**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 (≤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

□ Unsure 🡪 If unsure, then fill out Appendix E1 (contact information) and

follow-up in one week.

**Notes about eligibility determination:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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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 \_ \_ - \_ - \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_