

SAMPLE: DO NOT FAX TO DATAFAX



MTN 016 (164)

DEM-1 (001)

Participant ID

Site Number - Participant Number - Chk - Cohort

Woman Demographics

Visit Date

dd MMM yy

- 1. What is the participant's date of birth? ... dd MMM yy ... If unknown, record age: years
2. What is the participant's gender? ... male female
3. Does the participant earn an income of her own? ... If no, go to item 4.
3a. How does she earn her income? Mark all that apply.
4. What is the participant's highest level of education?
5. Does the participant, or someone in her family, own the home she currently lives in? ... yes no
6. How many rooms are in the participant's household? ... # of rooms
7. Is the participant currently married? ... yes no
8. What is the participant's ethnic group or tribe? ... ethnic/tribe code

U.S. SITES ONLY:

- 9. Does the participant consider herself to be Latina or of Hispanic origin? ... yes no

08-JUL-09

01 Language

Staff Initials / Date

Woman Demographics (DEM-1)

Purpose: This form is used to document general demographic information.

General Information/Instructions: This form is completed once for each participant, at the Enrollment Visit.

Note: There is no visit code field on this form since this form is only completed at the Enrollment Visit.

Item-specific Instructions:

- **Item 2:** This item has already been completed based on the expected study population. Please skip this item.
- **Item 3a:** Record whether the participant’s source(s) of income is/are from formal employment (e.g., shop clerk, farmer, seamstress, teacher), self-employment (e.g., shop owner, artist, restaurant owner), or other type of employment.
- **Item 5:** Record whether or not the participant or someone in her family owns the home where she lives.
- **Item 8:** This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant’s ethnic group or tribe. If the participant responds with “other,” record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.

MALAWI	SOUTH AFRICA	UGANDA	UNITED STATES	ZAMBIA	ZIMBABWE
01 - Chichewa	07 - Zulu	11 - Black	18 - American Indian or Alaskan Native	12 - Bemba	16 - Shona
02 - Lomwe	08 - Xhosa	06 - White	19 - Asian	13 - Chewa	17 - Ndebele
03 - Yao	09 - Indian	99 - Other	20 - Black or African American	14 - Tonga	05 - Other African tribe
04 - Tumbuka	10 - Colored		21 - Native Hawaiian or other Pacific Islander	15 - Lozi	06 - White
05 - Other African tribe	05 - Other African tribe		06 - White	05 - Other African tribe	99 - Other
06 - White	06 - White		99 - Other	06 - White	
99 - Other	99 - Other			99 - Other	

- **Item 9:** This item is only completed by U.S. sites. All non-U.S. sites leave this item blank.

SAMPLE. Do NOT FAX TO DATAFAX

MTN 016 (168)



IEN-1 (070)

Participant ID

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Site Number Participant Number Chk Cohort

Infant Enrollment

Visit Date

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dd MMM yy

1. Does the participant meet all eligibility criteria? yes no

If no, participant is ineligible. End of form. Do not fax to SCHARP DataFax.

2. Date study informed consent signed or thumbprinted:

dd MMM yy

2a. Did the guardian provide informed consent for photographic documentation of suspected or confirmed anomalies? yes no

If no, go to item 3.

2b. Date informed consent given for photographic documentation of suspected or confirmed anomalies.

dd MMM yy

3. Date of birth:

dd MMM yy

If equal to or greater than one year ago, participant is ineligible. End of form. Do not fax to SCHARP DataFax.

4. Gestational age based on pediatric assessment (using Ballard): weeks OR not assessed

Comments: _____

Infant Enrollment (IEN-1)

Purpose: This form is used to document an infant participant's study enrollment. This form is completed when the infant is determined to be eligible for the study.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant is enrolled (that is, the infant is eligible and the guardian has provided informed consent).

- **Participant ID:** complete the Participant ID as follows:
 - the first 8 digits are identical to the mother's PITD
 - the last digit, the cohort, is completed as follows:
 - for the first infant born **and** enrolled in MTN 016, cohort = 1
 - for the second infant born **and** enrolled in MTN 016, cohort = 2
 - for the third infant born **and** enrolled in MTN 016, cohort = 3
 - for the fourth infant born **and** enrolled in MTN 016, cohort = 4; etc.

Refer to the Study-Specific Procedures (SSP) Manual for more specific information on Participant IDs for MTN 016.

Note: There is no visit code field on this form since this form is only completed once for each infant participant.

Item-specific Instructions:

- **Item 1:** If the response to this item is "no" (the participant does not meet all eligibility criteria), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.
- **Items 2 and 2b:** If the guardian marks the informed consent using his/her thumbprint, record the date the thumbprint was made.
- **Item 3:** A complete date is required. If the date of birth is greater than one year ago, the participant is ineligible, end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.