

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): Age today: _____

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

Date of LMP: ____/____/____ (DD/MMM/YYYY) Unsure

Gestational age at eligibility: _____ weeks _____ days

NOTE: Use EDD to calculate gestational age, and if ED is unknown, then use LMP

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

CDC estimates the average public reporting burden for this collection of information as 5 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB

control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).

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 –STOP, thank the participant and fill out non-participant ID
- 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, do not enroll, 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 _ _ - _ - _ _ _ _ _ _ _ _ _ _ _ _