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?..............................

3a. How does she earn her income? Mark all that apply.

☐ 3a1. formal employment
☐ 3a2. self-employed
☐ 3a3. other, specify: ________________________________

4. What is the participant's highest level of education?

☐ no schooling
☐ primary school, not complete
☐ primary school, complete
☐ secondary school, not complete
☐ secondary school, complete
☐ attended college or university

5. Does the participant, or someone in her family, own the home she currently lives in? ....................................................

6. How many rooms are in the participant's household? .......................

7. Is the participant currently married? ..................................................

8. What is the participant's ethnic group or tribe? .................................

U.S. SITES ONLY:

9. Does the participant consider herself to be Latina or of Hispanic origin? .................................................................

10. Visit Date dd MMM yy

11. Language

12. Staff Initials / Date

Participant ID Site Number Participant Number Chk Cohort

Visit Date

Language

Staff Initials / Date

08-JUL-09

If other, specify:

ethnic/tribe code

# of rooms

yes no

yes no

yes no
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.

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

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