

If expected delivery date is unknown:

Date of LMP: _____/_____/_____ (DD/MMM/YYYY) ☐ Unsure

Gestational age at eligibility: _____ weeks _____ days

Inclusion Criteria

Is the woman pregnant? (by confirmed clinic pregnancy test or ultrasound)	☐ Yes	☐ No
Is the woman in the first trimester of pregnancy ($\leq 14^{+6}$)? (by LMP or ultrasound)	☐ Yes	☐ No
Is the woman planning to have prenatal care at a participating clinic?	☐ Yes	☐ No
Is the woman 16 years of age or older?	☐ Yes	☐ No
Does this woman speak Spanish?	☐ Yes	☐ No

Exclusion Criteria

Is the pregnancy an ectopic or a molar pregnancy?	☐ Yes	☐ No
Is the woman incarcerated?	☐ Yes	☐ No
Is the woman unable to physically or psychologically participate based on clinical judgement?	☐ Yes	☐ No

Eligibility Determination

The woman is eligible for the study. (All answers to inclusion criteria questions are Yes AND all answers to exclusion criteria are No.)

☐ Yes → Eligible

☐ No → Not Eligible

☐ Unsure → If unsure, then fill out Appendix E1 (contact information) and follow-up in one week.

Notes about eligibility determination: _____

_____

_____

If eligible, please complete the sections below.

Informed Consent Determination

Did the woman receive and provide informed consent or assent for participation?

☐ Yes → Enroll

☐ Unsure → If unsure, then fill out Appendix E1 (contact information) and follow-up in one week.

☐ No → If no, thank the patient for their time and note that they declined participation in the study.

Reason(s) for declining (*check all that apply*):

☐ Not interested

☐ Concerned about study protocol (safety, invasive)

☐ Concerns about time/transportation

☐ Concerns about family member approval (e.g. partner, parents)

☐ Other concern:_____

Zika Study Kit

Did you give the woman a Study Kit before she left?

☐ Yes, she took it

☐ Offered it to her, but she didn't want/take it

☐ Did not offer → **STOP**. Do not enroll if no study kit is available. Schedule enrollment visit for another day.

If not offered, why?: _____

ZEN Participant and Non-Participant Identification Numbers

If the woman was eligible and has consented, assign a ZEN Participant ID. If the woman was not eligible or was eligible and did not consent, assign a ZEN Non-Participant ID (see SOP ZEN-2-02).

ZEN Participant ID: _ _ _ _ _ _- _ - _ _ _ _ _ _ _ _ _ _ _

ZEN Non-Participant ID: N _ _ - _ - _ _ _ _ _ _ _ _ _ _ _