

INTERGROWTH-21st

International Fetal and Newborn Growth Standards for the 21st Century

The International Fetal and Newborn Growth Consortium



FETAL GROWTH LONGITUDINAL STUDY

OPERATION MANUAL

August 2009



**Please read this manual carefully and refer to it throughout the study
if any clarification is needed**

This Operations Manual was produced by the International Fetal and Newborn Growth Consortium, based on the INTERGROWTH-21st protocol.

www.intergrowth21.org.uk

INTERGROWTH-21st is a large project involving health institutions from eight geographically diverse countries. It is therefore essential that the participating institutions follow the same data collection procedures. This manual is designed to familiarize all staff involved in the study and its implementation with the study procedures for patient selection, data collection and general methodological issues.

Table of Contents

Fetal Growth Longitudinal Study (FGLS) Summary	4
General Instructions for Form Completion	9
Screening: Interview Form (SCR)	10
<i>Form Header</i>	11
<i>Section 1: Demographic, Socioeconomic and Nutritional Characteristics</i>	11
<i>Section 2: Medical History</i>	15
<i>Section 3: Gynaecological History</i>	16
<i>Section 4: Obstetric History</i>	19
<i>Section 5: Current Pregnancy</i>	22
<i>Section 6: Consent</i>	23
Screening: Ultrasound Dating Form (USD)	24
<i>Form Header</i>	25
<i>Section 1: Last Menstrual Period</i>	25
<i>Section 2: Pregnancy Observations</i>	26
<i>Section 3: Crown Rump Length (CRL) Measurement</i>	27
<i>Section 4: Eligibility</i>	28
Maternal Study Entry Form (MSE)	29
<i>Form Header</i>	30
<i>Section 1: Demography</i>	30
<i>Section 2: Obstetric History</i>	31
<i>Section 3: Current Pregnancy</i>	32
<i>Section 4: Nutritional Supplements/Medications</i>	33
<i>Section 5: Next Appointment</i>	34
Ultrasound Follow-up Form (UFU)	35
<i>Form Header</i>	36
<i>Section 1: Ultrasound observations and measurements</i>	36
<i>Section 2: Symphysis Fundus Height</i>	38
<i>Section 3: Next Appointment</i>	38
Pregnancy Follow-up Form (PFU)	39
<i>Form Header</i>	40
<i>Section 1: Pregnancy Status</i>	40
<i>Section 2: Current Health</i>	44
<i>Section 3: Current Health (continued)</i>	45
<i>Section 4: Nutritional Supplements/Medications</i>	46
<i>Section 5: Referral</i>	46
<i>Section 6: Next Appointment</i>	47
Maternal Referral/Admission Form (MRE)	48
<i>Form Header</i>	49
<i>Section 1: Pregnancy Status</i>	49
<i>Section 2: Lab results</i>	50
<i>Section 3: Non-pregnancy-related diagnosis for this admission or referral</i>	51
<i>Section 4: Pregnancy-related diagnosis for this admission or referral</i>	53
<i>Section 5: Medications and treatment</i>	54
<i>Section 6: Final Outcome</i>	55
<i>Section 7: Next Appointment</i>	55
Appendix 1. Occupational classification scheme	56
Appendix 2. Blood Pressure Measurement Protocol	57
Appendix 3. Measurement of Symphysis Fundal Height	59

Fetal Growth Longitudinal Study (FGLS) Summary

The primary purpose of the project is to develop new "prescriptive" standards describing normal fetal growth in eight geographically diverse populations, and to relate these standards to neonatal health risk. The worldwide use of these tools should improve infants' healthcare and nutritional status. These new standards will be incorporated into national and international maternal and neonatal programs, and they will be used to monitor and evaluate maternal wellbeing, infant health and nutrition at a population level.

To achieve these objectives, primary data will be collected on a population-based sample of healthy pregnant women. The tools will describe how fetuses should grow in all countries rather than the more limited objective of past growth references which describe how they have grown at specific times and locations. They will allow for evidence-based evaluation of nutritional status at birth and measurement of the impact of preventive and treatment interventions in the community.

Approximately 5,000 pregnancies will be included in FGLS study. Women will be screened between 9 and 14 weeks gestation at the time of their early antenatal visit and followed-up with standard clinical and 2D ultrasound examinations every five weeks, i.e. up to six times during a term pregnancy.

Patient Flow

Patient flow for the Fetal Growth Longitudinal Study is presented in Figure 1. The text below describes the recruitment process and makes reference to Figure 1.

Recruitment

Potentially eligible women who come for an early appointment at the antenatal or gynaecological clinic (at between 9⁺⁰ and 13⁺⁶ weeks gestation) will be given information that briefly describes the study. Those women who are willing to undergo a more detailed evaluation will have a Screening Form completed by the research staff or assistant/nurse/midwife. Information for this form is to be extracted from the medical record or gained by conducting a direct interview with the patient or the care provider (Fig. 1).

Women meeting all the inclusion criteria for the study will be offered a dating scan at the study ultrasound unit to confirm the gestational age.

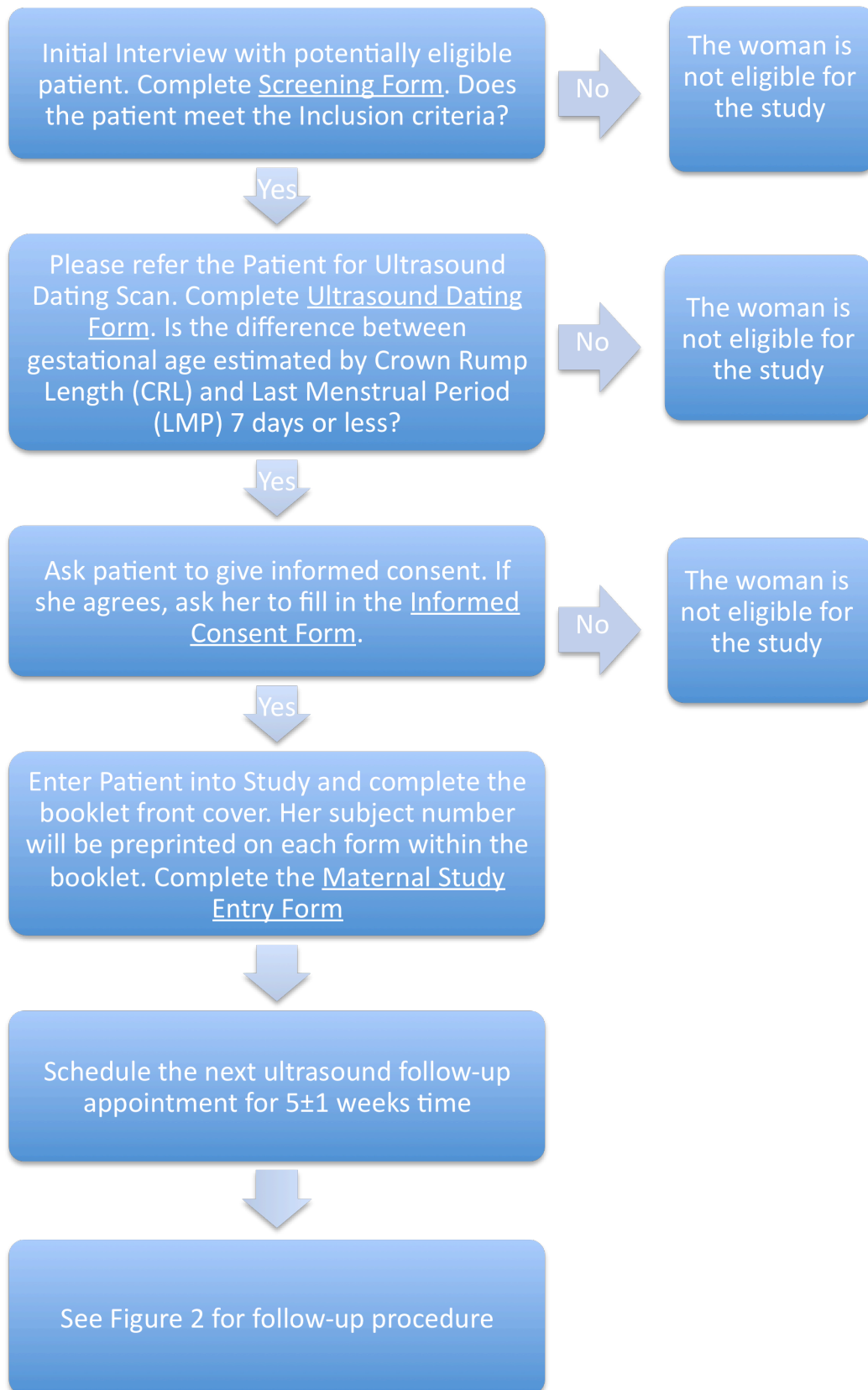
After the dating scan the Ultrasound Dating Form must be completed. If she is eligible and willing to participate she should be asked to sign an Informed Consent Form.

All eligible women should receive an appointment card with the dates of their follow-up appointments. Before she leaves a booklet front cover must be completed and the Maternal Study Entry form filled in, including any required clinical information. Each booklet is preprinted with a unique study subject number that can be used to identify the woman.

The next ultrasound appointment should be scheduled 5 (\pm 1) weeks from the dating scan. The scan takes place at the study ultrasound unit with one of the study ultrasonographers. She should be advised to follow her routine antenatal care as planned and to remember to carry her ANC booklet or similar document with her to all ultrasound visits.

If it can be arranged, the father should come to one of the ultrasound follow-up appointments so that his height can be taken.

Figure 1: FGLS patient flow: Recruitment

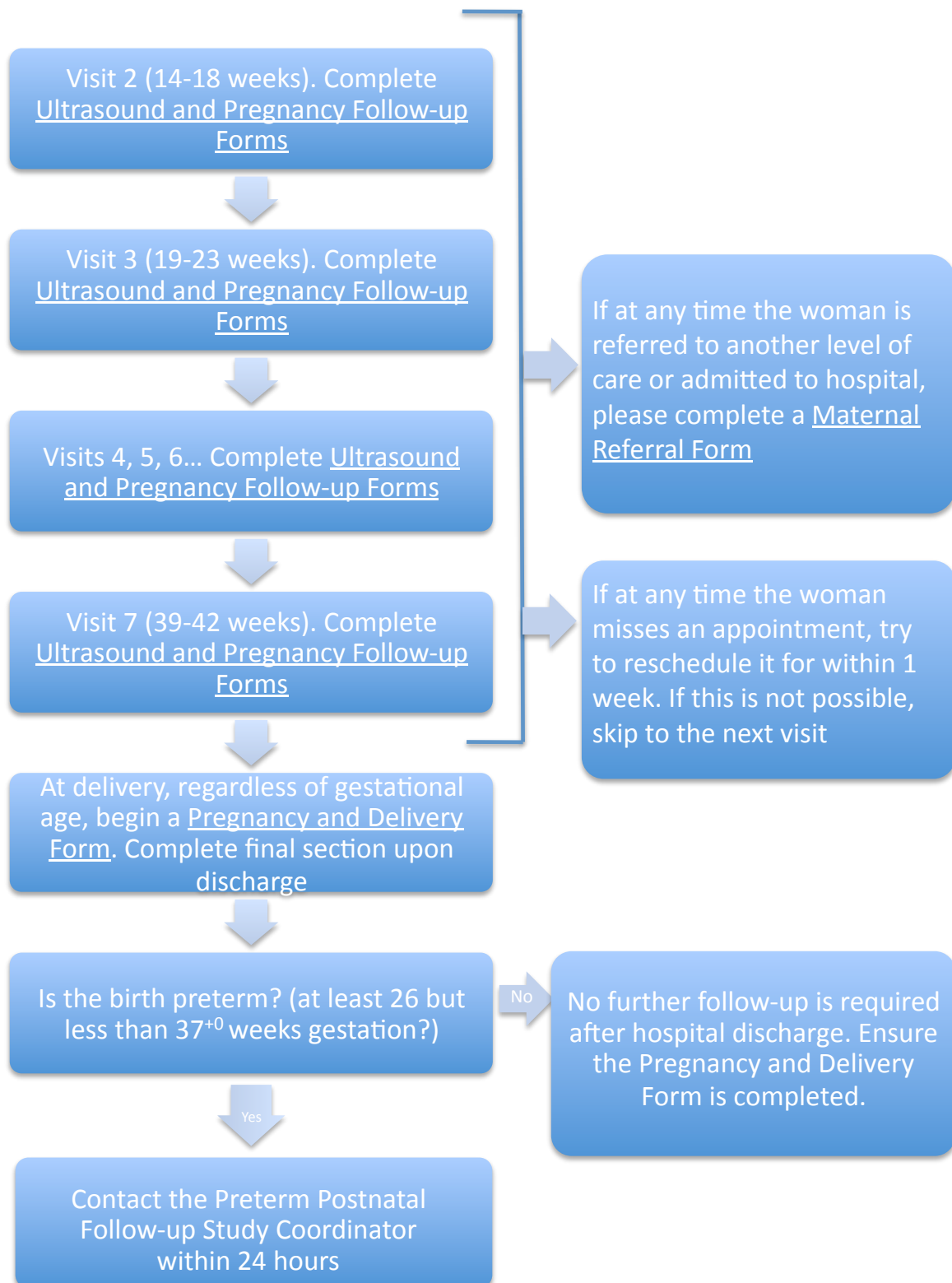


Follow-up

After the initial dating scan, a further 6 ultrasound visits will be scheduled at 5 ± 1 week intervals, e.g. if the initial scan is at 10 weeks, she will have further scans at 15, 20, 25, 30, 35 and 40 weeks. The exact dates will depend on gestational age at recruitment and the total number of scans will depend on the duration of the pregnancy. Once a woman enters the study, the follow-up process is as follows. A schematic representation is given in Figure 2.

- All women will receive routine antenatal care. The content of this care will be standardized but local variability is to be expected.
- All women will be followed throughout pregnancy irrespective of any antenatal event, missing information or pregnancy outcome.
- If the woman is referred for another level of care at any stage during her pregnancy, e.g. high-risk clinic, a **Maternal Referral Form** should be completed. Local medical or obstetrical protocols should be adhered to (Fig. 2).
- *Ultrasound Schedule:* After the dating scan, a total of 6 further visits (for ultrasound scans) will be scheduled at 5 weekly (± 1 week) intervals (i.e. 14-18, 19-23, 24-28, 29-33, 34-38 and 39-42 weeks). Seven fetal measurements will be taken at each visit after the dating scan: Biparietal diameter (BPD), Occipito-Frontal Diameter (OFD), Head circumference (HC) using the ellipse facility, Transverse abdominal diameter (TAD), Antero-posterior abdominal diameter (APAD), Abdominal circumference (AC) using the ellipse facility, and Femur length (FL). Data from the fetal measures will be transferred electronically to the database. An **Ultrasound Follow-up Form** must be completed by the ultrasonographer at each appointment.
- In addition, at each ultrasound visit, a **Pregnancy Follow-up Form** must be completed by the study staff by asking women a few questions about her health, taking three required clinical measures (weight, blood pressure and Symphysis-Fundus height), collecting lab results for haemoglobin and proteinuria if available, and/or abstracting data from the antenatal care booklet of the woman or her medical record.
- If the woman misses a visit at any point in her follow-up, try to reschedule the appointment within the next 7 days. If this is not possible, skip to the next scheduled appointment in 5 ± 1 weeks time. To avoid this situation, women should always be alerted of the next visit date in advance. The system to do this should be coordinated based on local practices.
- At delivery, regardless of gestational age, the **Pregnancy and Delivery Form** must be completed. The mechanism for this should be organized and coordinated with the local delivery hospitals.
- If the birth is preterm, (less than 37^{+0} completed weeks), the baby should be entered into the Preterm Postnatal Follow-up Study (PPFS). Contact the PPFS Coordinator.

Figure 2. FGLS Patient Flow: Follow-up



General Instructions for Form Completion

1. A black ballpoint pen should be used to complete the forms and the writing should be legible and in block capitals where appropriate.
2. Do not write on the forms except in the data boxes. Where there is the option, place a 'X' in boxes that correspond to your answer. Where values need to be written, please write numbers clearly. All dates should be written in the format dd-mm-yy, for example 20th May 2010 should be written 20-05-10.
3. If there is an error made in writing, it must be crossed out, and the correct answer written outside the box and initialed. Correction fluids should not be used.
4. The person completing the form should fill in his/her name, signature and their researcher code (provided by the coordinating unit) at the bottom of each form.
5. After completion, each white top copy should be separated out and given to the local research coordinator for review and forwarded on to the data entry unit at regular intervals (to be decided locally). The patient booklet containing the duplicate (yellow) forms should be kept in a separate filing system within the facility.
6. It is up to each institution to organize the local arrangements to facilitate this process.

Screening: Interview Form (SCR)

Important: Complete ALL questions. If the answer is unknown to the woman or unavailable, please check all available records. If still unavailable, please refer to the specific question in this manual for instructions.

The information required to complete this form can be obtained either directly from the woman or from her medical records.

For height and weight measurements, please use the information available from the medical records or take the measurements using the equipment available

Questions 9-13 in Section 1 regarding high-risk activities and socioeconomic status will need to be asked directly to the woman.

When completing the form:

If at any point a woman becomes ineligible (i.e. one of the white boxes is crossed) stop the screening process immediately – you do not need to continue to the next question. Inform her that she is ineligible for the study and that she will continue with her routine antenatal care. Sign the bottom of the form (completing also the researcher code and your name) and then pass the form to the local research coordinator, who will take it to the *Data Entry and Quality Control Unit* for entry onto the database.

If a woman meets all the eligibility criteria: (i.e. if all the shaded boxes are crossed and the answer to Question 59 is 'YES') then the woman is eligible. Please book her dating scan at the Study Ultrasound Centre for within 3 days. Complete the form fully and then pass the form to the local research coordinator, who will take it to the *Study Ultrasound Clinic* in time for the appointment. The completed Screening and Ultrasound Dating forms will then be taken to the *Data Entry and Quality Control Unit* for entry onto the database.

Form Header

Country Code	<input type="text" value="0"/> <input type="text" value="1"/>	Interview date	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
Study Antenatal Clinic Code	<input type="text"/> <input type="text"/>		
Patient Screening Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

Country Code: This code corresponds to your country and will be preprinted. You do not have to write the country code.

Study Antenatal Clinic Code: Please enter the number of the antenatal clinic (assigned by the coordinating unit) where the woman is interviewed. Please ensure that you enter the correct number from the list as this is vital in enabling us to identify the woman.

Patient Screening Number: Please give the woman the next available number from your allocated batch. Each antenatal clinic will begin at 0001. Ensure that you do not give her a duplicate number that has already been allocated by keeping an updated log-book in each clinic.

Interview Date: Please enter the date of the interview in the format dd-mm-yy, for example, 20th May 2010 should be written 20-05-10.

Section 1: Demographic, Socioeconomic and Nutritional Characteristics

Section 1: Demographic, socioeconomic and nutritional characteristics	
1. Age (years)	<input type="text"/> <input type="text"/> yrs
2. Is she between 18 and 35 years old?	<input type="checkbox"/> yes <input type="checkbox"/> no
3. Height (cm)	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm
4. Is she more 153cm?	<input type="checkbox"/> yes <input type="checkbox"/> no
5. Weight (kg)	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg
6. Calculate the body mass index (BMI) using the BMI calculator provided.	<input type="text"/> <input type="text"/> . <input type="text"/> kg/m ²
7. Is her BMI between 18.5 and 29.9 kg/m ² ?	<input type="checkbox"/> yes <input type="checkbox"/> no
8. Have you smoked/chewed tobacco in the last 3 months?	<input type="checkbox"/> yes <input type="checkbox"/> no
9. Have you used any recreational drugs in the last 3 months?	<input type="checkbox"/> yes <input type="checkbox"/> no
10. Have you had 5 or more units of alcohol per week since discovering you were pregnant? (1 unit = small (125ml) glass of wine or one bottle (330ml) of beer)	<input type="checkbox"/> yes <input type="checkbox"/> no
11. Are you involved in any high risk occupation and/or vigorous or contact sport? (Show table)	<input type="checkbox"/> yes <input type="checkbox"/> no
12. Do you follow any special diets e.g. vegetarian with no animal products, weight loss programme, malabsorption treatments, gluten-free diet? (Show table)	<input type="checkbox"/> yes <input type="checkbox"/> no
13. Country specific socioeconomic question	<input type="checkbox"/> yes <input type="checkbox"/> no

1. Age (years)

Write the age of the woman in years. You are to obtain her age in completed years; that is, the age at the time of her last birthday. If you are working from medical records, you may have to calculate the age from her date of birth.

2. Is she between 18 and 35 years old?

Place a 'X' in the box marked 'YES' if she is 18 or more AND less than 36.

Place a 'X' in the box marked 'NO' if she is 35 or more OR less than 18.

Example: if the woman is 18, place an 'X' in the box marked 'YES', but if she is 17, place an 'X' in the box marked 'NO'. Likewise, if she is 35, place a 'X' in the box marked 'YES' but if she has had her 36th birthday, place an 'X' in the box marked 'NO'.

3. Height (cm)

Take the woman's height using an adult stadiometer or similar equipment available in your clinic. Write the woman's height in centimetres (cm) to 1 decimal place. Example: a height of 152.9cm should be written as 152.9cm and not rounded up to 153cm.

4. Is she more than 153cm?

Place an 'X' in the box marked 'YES' if the height in centimetres is MORE THAN 153cm.

Place a 'X' in the box marked 'NO' if it is LESS THAN OR EQUAL TO 153cm.

Example: if she is 153cm, place a 'X' in the box marked 'NO'; if she is 153.1cm or more, place a 'X' in the box marked 'YES'.

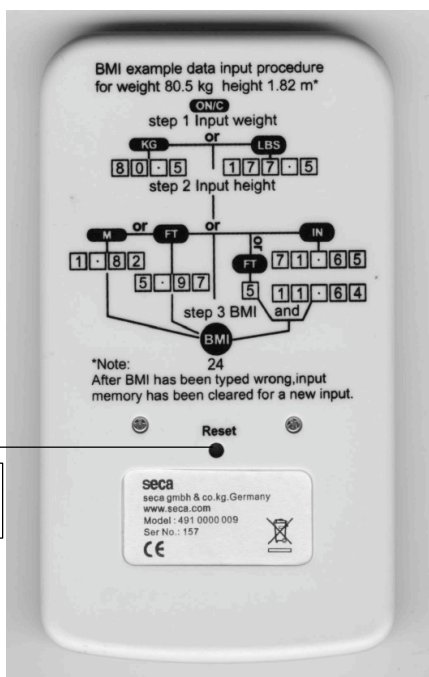
5. Weight (kg)

Take the woman's weight using a reliable weighing scale (that measures in kg) in your clinic. Write the woman's weight in kilograms (kg) to 1 decimal place. Example: a weight of 60.4kg should be written as 60.4kg, not rounded down to 60kg or up to 60.5kg.

6. Calculate the woman's Body Mass Index (BMI) using the calculator provided.

BMI should be calculated using the BMI calculator. Instructions can be found on the back of the calculator. Pull the plastic tab from the bottom of the calculator before first use.

If the BMI calculator stops working, the reset button can be found on the back (see below). Press the button for one second using the tip of a pen or pencil.



Important: please note that height is to be entered into the calculator in METRES (M) not centimeters, for example if she is 163 cm tall, her height in metres is 1.63.

The formulae for BMI is kg/m^2 .

Example: For a woman who weighs 60kg and is 163cm tall:

1. Press (ON/C)
2. Press the button (KG) then enter 60
3. Press the button (M) then enter 1.63
4. Press the green BMI button for the result (which should be 22.58)

Write the BMI value to 1 decimal place: a BMI of 22.58kg/m^2 should be written as 22.6kg/m^2 , not rounded down to 22.5kg/m^2 or up to 23.0kg/m^2 .

7. Is her BMI between 18.5 and 29.9kg/m²?

Place a 'X' in the box marked 'YES' if the BMI is AT LEAST 18.5 AND LESS THAN 30.

Place a 'X' in the box marked '**NO**' if it is LESS THAN 18.5 OR AT LEAST 30.

Example: If the BMI is 18.4, place a 'X' in the box marked 'No'; if it is 18.5, place a 'X' in the box marked 'Yes'. Likewise if it is 30, place a 'X' in the box marked 'No' but if it is 29.9, place a 'X' in the box marked 'Yes'.

8. Have you smoked or chewed tobacco in the last 3 months?

Place a 'X' in the box marked '**YES**' if:

- The woman reports smoking cigarettes/cigars/shisha or chewing tobacco any time in the last 3 months.
- The woman cannot remember if she has smoked in the last 3 months

Place a 'X' in the box marked '**NO**' if:

- The woman HAS NOT smoked/chewed tobacco in the last 3 months.

9. Have you used any recreational drugs in the last 3 months?

Recreational drugs include heroin, methadone, cocaine, amphetamines, hallucinogens, and cannabis.

Place a 'X' in the box marked '**YES**' if:

- The woman has used ANY of the recreational drugs listed in the last 3 months
- The woman cannot remember if she has used recreational drugs in the last 3 months

Place a 'X' in the box marked '**NO**' if:

- The woman HAS NOT taken any recreational drugs in the last 3 months in the last 3 months.

10. Have you had 5 or more units of alcohol per week since discovering you were pregnant?

One unit of alcohol is equivalent to a small glass (125ml) of wine, a bottle/can (330ml) of beer or a 25ml measure of whisky, gin, vodka, rum, pisco, tequila, schnapps, ouzo, baijiu or similar.

Place a 'X' in the box marked '**YES**' if:

- The woman's alcohol intake has been 5 or more units per week (on average) since discovering she was pregnant.

Place a 'X' in the box marked '**NO**' if:

- The woman has had less than 5 units of alcohol per week since discovering she was pregnant.

If she is unsure whether she has had 5 or more units per week since discovering she was pregnant, explain to her the unit measurement and show her the relevant page on the flip-chart. If she thinks she may have had 5 or more units since discovering she was pregnant, place a 'X' in the box marked '**YES**'

11. Are you involved in any high-risk occupation and/or vigorous or contact sports?

Here is a list of possible high-risk occupations and activities:

Please show the woman the relevant page on the flip-chart.

Frequent exposure to the following chemicals or toxic substances:	Physically demanding work:	High-risk sports/vigorous exercise:
Pesticides Lead or Mercury Solvents Petrochemicals Anaesthetic gases Tetrachloroethylene	More than 7 hours standing per day More than 50 hours work per week Work involving heavy lifting or very awkward postures	Sports that involve a high risk of abdominal trauma, falls or excessive joint stress (e.g. martial arts, rugby, long-distance running or cycling, weight-lifting) Women planning to do 1 hour of vigorous exercise more than 4 times per week into the 2 nd half of pregnancy

Place a 'X' in the box marked 'YES' if:

- The woman is involved in one or more of the high-risk activities listed above
- The woman is unsure but thinks she may have been involved in one or more of the high-risk activities listed above.

Place a 'X' in the box marked 'NO' if she DOES NOT take part in ANY high-risk activity.

12. Do you follow any special diets, e.g. vegetarian with no animal products at all (vegan), weight-loss reduction program, gluten-free diet?

Please show the woman the relevant page from the flip-chart.

Vegetarian with 'no animal products' (i.e. vegan) is defined as a diet that does not include any animal products. That means none of the following foods: meat, fish, milk, cheese, yoghurt, eggs, gelatine.

Simple vegetarianism (no meat or fish) does not constitute a special diet.

A gluten-free diet is defined as no wheat, oats, barley or rye products (bread, pasta, breakfast cereals etc.)

Place a 'X' in the box marked 'YES' if the woman follows a special diet.

Place a 'X' in the box marked 'NO' if the woman does not follow a special diet.

13. Socioeconomic Status (country-specific) Please ask and complete this question as stated in the forms for your centre.

Place a 'X' in the box marked 'YES' if the woman is above the socioeconomic cut-off.

Place a 'X' in the box marked 'NO' if the woman is below the socioeconomic cut-off.

If she cannot answer the question, place a 'X' in the box marked 'NO'.

Section 2: Medical History

Section 2: Medical History			
Have you ever been diagnosed with or treated for any of the following medical conditions?			
14. Diabetes	<input type="checkbox"/> yes	<input type="checkbox"/> no	
15. Thyroid disease	<input type="checkbox"/> yes	<input type="checkbox"/> no	
16. Other endocrinological conditions	<input type="checkbox"/> yes	<input type="checkbox"/> no	
17. Cardiac disease	<input type="checkbox"/> yes	<input type="checkbox"/> no	
18. Hypertension/chronic hypertension with treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no	
19. Chronic respiratory diseases (including chronic asthma)	<input type="checkbox"/> yes	<input type="checkbox"/> no	
20. Proteinuria or kidney disease or chronic renal disease	<input type="checkbox"/> yes	<input type="checkbox"/> no	
21. Any type of malignancy/cancer	<input type="checkbox"/> yes	<input type="checkbox"/> no	
22. Lupus erythematosus	<input type="checkbox"/> yes	<input type="checkbox"/> no	
23. Any blood clotting disorder including sickle-cell anaemia	<input type="checkbox"/> yes	<input type="checkbox"/> no	
24. Any haematological conditions e.g. Leukaemia	<input type="checkbox"/> yes	<input type="checkbox"/> no	
25. Epilepsy	<input type="checkbox"/> yes	<input type="checkbox"/> no	
26. HIV or AIDS	<input type="checkbox"/> yes	<input type="checkbox"/> no	
27. Malaria	<input type="checkbox"/> yes	<input type="checkbox"/> no	
28. Tuberculosis	<input type="checkbox"/> yes	<input type="checkbox"/> no	
29. Any congenital abnormality or genetic disease	<input type="checkbox"/> yes	<input type="checkbox"/> no	
30. Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition	<input type="checkbox"/> yes	<input type="checkbox"/> no	
31. Any other clinically relevant condition	<input type="checkbox"/> yes	<input type="checkbox"/> no	

Have you ever been diagnosed with or treated for any of the following medical conditions?:

For each condition:

Place a 'X' in the box marked '**NO**' if the woman has NEVER been diagnosed with or taken any medication for the condition.

Place a 'X' in the box marked '**YES**' if the woman has EVER been diagnosed with or taken any medication for the condition.

If she is uncertain whether she has one or more of the conditions listed, please check in her medical records. If there is no mention of the condition, and she does not have any symptoms, assume that she does not have it and place a 'X' in the box marked '**NO**'.

14. **Diabetes** (any type)

15. **Thyroid Disease** (any type)

16. **Other endocrinological/glandular conditions** (examples - Addison's disease, adrenal gland disorders, hypo- or hyper-thyroidism)

17. **Cardiac disease** (examples - arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, pericarditis, cardiomyopathy etc.) Do not exclude women who experience heart palpitations as these are common in women of childbearing age.

18. **Hypertension/chronic hypertension with treatment** (defined as 140/90 or greater. Include in this category any woman who have ever been treated for hypertension.)

19. **Chronic respiratory diseases (including chronic asthma during adult life)**. Do not exclude women who had childhood asthma that is no longer present or very mild cases/allergies. Only exclude women who take treatment (Salbutamol inhaler or similar) regularly.

20. **Proteinuria or kidney disease or chronic renal disease** (Proteinuria is defined as the presence of excessive protein substance, chiefly albumin, in the urine)
21. **Any type of malignancy/cancer**
22. **Lupus Erythematosus** (a chronic inflammatory collagen disease affecting connective tissue).
23. **Any blood clotting disorder including sickle cell anaemia** (if a woman knows that she is a heterozygous carrier of the sickle cell trait, do not exclude her.)
24. **Any haematological conditions** (example – leukaemia) Do not exclude women with a history of mild anaemia. There are further questions on anaemia later in the form (49 and 55).
25. **Epilepsy** (any type)
26. **HIV or AIDS**
27. **Malaria** (any episode)
28. **Tuberculosis**
29. **Any congenital abnormality or genetic disease** (examples – cystic fibrosis, congenital heart defects. Do not exclude women with very mild abnormalities such as extra digits, skin tags, hare lips, colobomas).
30. **Crohn's disease, Coeliac disease or ulcerative colitis or any severe malabsorption condition** requiring special diet. Women with moderate lactose intolerance are eligible.
31. **Any other clinically relevant condition** (any other significant medical or surgical problem judged by the attending staff as a serious condition requiring special care, that does not fall into one of the categories above.)

Section 3: Gynaecological History

Section 3: Gynaecological History	
32. Have you had regular (24-32 day) menstrual cycles in the 3 months prior to your current pregnancy?	<input type="checkbox"/> yes <input type="checkbox"/> no
33. Have you used hormonal contraceptives or been breastfeeding in the 2 months prior to your current pregnancy?	<input type="checkbox"/> yes <input type="checkbox"/> no
34. Was this pregnancy conceived with fertility treatment?	<input type="checkbox"/> yes <input type="checkbox"/> no
35. First day of the last menstrual period (LMP)	Date <input type="text" value="D"/> <input type="text" value="D"/> – <input type="text" value="M"/> <input type="text" value="M"/> – <input type="text" value="Y"/> <input type="text" value="Y"/>
36. Are you certain of the date of your LMP?	<input type="checkbox"/> yes <input type="checkbox"/> no
37. Gestational age estimated by LMP (Calculate using the wheel provided)	<input type="text" value=""/> <input type="text" value=""/> Weeks <input type="text" value=""/> Days
38. Is the estimated gestational age, from question 37 less than 14 weeks?	<input type="checkbox"/> yes <input type="checkbox"/> no

32. **Have you had regular (24-32 day) menstrual cycles in the 3 months prior to your current pregnancy?**

Regular menstrual cycles are defined as 24-32 days between the first day of bleeding during one menstrual period and the first day of bleeding during the next menstrual period.

Place a 'X' in the box marked 'YES' if she HAS had regular cycles in the 3 months before becoming pregnant.

Place a 'X' in the box marked 'NO' if she HAS NOT had regular cycles in the 3 months before becoming pregnant, or is unsure of her cycle regularity.

33. Have you used hormonal contraceptives or been breastfeeding in the 2 months prior to your current pregnancy?

Place a 'X' in the box marked 'YES' if she HAS used hormonal contraception or breastfed in the 2 months before becoming pregnant.

Place a 'X' in the box marked 'NO' if she HAS NOT used hormonal contraceptives and HAS NOT breastfed in the 2 months before becoming pregnant.

If she is unsure, place a 'X' in the box marked 'YES'.

34. Was this pregnancy conceived with fertility treatment?

Place a 'X' in the box marked 'YES' if the woman conceived using ANY FORM of fertility treatment including ovulation stimulation injections or similar.

Place a 'X' in the box marked 'NO' if she did not use any form of fertility treatment, ovulation stimulation injections or similar.

If she is unsure, place a 'X' in the box marked 'YES'.

35. First day of the last menstrual period (LMP)

Use a laminated calendar as a memory aid to help the woman remember the day on which her LMP started (the first day of bleeding). If she cannot remember at first, tell her to take her time and to try to remember as accurately as possible.

Write the date in the format dd-mm-yy, e.g. 20th May 2010 = 20-05-10.

36. Are you certain of the date of your LMP?

Place a 'X' in the box marked 'YES' if the woman is CERTAIN of the day of her last menstrual period.

Place a 'X' in the box marked 'NO' if she is NOT CERTAIN or expresses any doubt over this date.

37. Gestational age estimated by LMP (calculated using the Obdisc gestational age wheel provided)

Using the wheel provided, calculate the gestational age of the baby using the first day of the last menstrual period as a starting point. See next page for instructions.

Enter the gestational age in weeks and days (0 to 6 days)

38. Is the gestational age estimated from question 37 less than 14 weeks?

Place a 'X' in the box marked 'YES' if the gestational age is LESS THAN 14 weeks.

Place a 'X' in the box marked 'NO' if it is MORE THAN OR EQUAL TO 14 weeks.

Example: if the gestational age (by LMP) is 13 weeks and 6 days (97 days), Place a 'X' in the box marked 'Yes'; if it is 14 weeks (98 days) weeks, Place a 'X' in the box marked 'No'.

Instructions for use of Obdisk

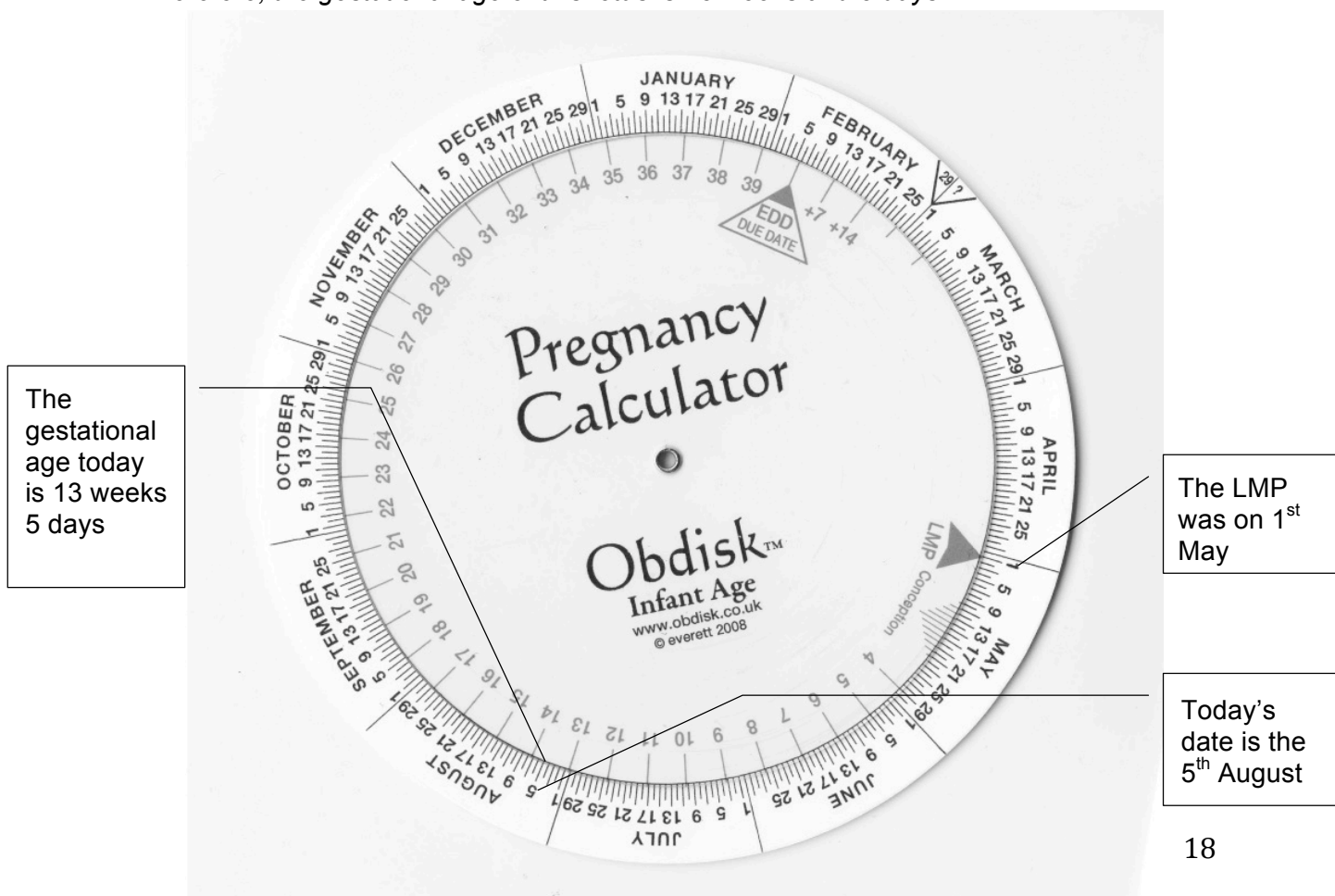
Turn the Obdisk to the side that reads 'Pregnancy Calculator'.

The Pregnancy Calculator consists of 2 circular wheels. The bottom wheel is stationary and is the calendar wheel. The top wheel rotates and is the pregnancy calculator.

To calculate the fetal gestational age from the last menstrual period (LMP):

1. Determine the date of LMP. This date should already be recorded in question 35 of the screening form.
2. Turn the rotating disk so that the bold pink arrow labeled 'LMP' points to the date of the LMP (month and day) on the stationary circular calendar.
3. Follow the wheel round clockwise with your eyes to locate today's date on the stationary circular calendar
4. Find the last completed week on the rotating disk (in pink) and then count the number of small increments (days) up until today's date on the stationary disk. This gives you the gestational age in weeks and days
5. Always line up the weeks and days carefully as you follow the calendar around – you may need to adjust the discs a little, to match the days exactly.

In the example below, the woman's LMP was on the 1st May and today's date is the 5th August. The pink arrow is turned to point exactly at 1st May. Follow the wheel round until you reach the 5th August and look for the last completed week (in pink). In this case the last completed week is 13. Then count the number of day increments since week 13 until you reach today's date (5th August). In this case the number of smaller increments is 5. Therefore, the gestational age of this fetus is 13 weeks and 5 days.



Section 4: Obstetric History

Section 4: Obstetric History			
39. Number of previous pregnancies, excluding current pregnancy (if 0, go to section 5)		<input type="text"/>	<input type="text"/>
40. Have your last two pregnancies ended in miscarriage?	<input type="checkbox"/>	yes	<input type="checkbox"/>
41. How many previous births have you had? (if 0, go to Section 5)		<input type="text"/>	<input type="text"/>
42. Have ANY of your babies weighed less than 2.5kg or more than 4.5kg?	<input type="checkbox"/>	yes	<input type="checkbox"/>
43. Have ANY of your babies been born preterm (<37 weeks gestation)?	<input type="checkbox"/>	yes	<input type="checkbox"/>
44. Have you had ANY stillbirths or neonatal deaths?	<input type="checkbox"/>	yes	<input type="checkbox"/>
During any previous pregnancy, have you been diagnosed with or treated for any of the following conditions?			
45. Pre-eclampsia/eclampsia/HELLP syndrome/placental abruption	<input type="checkbox"/>	yes	<input type="checkbox"/>
46. Gestational diabetes	<input type="checkbox"/>	yes	<input type="checkbox"/>
47. Rhesus disease	<input type="checkbox"/>	yes	<input type="checkbox"/>
48. Pyelonephritis or renal condition requiring bed rest >1 week or hospitalisation	<input type="checkbox"/>	yes	<input type="checkbox"/>
49. Severe anaemia that required hospitalisation	<input type="checkbox"/>	yes	<input type="checkbox"/>
50. Any other pregnancy-related condition requiring bed rest >1 week or hospitalisation (excluding delivery)	<input type="checkbox"/>	yes	<input type="checkbox"/>

39. Number of previous pregnancies, excluding current pregnancy. (If 0, go to section 5)

Enter the number of previous pregnancies in the box. If this is her first pregnancy, enter 00 and go to section 5: Current Pregnancy. If she has had one previous pregnancy, enter 01.

Include all known pregnancies, including those that were non-viable, ended in miscarriage or termination.

Example: if a woman has had one previous miscarriage, one previous abortion and one term pregnancy, enter a value of 03 in the corresponding box.

40. Have your last two pregnancies ended in miscarriage?

Place a 'X' in the box marked 'NO' if:

- she has not had a miscarriage
- she has only had ONE miscarriage in her last two pregnancies
- she has had previous miscarriages, BUT not in the last two consecutive pregnancies
- she is uncertain

Place a 'X' in the box marked 'YES' if the woman's last two consecutive pregnancies have resulted in miscarriage.

41. How many previous births have you had? (If 0, go to section 5)

A birth is defined as a delivery after 24 weeks of gestation, regardless of outcome. Thus, include any still-born infants in the value.

Write the appropriate number in the corresponding box. For 0, enter 00; for 1, enter 01, etc.

If the woman has had no previous births, do not complete questions 42, 43 and 44. Go straight to question 45.

42. Have ANY of your babies weighed less than 2.5kg or more than 4.5kg?

2.5kg is approximately the equivalent of 5.5lb and 4.5kg is approximately equivalent to 10lb.

If the woman does not remember the birth weights of her last baby, check her medical records or those of her children.

Place a 'X' in the box marked '**YES**' if she HAS had a low birth weight (<2500g) or high birth weight (>4500g) baby.

Place a 'X' in the box marked '**NO**' if she has NEVER had a low birth weight (<2500g) or high birth weight (>4500g) baby.

If she is unsure, check the medical records. If the birth weights are not available on the medical records, place a 'X' in the box marked '**NO**'

43. Have ANY of your babies been born preterm (<37⁺⁰ weeks of gestation)?

<37 weeks gestation equates to at least 259 days since the first day of the LMP.

Place a 'X' in the box marked '**YES**' if she HAS had a preterm baby.

Place a 'X' in the box marked '**NO**' if she has NEVER had a preterm baby.

If she is unsure, check the medical records. If the birth weights are not available on the medical records, place a 'X' in the box marked '**NO**'

44. Have you had ANY previous stillbirths or neonatal deaths?

A stillbirth is defined as giving birth to a baby born dead after 24 weeks of gestation.

A neonatal death is defined as a death within 28 days of a live birth.

Place a 'X' in the box marked '**YES**' if any of the woman's previous pregnancies have resulted in stillbirth or neonatal death.

Place a 'X' in the box marked '**NO**' if she has had NO previous pregnancies resulting in stillbirth or neonatal death.

Have you been affected by any of the following conditions during any previous pregnancy?:

In each box:

Place a 'X' in the box marked '**YES**' if the woman has EVER been diagnosed with or taken any medication for each condition listed above in any previous pregnancy.

Place a 'X' in the box marked '**NO**' if the woman has NEVER been diagnosed with or taken any medication for each condition listed above in any previous pregnancy.

If she is uncertain whether she has one or more of the conditions listed, please check in her medical records. If there is no mention of the condition, assume that she does not have it and place a 'X' in the box marked '**NO**'.

45. Pre-eclampsia / eclampsia / HELLP syndrome / abruptio placentae

Preeclampsia is defined as high blood pressure 140/90 or greater, or an increase of 30mmHg systolic or 15 mmHg diastolic over baseline values on at least two occasions six or more hours apart, that develops after 20 weeks gestation in a previously

normotensive pregnancy, or proteinuria (presence of excessive protein substance, chiefly albumin, in the urine).

Eclampsia is defined as the occurrence of convulsions and/or coma unrelated to her cerebral conditions in a woman with signs and symptoms of pre-eclampsia. Seizures are of grand mal type and may first appear before labour, during labour or up to 48 hours postpartum.

HELLP syndrome is a group of symptoms that occur in pregnant women who have pre-eclampsia or eclampsia and who also show signs of liver damage and abnormalities in blood clotting. It is characterised by: **H**aemolysis, **EL** (elevated) liver enzymes and **LP** (low platelet) count.

Abruptio placentae (i.e. placental abruption) refers to separation of the normally located placenta after the 20th week of gestation and prior to birth.

46. **Gestational diabetes** (defined as any degree of glucose intolerance with onset or first recognition during pregnancy).
47. **Rhesus disease** also known as isoimmunisation or RH- can occur when the mother is Rh negative and the baby is Rh positive.
48. **Pyelonephritis / renal condition that required bed rest >1 week or hospitalization.** Pyelonephritis is an inflammation of the kidney and upper urinary tract that usually results from non-contagious bacterial infection of the bladder (cystitis) or other urinary infections.
49. **Severe anaemia that required hospitalization.** Severe anaemia is clinically defined as <7 g/dl during pregnancy.
50. **Any other pregnancy-related condition requiring hospitalization or bed rest >1 week (excluding delivery)**

Do not include miscarriage as this is covered in question 40.

Place a 'X' in the box marked '**YES**' if the woman was admitted to hospital for a serious pregnancy-related condition during a previous pregnancy.

Place a 'X' in the box marked '**NO**' if the woman has NOT been admitted to hospital for a serious pregnancy-related condition during a previous pregnancy.

Section 5: Current Pregnancy

Section 5: Current Pregnancy	
During this pregnancy, have you been diagnosed with or treated for any of the following conditions?	
51. Threatened miscarriage	<input type="checkbox"/> yes <input type="checkbox"/> no
52. Mental illness e.g. depression	<input type="checkbox"/> yes <input type="checkbox"/> no
53. Severe vomiting requiring hospitalisation	<input type="checkbox"/> yes <input type="checkbox"/> no
54. Any sexually transmitted infections e.g. Syphilis, Gonorrhoea, Trichomoniasis, Genital warts, Condyloma acuminata	<input type="checkbox"/> yes <input type="checkbox"/> no
55. Anaemia	<input type="checkbox"/> yes <input type="checkbox"/> no
56. Rhesus disease	<input type="checkbox"/> yes <input type="checkbox"/> no
57. High blood pressure	<input type="checkbox"/> yes <input type="checkbox"/> no

During this pregnancy, have you had any signs of, or treatment for, any of the following medical conditions?:

Place a 'X' in the box marked '**YES**' if there are ANY signs or symptoms of the condition.

Place a 'X' in the box marked '**NO**' if there are NO signs of any of the condition.

If she is uncertain whether she has one or more of the conditions listed, please check in her medical records. If there is no mention of the condition, and she does not have any symptoms, assume that she does not have it and place a 'X' in the box marked '**NO**'.

51. **Threatened miscarriage.** Do not include mild spotting or brown loss in this category, as this is a common occurrence around the time of the first missed periods. Only exclude women who have required hospitalization or bed rest more than 1 week during this pregnancy.

52. **Mental illness e.g. depression** (excluding mild depression without treatment) Include all forms of mental illness requiring current treatment. Examples: depression, schizophrenia, bipolar disorder, OCD, generalized anxiety disorder.

53. **Severe vomiting requiring hospitalization**

54. **Evidence of any sexually transmitted infections (STIs) including clinically evidence trichomoniasis.** (Examples: gonorrhoea, Chlamydia)

55. **Anaemia** (A result of HB <11g/dl which has been taken during the current pregnancy. If the woman has not yet had any blood tests during this pregnancy, and has no symptoms of anaemia, please tick '**NO**')

56. **Rhesus disease** can occur when the mother is Rh negative and the baby is Rh positive.

57. **High blood pressure** (systolic blood pressure >140 and/or diastolic blood pressure >90)

Section 6: Consent

Section 6: Consent	
58. Are you planning to deliver at a hospital participating in the study? (Show list)	<input type="checkbox"/> yes <input type="checkbox"/> no
59. Are you willing to give informed consent to participate in the study?	<input type="checkbox"/> yes <input type="checkbox"/> no

58. Are you planning to deliver at a hospital participating in the study? See the list of participating institutions in your area.

Place a 'X' in the box marked '**YES**' if she is planning to deliver in a hospital/institution that IS participating in the INTERGROWTH-21st study.

Place a 'X' in the box marked '**NO**' if she is planning to deliver in a hospital or institution that is NOT participating in the INTERGROWTH-21st study.

59. Are you willing to give informed consent to participate in the study?

If '**YES**' continue to question 59.

If '**NO**' the woman cannot take part in the study. She should continue with her routine antenatal care.

60. Is the woman eligible for the study? (She is eligible if all the shaded boxes(<input type="checkbox"/>) in this screening form have been marked with an 'X')	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, please now arrange an ultrasound dating appointment, for within the next 3 days and enter details below	

60. Is the woman eligible for the study?

Place a 'X' in the box marked '**YES**' if **ALL** of the shaded boxes above have been marked with a 'X'.

Place a 'X' in the box marked '**NO**' if **ANY** of the shaded boxes above have not been marked with a 'X'.

If she is not eligible, she should continue with routine antenatal care.

If the woman is eligible for the study, please book her an ultrasound dating scan at the study ultrasound centre, for within 3 days of the date of the initial screening.

61. Is the ultrasound dating appointment confirmed?	<input type="checkbox"/> yes <input type="checkbox"/> no
62. Date of the ultrasound dating appointment	Date <input type="text" value="D"/> <input type="text" value="D"/> — <input type="text" value="M"/> <input type="text" value="M"/> — <input type="text" value="Y"/> <input type="text" value="Y"/>

61. Is the ultrasound dating appointment confirmed?

Place a 'X' in the box marked '**YES**' if the appointment is confirmed. Please write the date of her appointment.

Place a 'X' in the box marked '**NO**' if the appointment is not confirmed. Please book the appointment as soon as possible and confirm the date with the woman.

62. Date of the ultrasound dating appointment

Write down the date of the scheduled appointment in the format dd-mm-yy, Example: 20th May 2010 = 20-05-10. Ensure that the **Ultrasound Dating Form** is completed immediately after the Ultrasound Dating appointment or within that week.

Screening: Ultrasound Dating Form (USD)

Important: Complete the answer to ALL questions.

All women found to be eligible after completing the **Screening: Interview** form should have an ultrasound dating appointment within 3 days. *All scanning must be done by a trained INTERGROWTH ultrasonographer, using the Philips HD9 ultrasound machine provided by the study, unless an alternative has been agreed with the coordinating unit. The ultrasonographer should follow the instructions given in the INTERGROWTH Ultrasound Handbook and follow the advice given during training.*

Important: Please copy across the woman's **patient screening number** and the study antenatal clinic code from the header of her *Screening: Interview* form to the header of this form.

The information required to complete this form should be obtained during the Ultrasound Dating Scan. The form should be completed either by the ultrasonographer or his/her assistant.

If the woman IS found to be eligible after the dating scan:

1. Provide her with a patient information leaflet, make sure she understands what the study involves, and ask her to fill in and sign the **Informed Consent** form
2. Begin a **Study Forms Booklet** for her. Complete the front cover and the **Maternal Study Entry** form. See p.22-27. *Important: you will need the Patient Screening Number and the date of LMP (which can found on the Screening forms) to complete the Maternal Study Entry form.*
3. Give her an **Appointment Card**, with the dates of her follow-up appointments and the contact details of the ultrasound clinic filled in.
4. Once all forms are completed (**Screening: Interview, Screening: Ultrasound Dating; Informed Consent and Maternal Study Entry form**) please review them for inconsistencies and missing data.
5. Now pass them to the Local Research Coordinator, who will take it to the Data Entry and Quality Control Unit.

If the woman IS NOT eligible after the dating scan:

1. She should be informed that she is not a candidate for the study and that she will proceed with her routine antenatal care
2. Pass the Screening: Interview and Screening: Ultrasound Dating forms to the local research coordinator, who should take them to the Data Entry and Quality Control Unit

Form Header

Country Code	<input type="text" value="0"/> <input type="text" value="1"/>	
Study Antenatal Clinic Code	<input type="text"/> <input type="text"/>	Date of Ultrasound <input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
Patient Screening Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Country Code: This code corresponds to your country and will be preprinted.

Antenatal Clinic Number: Please enter the number that corresponds to the antenatal clinic at which the woman was first interviewed. Please ensure that you enter the correct number from the list as this is vital in enabling us to identify the woman.

Patient Screening Number: Please copy across the screening number from the woman's screening form. If this is not available, please ring the antenatal clinic from which the woman was referred or the local research coordinator.

Date of Ultrasound: Please enter the date that the ultrasound dating scan was conducted in the format dd-mm-yy. For example the 20th May 2010 should be written 20-05-10.

Section 1: Last Menstrual Period

Section 1: Last Menstrual Period (LMP)	
1. First day of the LMP (take from Question 35 on the Screening Form)	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
2. Estimated gestational age by LMP (using the wheel provided)	<input type="text"/> <input type="text"/> Weeks <input type="text"/> Days

1. Date of the first day of the Last Menstrual Period (LMP)

dd-mm-yy, e.g. 20th may 2010 = 20-05-2010

Obtain this information from question 35 of the Screening Form.

2. What is the estimated gestational age by LMP?

Use the wheel provided to calculate gestational age by LMP.

Write down the estimated gestational age by LMP in completed weeks and days

DO NOT modify the gestational age based on any clinical or ultrasound information at this visit.

Example: if it is 76 days since the first day of the LMP, write 10 weeks and 6 days.

Section 2: Pregnancy Observations

Section 2: Ultrasound Observations	
3. Is this an intrauterine pregnancy?	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
4. Is fetal heart activity visible?	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
5. Is more than one fetus visible?	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
6. Are there any signs of congenital abnormality?	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no

3. Is this an intrauterine pregnancy?

Place a 'X' in the box marked '**YES**' if the dating scan reveals that the pregnancy is intrauterine.

Place a 'X' in the box marked '**NO**' if the dating scan reveals that the pregnancy is ectopic.

4. Is fetal heart activity visible?

Place a 'X' in the box marked '**YES**' if fetal heart activity is visible.

Place a 'X' in the box marked '**NO**' if fetal heart activity is NOT visible.

5. Is more than one fetus visible?

Place a 'X' in the box marked '**YES**' if the dating scan reveals MORE THAN one fetus.

Place a 'X' in the box marked '**NO**' if the dating scan reveals only ONE fetus.

6. Are there any signs of congenital abnormality?

Place a 'X' in the box marked '**NO**' if there is NO evidence of congenital abnormality.

Place a 'X' in the box marked '**YES**' if there is ANY evidence of congenital abnormality.

Please refer to your local protocol for early congenital abnormality detection.

Section 3: Crown Rump Length (CRL) Measurement

Section 3: Crown Rump Length (CRL) measurements	
7. What is the CRL measurement?	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mm
8. Estimated gestational age by CRL	<input type="text"/> <input type="text"/> Weeks <input type="text"/> Days
9. What is the discrepancy (in days) between the gestational age by LMP(question 2) and by CRL (question 8)?	<input type="text"/> <input type="text"/> Days
10. Is the discrepancy less than 8 days?	<input type="checkbox"/> yes <input type="checkbox"/> no

7. What is the CRL measurement? (mm)

In the corresponding box, write the value obtained for the crown rump length (in millimetres).

Write the value to one decimal place. Example: if the CRL is 60.8 mm, write 60.8mm in the box – do not round up to 61mm.

8. Estimated gestational age by CRL?

Write down the estimated gestational age by CRL in completed weeks and days. This information is obtained from the ultrasound machine.

Example: if the estimated the estimates age by CRL is 80 days, write 11 weeks and 3 days.

9. What is the discrepancy (in days) between the estimated gestational age by LMP (question 2) and by CRL (question 8)?

Calculate the discrepancy by subtracting the smaller value from the larger value and write this value in the corresponding box.

Example: if the answer to question 2 (estimated gestational age by LMP) is 10 weeks and 6 days and the answer to question 8 (gestational age by CRL) is 11 weeks and 3 days, the discrepancy is 4 days.

10. Is this discrepancy less than 8 days?

Place a 'X' in the box marked 'YES' if the discrepancy between estimated gestational age by LMP and by CRL is 7 DAYS OR LESS.

Place a 'X' in the box marked 'NO' if the discrepancy is 8 DAYS OR MORE

Example: if the discrepancy between estimates is 8 days, Place a 'X' in the box marked 'NO'; if the discrepancy is 7 days, Place a 'X' in the box marked 'YES.'

Section 4: Eligibility

Section 4: Eligibility	
11. Are all the shaded boxes (<input type="checkbox"/>) on this page marked with an X?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, the woman is eligible for the study. Please ask her to read and sign the Informed Consent Form and complete the Maternal Study Entry Form	

11. Are all the shaded boxes on this page marked with an X?

The shaded boxes correspond to questions 3, 4, 5, 6 and 10.

Place a 'X' in the box marked '**YES**' if **ALL** the shaded boxes have been marked with a 'X'. Inform the woman she is eligible for the study, and follow steps 1-5 on page 17.

Place a 'X' in the box marked '**NO**' if **ANY** of the non-shaded boxes have been marked with a 'X'. Inform the woman she is not a candidate for the study. She will continue with her routine antenatal care.

Please sign the bottom of every form and enter your Researcher Code.

Maternal Study Entry Form (MSE)

The form can be found at the front of the **Study Form Booklet** (one booklet per woman, preprinted with her unique Study Subject Number)

Check that the woman has read the patient information leaflet and signed the **Informed Consent** form.

The front page of a new form booklet, together with this form, should be completed immediately for all women who are found to be eligible for the study after the ultrasound dating scan is complete (i.e. the answer to question 11 on the **Screening: Ultrasound Dating** form is 'YES'.) Therefore, the stock of booklets should be kept at the study ultrasound clinic, in a filing cabinet ready when a subject is found to be eligible.

The information required for this form can be obtained directly from the woman or from her medical records. Question 8 requires that you refer to the **Screening: Ultrasound Dating** form, so please have this to hand.

Weight will need to be taken using the Adult Scale (Seca 877 portable digital scale) and height using the Seca 242 Stadiometer. Remember to calibrate the machines regularly according to the instructions in the Anthropometry Manual.

The screening number should be transcribed from either the woman's screening form, or her ultrasound dating form. It is *vital* that the number is written as it provides the only link between the woman's screening information and her study data.

Before she leaves, please make sure that she has an **Appointment Card**, with the dates of her next follow-up appointment and the contact details of the Ultrasound Clinic filled in. You may wish to keep a log-book or database of participant's names, contact details and Study Subject Numbers in the centre.

Once completed, all forms should then be given to the Local Research Coordinator, who will review them for missing values or inconsistencies before passing them on to the Data Entry and Quality Control Unit.

Form Header

Study Subject Number	<input type="text" value="0"/> <input type="text" value="1"/> - <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="1"/>	Visit Date	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
Study Antenatal Clinic Code	<input type="text"/> <input type="text"/>	Date of Birth	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
Antenatal Record Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Screening Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

The unique **Study Subject Number** will be preprinted on each form within the woman's booklet.

Please enter the Study **Antenatal Clinic Code** that corresponds to the clinic where the woman receives her routine ANC care and was screened for the study. This should be copied from the screening form and should also be copied to the front cover of the booklet

Enter the woman's **Antenatal Record number** (if available). This number is given by her routine antenatal care clinic

Please enter the **Visit Date** and the woman's **Date of Birth** in the format dd-mm-yy, for example, the 20th May 2010 = 20-05-10.

Transfer the woman's **Screening Number** from the Screening Form. This is very important since this number can be used to link the woman's screening and study data.

Section 1: Demography

Section 1: Demography	
<p>1. Marital status (please cross one box only)</p> <p>Single <input type="checkbox"/> Widowed <input type="checkbox"/></p> <p>Married/Cohabiting <input type="checkbox"/> Separated/Divorced <input type="checkbox"/></p> <p>2. Total number of years of formal education <input type="text"/> <input type="text"/></p> <p>3. Highest level of education she attended? (please cross one box only)</p> <p>Primary <input type="checkbox"/> Professional/technical training <input type="checkbox"/></p> <p>Secondary <input type="checkbox"/> University <input type="checkbox"/></p>	<p>4. Which of the following best describes her occupational status? (please cross one box only)</p> <p>Housework <input type="checkbox"/> Skilled manual work <input type="checkbox"/></p> <p>Manager/professional/technical <input type="checkbox"/> Unskilled manual work <input type="checkbox"/></p> <p>Clerical support, service or sales <input type="checkbox"/> Other <input type="checkbox"/></p> <p>5. Age of the father <input type="text"/> <input type="text"/> yrs</p>

1. Marital status

Cross only the ONE box that best applies to the woman.

- ◆ Place an 'X' next to **Single** if the woman has NEVER been married and does NOT live with a partner,
- ◆ Place an 'X' next to **Married/cohabiting** if the woman is married or living with a partner
- ◆ Place an 'X' next to **Widow** if the woman's partner has died.
- ◆ Place an 'X' next to **Separated/divorced** if the woman HAS been married but is now separated or divorced and NOT living with another partner.

2. Total number of years formal education

In the corresponding box, please enter the total number of years that the woman attended formal education (including primary school, secondary school, post school (college and university level) and any other intermediate levels in the formal school system). This definition of school does not include Bible or Koranic school or short courses like typing or sewing. However, it does include technical or vocational training

beyond primary school level, such as long-term courses in mechanics or secretarial work. One year of part-time education = 0.5 years. Round up to the nearest whole year.

Example: If she attended primary school from age 5 to 11 (6 years) and then secondary school from age 11 to 16 (5 years) then her total number of years of formal education is 11.

3. What is the highest level of education she has achieved?

Cross the ONE box that best applies to the woman.

- ◆ Primary School (Age 5-11 or similar)
- ◆ Secondary School (Age 11-16 or 11-18 in some cases)
- ◆ Professional/technical training (Vocational training/qualification e.g. Teaching, Nursing Training)
- ◆ University (Undergraduate or postgraduate degree. E.g. Ba/BSc/Ma/MSc/MD/PhD)

4. Which of the following best describes your occupational status?

Cross the ONE box that best applies to the woman.

See the occupational classification scheme in Appendix 1 for clarification as to which occupations fall under each category.

5. Age of the father

Enter the age of the father (if known) in completed years, that is his age at his last birthday. If not known, leave this field blank.

Section 2: Obstetric History

Section 2: Obstetric history	
6. Number of pregnancies (excluding current pregnancy) <input style="width: 40px;" type="text"/>	9. What is the average length of her menstrual cycle? <input style="width: 40px;" type="text"/> days
7. Number of births <input style="width: 40px;" type="text"/>	10. First day of the last menstrual period (LMP) take from the ultrasound dating form question 1.
8. Birth weight of the last baby <input style="width: 60px;" type="text"/> gms	<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> — <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> — <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>

6. Number of pregnancies (excluding current pregnancy) If 0 skip to question 8.

Enter the number of previous pregnancies in the box. For 0, enter 00; for 1, enter 01, etc. Include all known pregnancies, including any that ended in miscarriage or abortion.

Example: if a woman has had one previous miscarriage and one term pregnancy, enter a value of 2 in the corresponding box.

7. Number of births. If 0, skip to question 8.

This question refers to the number of times a woman has given birth *after 24 weeks gestation*. Include all births, including those that may have resulted in childhood death. If a woman has had any multiple births, count each baby as 1.

Example: if a woman has had two previous deliveries, one which resulted in childhood death and which survived, her parity is 2 and thus enter a value of 2.

8. Birth weight of last baby

In the corresponding box, please enter the birth weight (in grams) of the woman's last baby, without any decimal places. If not known, consult the medical records. If still not available, please leave blank.

9. Cycle length

Enter the average length of the woman's menstrual cycles in days. Length is measured from the first day of bleeding during one cycle to the first day of bleeding during the next cycle.

Example, if she says has her period every 28-30 days, enter 29 in the box.

10. First day of the last menstrual period (LMP)

dd-mm-yy, for example, the 20th May 2010 = 20-05-10

Obtain this information from Question 1 of the Ultrasound Dating form.

Section 3: Current Pregnancy

Section 3: Current pregnancy			
11. Height	12. Weight (at this visit)	15. Proteinuria (by dipstick). Cross one box only	
<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg	0 <input type="checkbox"/>	+ <input type="checkbox"/>
	1st measurement	+++ <input type="checkbox"/>	++++ <input type="checkbox"/>
	2nd measurement	no urine test available <input type="checkbox"/>	
13. Has she had a positive syphilis test result?	yes <input type="checkbox"/> no <input type="checkbox"/>	and/or actual result (from urine sample) received from laboratory <input type="text"/> <input type="text"/> <input type="text"/> mg/dl	
14. Blood Pressure		16. Haemoglobin level <input type="text"/> <input type="text"/> . <input type="text"/> g/dl	
Systolic <input type="text"/> <input type="text"/> <input type="text"/> mmHg	Diastolic <input type="text"/> <input type="text"/> <input type="text"/> mmHg		

11. Height (cm)

Take the woman's height **once** using the Adult Stadiometer (Seca 242 Digital Display).

Please follow the instructions in the Anthropometry Handbook, and adhere to the advice given during training sessions.

Write the woman's height in centimetres (cm) to 1 decimal place.

Example: a height of 160.8cm should be written as 160.8cm and not rounded up to 161cm.

12. Weight (at this visit)

Take the woman's weight **TWICE** using the Adult Scale (Seca 877 Portable Digital Scale)

Please follow the instructions in the Anthropometry Handbook, and adhere to the advice given during training sessions.

Write the woman's weight in kilograms (kg) to 1 decimal place.

Example: a weight of 60.4kg should be written as 060.4kg, not rounded down to 60kg or up to 60.5kg.

13. Has she had a positive syphilis test?

Place an 'X' next to 'YES' if she has had a positive VDRL test.

Place an 'X' next to 'NO' if she has not had a positive VDRL test.

If the test has not been done, leave the field blank.

14. Blood Pressure

Take the blood pressure reading using the study Microlife Blood Pressure Monitor for use in Pregnant Women, following the manufacturers guidelines and the instructions in Appendix 2.

Enter the values for systolic and diastolic pressure (in mmHg) separately in the corresponding boxes.

15. Proteinuria

Obtain the results of the urinalysis from the lab report and enter the number that corresponds to the woman's proteinuria level in the corresponding box.

If proteinuria is reported from the dipstick, enter the number corresponding to the number of + in the box.

If proteinuria is reported in the lab results, enter the actual value (in g/l) in the corresponding box.

If the test has been done but the lab results are not yet available, please endeavor to get the results before sending this form for data entry.

If the test has not been done, leave the field blank.

16. Haemoglobin level

Obtain the results from the lab and in the corresponding box, enter the haemoglobin level in milligrams/decilitre.

If the test has been done but the lab results are not yet available, please endeavor to get the results before sending this form for data entry.

If the test has not been done, leave the field blank.

Section 4: Nutritional Supplements/Medications

Section 4: Nutritional supplements					
Does she routinely take any of the following nutritional supplements?					
17. Iron	<input type="checkbox"/> yes	<input type="checkbox"/> no	19. Calcium	<input type="checkbox"/> yes	<input type="checkbox"/> no
18. folic acid	<input type="checkbox"/> yes	<input type="checkbox"/> no	20. Food supplements	<input type="checkbox"/> yes	<input type="checkbox"/> no
				21. Multi-vitamin/mineral	<input type="checkbox"/> yes <input type="checkbox"/> no

Does she take any of the following nutritional supplements?

Please cross ALL boxes that apply.

17. Iron

18. Folic acid

19. **Calcium**

20. **Food supplements** e.g. high energy/calorie supplements for weigh gain during pregnancy

21. **Multivitamins/minerals**

Section 5: Next Appointment

Section 5: Next appointment		
Please now arrange the next ultrasound appointment for within 5 weeks (\pm 1 week) of today		
22. Date of the next ultrasound appointment	<input type="text" value="D"/> <input type="text" value="D"/>	<input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="Y"/> <input type="text" value="Y"/>

Please now arrange the next ultrasound appointment for within 5 weeks (+/- 1 week) of today.

Make the appointment for the woman's first follow-up ultrasound visit **This follow-up scan must be done using the study machine with an INTERGROWTH-21st study ultrasonographer.**

Ensure she has a written record of the date of her next visit in her appointment card.

22. Date of the next ultrasound appointment

dd-mm-yy, e.g. 20th may 2010 = 20-05-10

Ultrasound Follow-up Form (UFU)

This form should be completed by the study ultrasonographer or his/her assistant at every follow-up visit to the ultrasound clinic (6 times in total throughout pregnancy). The ultrasound visits are to be scheduled at ~5 weekly (\pm 1 week) intervals (i.e. at 14-18, 19-23, 24-28, 29-33, 34-38 and 39-42 weeks).

All the information required for this form should be collected during the scan. Please follow the instructions in the Ultrasound Handbook carefully and adhere to the guidance given during training.

The ultrasonographer should rate his/her own images using the Image Quality rating scale. The measurements will then be downloaded from the machine and uploaded onto the online database. Images will be downloaded from the machine and transferred to disk/usb. These images will then be sent by courier to the Ultrasound Quality Control Unit, Oxford, for analysis.

If the woman misses an appointment, please contact her as soon as possible to arrange another appointment *within the same week*. If this is not possible, please skip to the next scheduled follow-up visit.

If any of the following events have taken place since the woman's last visit, please do not complete this form and proceed straight to the Pregnancy and Delivery Form.

- Delivery of any kind (term or preterm)
- Miscarriage/Fetal Death/Induced Abortion
- Maternal Death

Form Header

Study Subject Number	<input type="text" value="0"/> <input type="text" value="1"/> - <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="1"/>	Date of ultrasound	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
Study Antenatal Clinic Code	<input type="text"/> <input type="text"/>	Date of Birth	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
Antenatal Record number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

The **Study Subject Number** will be preprinted on each form within the booklet.

Please enter the **Study Antenatal Clinic Code** that corresponds to the clinic where the woman receives her routine ANC care. This can be found on the booklet front cover.

Enter the woman's **Antenatal Record number** (if available). This can be found on the booklet front cover.

Please enter the **Date of ultrasound** and the woman's **Date of Birth** in the format dd-mm-yy, e.g. 20th May 2010 = 20-05-10.

Section 1: Ultrasound observations and measurements

Section 1: Ultrasound observations and measurements	
1. Number of fetuses <input type="text"/>	Were the following measurements obtained from three separately generated images ? Maximum Image quality rating 0-6 6. Biparietal diameter (BPD) <input type="text"/> yes <input type="text"/> no <input type="text"/> 7. Occipito-frontal diameter (OFD) <input type="text"/> yes <input type="text"/> no <input type="text"/> 8. Head circumference (HC) <input type="text"/> yes <input type="text"/> no <input type="text"/> 9. Transverse abdominal diameter (TAD) <input type="text"/> yes <input type="text"/> no <input type="text"/> 10. Anterior-posterior abdominal diameter (APAD) <input type="text"/> yes <input type="text"/> no <input type="text"/> 11. Abdominal circumference (AC) <input type="text"/> yes <input type="text"/> no <input type="text"/> 12. Femur length (FL) <input type="text"/> yes <input type="text"/> no <input type="text"/> 13. Was the Amniotic fluid Index (AFI) measurement obtained? <input type="text"/> yes <input type="text"/> no
2. Are there any fetal abnormalities? <input type="text"/> yes <input type="text"/> no	
If yes, please complete the fetal abnormality form	
3. Fetal presentation (please cross one box only)	
Cephalic <input type="text"/> Transverse <input type="text"/>	
Breech <input type="text"/> Oblique <input type="text"/>	
4. Amniotic fluid volume (please cross one box only)	
Normal <input type="text"/> Moderately reduced <input type="text"/>	
Moderately increased <input type="text"/> Oligohydramnios <input type="text"/>	
Polyhydramnios <input type="text"/> Anhydramnios <input type="text"/>	
5. Placental localisation (please cross one box only)	
Fundal <input type="text"/> Low anterior <input type="text"/>	
High anterior <input type="text"/> Low posterior <input type="text"/>	
High posterior <input type="text"/> Low right lateral <input type="text"/>	
High left lateral <input type="text"/> Low left lateral <input type="text"/>	
High right lateral <input type="text"/>	

Please refer to the **Ultrasound Handbook** for any clarification on measurement technique.

1. Number of fetuses

In the corresponding box, write the number of fetuses that are visible.

2. Are there any signs of fetal abnormality?

Tick 'NO' if there is NO evidence of fetal abnormality.

Tick 'YES' if there is ANY evidence of congenital abnormality and complete a 'Fetal Abnormality Form'.

3. Fetal Presentation

Place an 'X' in the box that best corresponds to the fetal presentation.

4. Amniotic Fluid Volume

Place an 'X' in the box that best corresponds to the amniotic fluid volume.

5. Placental Localisation

Please place an 'X' in the box that best corresponds to the localisation of the placenta.

Were the following measurements obtained from 3 separately generated images?

Important: for each measurement, place a X in 'YES' if the image was obtained 3 times from 3 separately generated images; place a X in 'NO' if the image was not obtained 3 times from 3 separately generated images.

6. Biparietal diameter (BPD)

7. Occipio-frontal diameter (OFD)

8. Head circumference (HC)

9. Transverse abdominal diameter (TAD)

10. Anterior-posterior abdominal diameter (APAD)

11. Abdominal circumference (AC)

12. Femur length (FL)

13. Was the amniotic fluid measurement obtained? The amniotic fluid index is the summation of the deepest vertical pool depth in each of the four quadrants surrounding the fetus.

Place an X in the box marked YES if the measurement was successfully obtained

Place an X in the box marked NO if the measurement was not successfully obtained

Important: for questions 6-12, write down the Maximum Image Quality score of the 3 images in the third column, using the criteria in the table below.

BPD/ OFD/ HC	AC/TAD/APAD	FL
Symmetrical plane	Circular plane	Both ends of the bone clearly visible
Plane showing thalami	Image shows the stomach bubble	<45° angle to the horizontal
Cavum septum pellucidum 1/3 along midline echo	Image shows umbilical vein along 1/3 of the abdomen	Femoral plane occupying at least 30% of the total image size
Cerebellum not visible	Kidneys not visible	Calipers placed correctly
Fetal head occupies at least 30% of the total image size	Abdomen occupies at least 30% of the total image size	
Calipers and dotted ellipse placed correctly	Calipers and dotted ellipse placed correctly	

Section 2: Symphysis Fundus Height

Section 2: Symphysis fundal height		
14. Symphysis Fundal Height		
1 st Measurement	<input type="text"/> <input type="text"/> . <input type="text"/> cm	2 nd Measurement <input type="text"/> <input type="text"/> . <input type="text"/> cm

14. Symphysis Fundal Height

Repeat the measurement two times following the Instruction in Appendix 3 'Measurement of Symphysis Fundal Height'

For each of the repeated measurement, write the value obtained for each measurement (in centimetres) in the corresponding boxes, to one decimal place.

Section 3: Next Appointment

Section 3: Next appointment		
If not already done, please now arrange the next ultrasound appointment for within 5 weeks (± 1 week) of today		
15. Date of the next ultrasound appointment	<input type="text"/> <input type="text"/> — <input type="text"/> <input type="text"/> — <input type="text"/> <input type="text"/>	

15. Date of next ultrasound appointment

dd-mm-yy for example, 20th may 2010 = 20-05-10.

Pregnancy Follow-up Form (PFU)

This form accompanies the Ultrasound Follow-up Form and should also be completed at every follow-up visit to the ultrasound clinic (6 times in total throughout pregnancy).

The visits are to be scheduled at ~5 weekly (\pm 1 week) intervals (i.e. at 14-18, 19-23, 24-28, 29-33, 34-38 and 39-42 weeks).

If the woman misses an appointment, please contact her as soon as possible to arrange another appointment *within the same week*. If this is not possible, please skip to the next scheduled follow-up visit.

The information needed to complete this form should be obtained directly from the woman and/or from her medical records.

Weight will need to be taken using the Adult Scale (Seca 877 portable digital scale) and height using the Seca 242 Stadiometer. Remember to calibrate the machines regularly according to the instructions in the Anthropometry Manual.

Blood pressure is to be taken using Microlife 'Blood Pressure Monitor for Pregnant Women' following the supplier's instructions and the instructions in Appendix 2 of this document.

If lab tests for proteinuria and haemoglobin have been conducted since the last visit and the results are available, please enter the results in the appropriate section.

At the end of each visit, please remember to schedule the next appointment for 5 weeks time (\pm 1 week).

If any of the following events have taken place since the woman's last visit, please do not complete this form and proceed straight to the Pregnancy and Delivery Form.

- Delivery of any kind (term or preterm)
- Miscarriage/Fetal Death/Induced Abortion
- Maternal Death

Form Header

Study Subject Number	<input type="text" value="0"/> <input type="text" value="1"/> - <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="1"/>	Visit Date	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
Study Antenatal Clinic Code	<input type="text"/> <input type="text"/>	Date of Birth	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
Antenatal Record number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

The **Study Subject Number** will be preprinted on each form within the booklet.

Please enter the **Antenatal Clinic Number** that corresponds to the clinic where the woman receives her routine ANC care. This can be found on the booklet front cover.

Enter the woman's **Antenatal Record number** (if available). This can be found on the booklet front cover.

Please enter the **Visit Date** and the woman's **Date of Birth** in the format dd-mm-yy, e.g. 20th May 2010 = 20-05-10.

Section 1: Pregnancy Status

Section 1: Pregnancy status	
<p>1. Weight (at this visit)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg</p> <p><input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg</p> <p>2. Father's Height (if it can be obtained at this visit)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm</p> <p>3. Proteinuria (by dipstick). Cross one box only</p> <p>0 <input type="checkbox"/> + <input type="checkbox"/> ++ <input type="checkbox"/></p> <p>++ <input type="checkbox"/> ++++ <input type="checkbox"/> no urine test available <input type="checkbox"/></p> <p>and/or actual result (from urine sample received from laboratory) <input type="text"/> <input type="text"/> <input type="text"/> mg/dl</p>	<p>4. Urine culture (please cross one box only)</p> <p>Positive <input type="checkbox"/></p> <p>Negative <input type="checkbox"/></p> <p>No urine culture available <input type="checkbox"/></p> <p>5. If positive, was antibiotic treatment given? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>6. Haemoglobin level (if available) <input type="text"/> <input type="text"/> <input type="text"/> g/dl</p> <p>7. Blood pressure</p> <p>Systolic <input type="text"/> <input type="text"/> <input type="text"/> mmHg</p> <p>Diastolic <input type="text"/> <input type="text"/> <input type="text"/> mmHg</p>
<p>Since her last visit has she;</p>	
<p>8. Smoked? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>9. If yes, how many cigarettes a day <input type="text"/> <input type="text"/></p> <p>10. Lived with someone who smokes heavily at home? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>11. Taken any recreational drugs? <input type="checkbox"/> yes <input type="checkbox"/> no</p>	<p>12. Had more than 5 units of alcohol per week? (1 unit = small (125ml) glass of wine or a bottle/can (330ml) of beer) <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>13. Been involved in a high risk occupation or taken part in a vigorous/contact sport? (see table) <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>14. Followed any special diets? (vegetarian with no animal products, weight loss programme, malabsorption treatment, gluten free diet) <input type="checkbox"/> yes <input type="checkbox"/> no</p>

1. Weight at this visit

Please repeat the measurement twice, following the instructions in the Anthropometry Handbook and adhering to advice given during training.

Write the weight of the woman in kilograms (kg) in the corresponding box, to one decimal place.

Example: a weight of 60.4kg should be written as 60.4kg, and not rounded up to 60.5kg.

2. **Father's height (if it can be obtained at this visit)**

If the father is available to be measured, please take his height using the Seca Adult Stadiometer 242 following the instructions given in the Anthropometry Handbook and the advice given during training.

If he is not available now, leave this field blank. Try to coordinate his visit during the next follow-up.

3. **Proteinuria**

This is an optional field and should only be completed if a proteinuria test has been carried out since the woman's last follow-up appointment.

Obtain the results of the most recent urinalysis from the lab report or medical records and enter the number that corresponds to the woman's proteinuria level in the corresponding box.

If proteinuria is reported from the dipstick, enter the number corresponding to the number of + in the box.

If proteinuria is reported in the lab results, enter the actual value (in g/l) in the corresponding box.

If the results are not available and are not in the medical records, please leave these boxes blank.

4. **Urine culture (please cross one box only)**

Place an 'X' next to **'Positive'** if the urine culture showed evidence of a Urinary Tract Infection

Place an 'X' next to **'Negative'** if the urine culture showed no evidence of a Urinary Tract Infection

Place an 'X' next to **'No urine culture available'** if the test was not carried out.

5. **If positive, was antibiotic treatment given?**

Place an 'X' next to **'YES'** if antibiotic treatment was given

Place an 'X' next to **'NO'** if antibiotic treatment was not given.

6. **Haemoglobin level**

This is an optional field and should only be completed if a haemoglobin test has been carried out since the woman's last follow-up appointment.

Obtain the most recent results from the lab and in the corresponding box, enter the haemoglobin level in grams/deciliter (g/dl).

If the results are not available and are not in the medical records, please leave these boxes blank.

7. Blood Pressure (mmHg)

Take the blood pressure reading using the Microlife 'Blood Pressure Monitor for Pregnant Women' (one per centre.) following the instruction in Appendix 2 of this document.

Enter the values for systolic and diastolic pressure (in mmHg) separately in the corresponding boxes.

If you are unable to get a blood pressure reading for this visit, please leave these boxes blank.

Since her last visit has she:

8. Smoked

Tick **'YES'** if the woman has smoked/chewed tobacco since her last visit.

Tick **'NO'** if she has not smoked/chewed tobacco since her last visit.

9. If yes, how many cigarettes a day?

Write the number of cigarettes that she smokes on a typical day. If her smoking habits have changed during the course of the last 5 weeks, write the higher number. For example if she was smoking 20 per day but has cut down to 10 in the last 2 weeks, write 20 for this visit.

If she has chewed tobacco, write how many times per day.

For shisha, one puff = 1/2 cigarette. A whole pipe = 15

10. Lived with someone who smokes heavily at home?

Place a 'X' next to **'YES'** if the woman lives with someone who smokes heavily in the house in which she lives.

Place a 'X' next to **'NO'** if she does not with someone who smokes heavily in the house in which she lives.

11. Taken any recreational drugs?

Recreational drugs include heroin, methadone, cocaine, amphetamines, hallucinogens, cannabis and benzodiazepines.

Place a 'X' next to **'YES'** if the woman has taken any recreational drugs.

Place a 'X' next to **'NO'** if the woman has NOT taken any recreational drugs.

12. Had more than 5 units of alcohol per week?

1 unit is equivalent to a small 125ml glass of wine, a 330ml bottle of beer, or a 25ml measure of spirit.

Place a 'X' next to **'YES'** if alcohol intake has been 5 or more units per week

Place a 'X' next to 'NO' if her alcohol intake has not been more than 5 units per week since discovering she was pregnant.

13. Been involved in any high-risk occupation or taken part in any vigorous/contact sport?

Here is a list of possible high-risk activities:

Frequent exposure to the following chemicals or toxic substances:	Physically demanding work:	High-risk sports/vigorous exercise:
Pesticides Lead or Mercury Solvents Petrochemicals Anaesthetic gases Tetrachloroethylene	More than 7 hours standing per day More than 50 hours work per week Work involving heavy lifting or very awkward postures	Sports that involve a high risk of abdominal trauma, falls or excessive joint stress (e.g. martial arts, rugby, long-distance running or cycling, weight-lifting) Women planning to do 1 hour of vigorous exercise more than 4 times per week into the 2 nd half of pregnancy

Place a 'X' in the box marked 'YES' if the woman has been involved in one or more of the high-risk activities listed above since her last visit

Place a 'X' in the box marked 'NO' if she has not taken take part in any of the high-risk activities listed above since her last visit.

14. Followed any special diets (vegetarian with no animal products (i.e. vegan), weight loss program, malabsorption treatment)?

Special diets include: vegetarian with no animal products (sometimes known as vegan). This means that the woman eats no milk, cheese, eggs, gelatin, yoghurt); gluten-free diets; weight-loss programs; and malabsorption treatments.

Vegetarianism alone (with dairy products) does not constitute a special diet.

Place a 'X' next to 'YES' if the woman has followed any special diets.

Place a 'X' next to 'NO' if the woman has NOT followed any special diets.

Section 2: Current Health

Section 2: Current health			
Since her last visit has she been diagnosed with or treated for any of the following conditions?			
15. Cardiac disease	<input type="checkbox"/> yes	<input type="checkbox"/> no	
16. Chronic respiratory disease (including chronic asthma)	<input type="checkbox"/> yes	<input type="checkbox"/> no	
17. Malaria	<input type="checkbox"/> yes	<input type="checkbox"/> no	
18. Mental illness e.g. depression	<input type="checkbox"/> yes	<input type="checkbox"/> no	
19. Epilepsy	<input type="checkbox"/> yes	<input type="checkbox"/> no	
20. Thyroid disease or any other endocrinological condition	<input type="checkbox"/> yes	<input type="checkbox"/> no	
21. Lower urinary tract infections requiring antibiotic treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no	
			22. Pyelonephritis
			23. Respiratory tract infections requiring antibiotic/antiviral treatment
			24. Any other infections requiring antibiotic/antiviral treatment
			25. HIV or AIDS
			26. Any type of malignancy or cancer (if yes, please complete an adverse event form)
			27. Any sexually transmitted infections
			28. Any other medical/surgical condition requiring treatment (if yes, please complete an adverse event form)

Since her last visit, has she been diagnosed with any of the following conditions?

For each condition:

Place an X in the box marked '**YES**' if she has been diagnosed with or treated for that condition

Place an X in the box marked '**NO**' if she has not been diagnosed with or treated for that condition

Important: take care not to duplicate episodes of illness that were already documented during the last study visit. Only cross 'YES' if that illness was diagnosed since the last visit, or is continuing/still requiring treatment.

15. **Cardiac disease** (examples - arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, pericarditis, cardiomyopathy etc.) Do not exclude women who experience heart palpitations as these are common in women of childbearing age.
16. **Chronic respiratory disease** (including any episodes of asthma)
17. **Malaria** (any episode)
18. **Mental illness e.g. depression**
19. **Epilepsy** (any episode)
20. **Thyroid disease or any other endocrinological condition**
21. **Lower urinary tract infections requiring antibiotic treatment**
22. **Pyelonephritis**
23. **Respiratory tract infection requiring antibiotic/antiviral treatment**
24. **Any other infections requiring antibiotic/antiviral treatment.** If so, please complete further information in an **Adverse Event form**
25. **HIV or AIDS** diagnosis
26. **Any type of malignancy or cancer.** If so, please complete further information in an **Adverse Event form**
27. **ANY Sexually Transmitted Infections.** If so, please complete further information in an **Adverse Event form**

28. **Any other medical or surgical requiring treatment or referral.** If so, please complete further information in an **Adverse Event** form.

Section 3: Current Health (continued)

Section 3: Current health (continued)			
Since her last visit has she been diagnosed with or treated for any of the following pregnancy-related conditions?			
29. Severe vomiting requiring hospitalisation	<input type="checkbox"/> yes	<input type="checkbox"/> no	
30. Gestational diabetes	<input type="checkbox"/> yes	<input type="checkbox"/> no	
31. Vaginal bleeding	<input type="checkbox"/> yes	<input type="checkbox"/> no	
32. Pregnancy-induced hypertension	<input type="checkbox"/> yes	<input type="checkbox"/> no	
33. Preeclampsia	<input type="checkbox"/> yes	<input type="checkbox"/> no	
34. Severe Preeclampsia/ Eclampsia/HELLP Syndrome	<input type="checkbox"/> yes	<input type="checkbox"/> no	
			35. Rhesus disease
			36. Preterm labour without delivery
			37. Prelabour rupture of membranes (PROM)
			38. Fetal distress
			39. Suspected impaired fetal growth or small for gestational age
			40. Any other pregnancy related condition requiring treatment (if yes, please complete an adverse event form)

Since her last visit, has she been diagnosed with any of the following pregnancy-related conditions?

For each condition:

Place an X in the box marked 'YES' if she has been diagnosed with or treated for that condition

Place an X in the box marked 'NO' if she has not been diagnosed with or treated for that condition

Important: take care not to duplicate episodes of illness that were already documented during the last study visit. Only cross 'YES' if that illness was diagnosed since the last visit, or is continuing/still requiring treatment.

29. **Severe vomiting requiring hospitalization**

30. **Gestational Diabetes**

31. **Vaginal bleeding**

32. **Pregnancy-induced hypertension**

33. **Preeclampsia**

34. **Severe preeclampsia/Eclampsia/HELLP syndrome**

35. **Rhesus Disease**

36. **Preterm labour without delivery.** If there has been a delivery, place a 'X' in the box marked NO and proceed to the Pregnancy and Delivery Form

37. **Prelabour Rupture Of Membranes (PROM).** Prelabour rupture of membranes (PROM) is rupture of the membranes before labour has begun. If there has been a delivery, please proceed to the Pregnancy and Delivery Form.

38. **Fetal distress**

39. **Suspected impaired fetal growth or small for gestational age**

40. **Any other pregnancy related condition requiring treatment or referral** (please complete an **Adverse Events** form)

Section 4: Nutritional Supplements/Medications

Section 4: Nutritional supplements / Medications			
Since her last visit, has she routinely taken any of the following?		Since her last visit, has she been given any of the following?	
41. Iron	<input type="checkbox"/> yes <input type="checkbox"/> no	46. Aspirin	<input type="checkbox"/> yes <input type="checkbox"/> no
42. Folic acid	<input type="checkbox"/> yes <input type="checkbox"/> no	47. Non-steroidal anti-inflammatories	<input type="checkbox"/> yes <input type="checkbox"/> no
43. Calcium	<input type="checkbox"/> yes <input type="checkbox"/> no	48. Antibiotics or Antivirals	<input type="checkbox"/> yes <input type="checkbox"/> no
44. Food supplements	<input type="checkbox"/> yes <input type="checkbox"/> no	49. Insulin	<input type="checkbox"/> yes <input type="checkbox"/> no
45. Multi-vitamins/minerals	<input type="checkbox"/> yes <input type="checkbox"/> no	50. Any other treatment	<input type="checkbox"/> yes <input type="checkbox"/> no

Since her last visit, has she taken any of the following nutritional supplements?

- 41. Iron
- 42. Folic acid
- 43. Calcium
- 44. Food supplements
- 45. Multi-vitamins/minerals

Since her last visit, has she been given following medications?

- 46. Aspirin
- 47. Non-steroidal anti-inflammatoris
- 48. Antibiotics or Antivirals
- 49. Insulin
- 50. Any other treatment

Section 5: Referral

Section 5: Referral	
51. Since her last visit, has the woman been referred to another level of care, been admitted to a hospital or is she being referred or admitted at this visit?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, please complete a maternal referral form . If she has delivered please complete a pregnancy and delivery form	

51. Since her last visit, has the woman been referred to another level of care or been admitted to hospital, or is she being admitted or referred at this visit?

If **yes** please complete a Maternal Referral form, using information from the medical record/ interview with the woman/physician.

If she has **delivered**, please complete a **Pregnancy and Delivery Form**

Section 6: Next Appointment

Section 6: Next appointment									
If not already done, please now arrange the next ultrasound appointment for within 5 weeks (\pm 1 week) of today									
52. Date of the next ultrasound appointment	<table border="1"><tr><td>D</td><td>D</td><td>—</td><td>M</td><td>M</td><td>—</td><td>Y</td><td>Y</td></tr></table>	D	D	—	M	M	—	Y	Y
D	D	—	M	M	—	Y	Y		

52. **Date of the next ultrasound appointment** dd-mm-yy, e.g. 20th may 2010 = 20-05-10

Maternal Referral/Admission Form (MRE)

Complete this form if, at any stage during her pregnancy, a woman enrolled in FGLS is referred to another level of care or admitted to hospital for any reason other than routine check-ups.

One referral form is supplied in each patient booklet. Please print any additional Maternal Referral/Admission Forms needed.

If the woman has had more than one referral/admission since the last study visit, complete one form for each referral/admission.

The information required should be obtained from the medical records or from her physician. A trip to the place of referral or admission may be necessary in some cases to obtain all the required information.

Once the form is complete, please pass it to the Local Research Coordinator for review of missing values and inconsistencies. The local Research Coordinator should then pass the form on to the Data Entry and Quality Control Unit.

Form Header

The **Study Subject Number** will be preprinted on each form within the booklet. If you require more than one Maternal Referral/Admission form, please tear one from the pad provided and copy across the Subject Study Number from the woman's booklet.

Please enter the **Antenatal Clinic Code** that corresponds to the clinic where the woman receives her routine ANC care. The can be found on the booklet front cover.

Enter the woman's **Antenatal Record number** (if available). The can be found on the booklet front cover.

Please enter the **Visit Date** (the date that the woman was referred or admitted) and the woman's **Date of Birth** in the format dd-mm-yy, e.g. 20th May 2010 = 20-05-10.

Section 1: Pregnancy Status

Section 1: Pregnancy status			
1. Is this a referral to another level of outpatient care or admission to hospital (please cross one box only)			
Referral	<input type="checkbox"/>		
Admission	<input type="checkbox"/>		
2. Which department/unit/service has she been referred or admitted to? (please cross one box only)			
Gynaecology	<input type="checkbox"/>	Physiotherapy	<input type="checkbox"/>
High-risk clinic (obstetric)	<input type="checkbox"/>	Nutritional	<input type="checkbox"/>
Urology/ Nephrology	<input type="checkbox"/>	Gastroenterology	<input type="checkbox"/>
Psychiatry	<input type="checkbox"/>	Other	<input type="checkbox"/>
If she has she been referred or admitted for a nutritional problem, please indicate the diagnosis (please cross all the boxes that are applicable)			
3. Gestational diabetes	<input type="checkbox"/>	7. Food Allergy	<input type="checkbox"/>
4. Overweight	<input type="checkbox"/>	8. Heartburn	<input type="checkbox"/>
5. Underweight	<input type="checkbox"/>	9. Malabsorption syndrome	<input type="checkbox"/>
6. Anaemia	<input type="checkbox"/>	10. Specific dietary requirement	<input type="checkbox"/>

1. Is this a *Referral* (to another level of outpatient care) or an *Admission* (to inpatient care)?

Please cross one box only.

2. Which department/unit/service has she been referred to?

Please cross one box only from the list below:

- ◆ Gynaecology
- ◆ High-risk (obstetric)
- ◆ Urology/Nephrology
- ◆ Psychiatry

- ◆ Physiotherapy
- ◆ Nutritional
- ◆ Gastroenterology
- ◆ Other

If she has been referred or admitted for a nutritional consultation, please indicate the diagnosis.

Please cross any boxes that apply from the list below.

3. **Gestational Diabetes**
4. **Overweight**
5. **Underweight**
6. **Anaemia**
7. **Food allergy**
8. **Heartburn**
9. **Malabsorption syndrome**
10. **Specific dietary requirement**

Section 2: Lab results

Section 2: Lab information (If requested during admission/referral)	
11. Proteinuria (by dipstick). Cross one box only	
0 <input type="checkbox"/>	+ <input type="checkbox"/>
++ <input type="checkbox"/>	+++ <input type="checkbox"/>
++++ <input type="checkbox"/>	no urine test available <input type="checkbox"/>
and/or actual result (from urine sample) received from laboratory.	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> mg/dl
12. Urine culture (please cross one box only)	
Positive	<input type="checkbox"/>
Negative	<input type="checkbox"/>
No urine culture available	<input type="checkbox"/>
13. If positive was antibiotic treatment given?	
yes	<input type="checkbox"/>
no	<input type="checkbox"/>
14. Lowest haemoglobin level (if measured during admission)	
	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> g/dl

Please complete **only** the results of lab tests that have been done during this referral or admission. If the tests have not been done during the referral, leave the field blank

11. Proteinuria (by dipstick)

Obtain the results of the urinalysis from the lab report and enter the number that corresponds to the woman's proteinuria level in the corresponding box.

If proteinuria is reported from the dipstick, enter the number corresponding to the number of + in the box.

If proteinuria is reported in the lab results, enter the actual value (in g/l) in the corresponding box.

If not available, leave the field blank.

12. Urine culture

Place an 'X' next to **'Positive'** if the urine culture showed evidence of a Uriary Tract Infection

Place an 'X' next to **'Negative'** if the urine culture showed no evidence of a Urinary Tract Infection

Place an 'X' next to **'No urine culture'** if the test was not carried out.

13. If positive, was antibiotic treatment given?

Place an 'X' next to **'YES'** if antibiotic treatment was given

Place an 'X' next to **'NO'** if antibiotic treatment was not given.

14. Lowest Haemoglobin level (if measured during admission) g/dl

If haemoglobin was measured during admissiom, obtain the results from the lab and in the corresponding box, enter the haemoglobin level in grams/deciliter.

If not available, leave the field blank.

Section 3: Non-pregnancy-related diagnosis for this admission or referral

Important: This section refers only to diagnoses that are not directly related to pregnancy. If the diagnosis is related to pregnancy, please skip to Section 3.

Section 3: Final clinical diagnosis for this admission or referral					
Please provide the main diagnosis by referring to the medical records					
15. Cardiac disease	<input type="checkbox"/>	<input type="checkbox"/>	22. Pyelonephritis	<input type="checkbox"/>	<input type="checkbox"/>
16. Chronic respiratory disease (including chronic asthma)	<input type="checkbox"/>	<input type="checkbox"/>	23. Respiratory tract infection requiring antibiotic/antiviral treatment	<input type="checkbox"/>	<input type="checkbox"/>
17. Malaria	<input type="checkbox"/>	<input type="checkbox"/>	24. Any other infection requiring antibiotic/antiviral treatment	<input type="checkbox"/>	<input type="checkbox"/>
18. Mental illness e.g. depression	<input type="checkbox"/>	<input type="checkbox"/>	25. HIV or AIDS	<input type="checkbox"/>	<input type="checkbox"/>
19. Epilepsy	<input type="checkbox"/>	<input type="checkbox"/>	26. Any type of malignancy/cancer (if yes, please complete an adverse event form)	<input type="checkbox"/>	<input type="checkbox"/>
20. Thyroid disease or any other endocrinological condition	<input type="checkbox"/>	<input type="checkbox"/>	27. Any sexually transmitted infection	<input type="checkbox"/>	<input type="checkbox"/>
21. Lower urinary tract infection requiring antibiotic treatment	<input type="checkbox"/>	<input type="checkbox"/>	28. Any other medical/surgical condition requiring treatment or surgery (if yes, please complete an adverse event form)	<input type="checkbox"/>	<input type="checkbox"/>

For each condition:

Place an X in the box marked 'YES' if she has been diagnosed with or treated for that condition

Place an X in the box marked 'NO' if she has not been diagnosed with or treated for that condition

15. **Cardiac disease** (examples - arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, sarcoma, pericarditis, cardiomyopathy etc.)
16. **Chronic respiratory disease (including episodes of asthma)**
17. **Malaria**
18. **Mental illness e.g. depression** (examples: schizophrenia, bipolar disorder, generalized anxiety disorder)
19. **Epileptic episode**
20. **Thyroid disease or any other endocrinological condition** (examples - Addison's disease, adrenal gland disorders, parathyroidism (PTH), hypophysitis). If the woman developed gestational diabetes, do not cross 'YES' here but refer to the next section.
21. **Lower urinary tract infections requiring antibiotic treatment** (examples – cystitis)
22. **Pyelonephritis**
23. **Respiratory tract infection requiring antibiotic/antiviral treatment**
24. **Any other infections requiring antibiotic/antiviral treatment.** If so, please complete further information in an **Adverse Event** form
25. **HIV or AIDS**
26. **Any type of malignancy or cancer.** If so, please complete further information in an **Adverse Event** form
27. **ANY Sexually Transmitted Infections.** If so, please complete further information in an **Adverse Event** form
28. **Any other medical or surgical requiring treatment or referral.** If so, please complete further information in an **Adverse Event** form

Section 4: Pregnancy-related diagnosis for this admission or referral

Important: This section refers only to diagnoses that are related to pregnancy. If the diagnosis is not related to pregnancy, please complete Section 2 only.

Section 4: Pregnancy related diagnosis for the admission or referral			
Please provide the main diagnosis by referring to the medical records			
# Gestational diabetes	<input type="checkbox"/>	<input type="checkbox"/>	
30. Vaginal bleeding	<input type="checkbox"/>	<input type="checkbox"/>	
31. Miscarriage (please complete the pregnancy and delivery form)	<input type="checkbox"/>	<input type="checkbox"/>	
32. Pregnancy induced hypertension	<input type="checkbox"/>	<input type="checkbox"/>	
33. Preeclampsia	<input type="checkbox"/>	<input type="checkbox"/>	
34. Severe Preeclampsia	<input type="checkbox"/>	<input type="checkbox"/>	
35. Eclampsia/HELLP syndrome	<input type="checkbox"/>	<input type="checkbox"/>	
36. Multiple pregnancy	<input type="checkbox"/>	<input type="checkbox"/>	
37. Rhesus disease	<input type="checkbox"/>	<input type="checkbox"/>	
			38. Prelabour rupture of membranes (PROM) or Preterm Labour without delivery
			39. Preterm Labour or PROM and Delivery (if yes please complete the pregnancy and delivery form)
			40. Fetal death (if yes please complete the pregnancy and delivery form)
			41. Fetal distress
			42. Suspected impaired fetal growth or small for gestational age
			43. Pelvic mass
			44. Severe vomiting requiring hospitalisation
			45. Any other pregnancy related condition (if yes, please complete an adverse event form)

For each condition:

Place an X in the box marked 'YES' if she has been diagnosed with or treated for that condition

Place an X in the box marked 'NO' if she has not been diagnosed with or treated for that condition

29. **Gestational Diabetes**

30. **Vaginal bleeding**

31. **Miscarriage (please complete the pregnancy and delivery form)**

32. **Pregnancy-induced hypertension**

33. **Preeclampsia**

34. **Severe preeclampsia**

35. **Eclampsia/HELLP syndrome**

36. **Multiple pregnancy**

37. **Rhesus Disease**

38. **Prelabour rupture of membranes (PROM) or Preterm Labour WITHOUT delivery**

39. **Prelabour rupture of membranes (PROM) or Preterm Labour WITH delivery**

40. **Fetal death (if yes please complete a pregnancy and delivery form)**

41. **Fetal distress**

42. **Suspected impaired fetal growth or small for gestational age**

43. **Pelvic mass**

44. Severe vomiting requiring hospitalization

45. Any other pregnancy related condition requiring treatment or referral (if yes, please complete an adverse event form)

Section 5: Medications and treatment

Section 5: Medications and treatment			
Has she been prescribed any of the following medications?			
46. Aspirin	<input type="checkbox"/> yes	<input type="checkbox"/> no	
47. Antihypertensives	<input type="checkbox"/> yes	<input type="checkbox"/> no	
48. Treatments for asthma	<input type="checkbox"/> yes	<input type="checkbox"/> no	
49. Antipsychotics	<input type="checkbox"/> yes	<input type="checkbox"/> no	
50. Antidepressants	<input type="checkbox"/> yes	<input type="checkbox"/> no	
			51. Antibiotics/Antivirals
			52. Corticosteroids
			53. Magnesium Sulphate
			54. Any other treatment
			55. Just bed rest /observation

46. Aspirin

47. Antihypertensives

48. Treatment for asthma

49. Antidepressants

50. Antipsychotics

51. Antibiotics/Antivirals

52. Corticosteroids

53. Magnesium Sulohate

54. Any other treatment

55. No treatment required, just bed rest/observation

Section 6: Final Outcome

Section 6: Final outcome	
56. Final outcome of the admission (cross one box only)	
Discharged <input type="checkbox"/>	Maternal Death (complete the pregnancy and delivery and adverse event forms) <input type="checkbox"/>
Transferred to another level of care or hospital (please inform study co-ordinator) <input type="checkbox"/>	Left hospital or treatment against medical advice (please inform study co-ordinator) <input type="checkbox"/>
Delivered/miscarried (complete the pregnancy and delivery form) <input type="checkbox"/>	
57. Date of discharge from hospital	<input type="text" value="D"/> <input type="text" value="D"/> — <input type="text" value="M"/> <input type="text" value="M"/> — <input type="text" value="Y"/> <input type="text" value="Y"/>

56. Final Outcome

Please cross one box only. If she has delivered during the referral or admission and was then discharged, please cross 'Delivered' and then complete a Delivery Outcome Form.

- ◆ Discharged
- ◆ Transferred to another level of care or hospital
- ◆ Delivered/miscarried. Include in this category fetal death and miscarriage. **Complete the Pregnancy and Delivery Form in all cases.**
- ◆ Maternal Death (**complete Pregnancy and Delivery Form**)
- ◆ Left hospital or treatment against medical advice (please inform study coordinator)

57. Date of Discharge

Please write the date that the woman left the hospital/referral clinic in the format dd-mm-yy. E.g. 20th May 2010 = 20-05-10.

Section 7: Next Appointment

Section 7: Next appointment	
If the woman is still pregnant, even if still admitted, please check the date of the next ultrasound appointment	
58. Date of the next ultrasound appointment	<input type="text" value="D"/> <input type="text" value="D"/> — <input type="text" value="M"/> <input type="text" value="M"/> — <input type="text" value="Y"/> <input type="text" value="Y"/>
If the woman is still admitted please inform the study co-ordinator	

If the woman is still pregnant, even if still admitted, please check the date of the next ultrasound appointment.

58. Date of the next ultrasound appointment

Only complete this question if the woman is still pregnant after the referral/admission.

Please refer to the last Ultrasound Follow-up Form or Pregnancy Follow-up Form in the booklet for the date of the next ultrasound appointment. Write the date in the format dd-mm-yy. E.g. 20th May 2010 = 20-05-10.

Appendix 1. Occupational classification scheme

Housework (including child care/care of elderly relative)

Manager/Professional/Technical

- ◆ Chief executives, senior officials and legislators and associated professionals
- ◆ Administrative and commercial managers and associated professionals
- ◆ Health professionals and associated professionals
- ◆ Teaching professionals and associated professionals
- ◆ Business and administration professionals and associated professionals
- ◆ Information and communications technology professionals and technicians
- ◆ Legal, social and cultural professionals
- ◆ Production and specialized services managers
- ◆ Hospitality, retail and other services managers
- ◆ Science and engineering professionals

Clerical/Sales/Services

- ◆ General and keyboard clerks
- ◆ Customer services clerks
- ◆ Numerical and material recording clerks
- ◆ Other clerical support workers
- ◆ Service and sales workers
- ◆ Personal service workers
- ◆ Sales workers
- ◆ Personal care workers
- ◆ Protective services workers

Skilled Manual Worker

- ◆ Market-oriented skilled agricultural, forestry, fishing and hunting workers
- ◆ Subsistence farmers, fishers, hunters and gatherers
- ◆ Craft and related trades workers
- ◆ Building and related trades workers, excluding electricians
- ◆ Metal, machinery and related trades workers
- ◆ Handicraft and printing workers
- ◆ Electrical and electronic trades workers
- ◆ Food processing, wood working, garment and other craft and related trade workers
- ◆ Stationary plant and machine operators
- ◆ Assemblers
- ◆ Drivers and mobile plant operators

Unskilled Manual Worker

- ◆ Cleaners and helpers
- ◆ Agricultural, forestry and fishery labourers
- ◆ Labourers in mining, construction, manufacturing and transport
- ◆ Food preparation assistants
- ◆ Street and related sales and service workers
- ◆ Refuse workers and other elementary workers

Other

- ◆ **Student**
- ◆ **Redundancy/unemployed**

Appendix 2. Blood Pressure Measurement Protocol

The equipment:

Microlife Blood Pressure Monitor for Pregnant Women
Cuffs of two sizes (for medium and large arms)
Rubber bladder
Pump with control valve

The circumstances:

Blood pressure is to be taken during every follow visit of the women in the Fetal Growth Longitudinal Study. The blood pressure monitor should be placed in an accessible location, near to the ultrasound room.

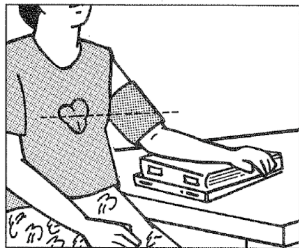
Blood pressure can rise if the patient has recently exercised or is nervous. In late pregnancy, even walking can be strenuous. Ensure that the patient has had time to rest (5-10 minutes) since arriving at the clinic. Put her at ease and make sure the temperature of the clinic is comfortable.

Position of the patient:

The patient should be seated during the blood pressure reading and for 5 minutes before it.

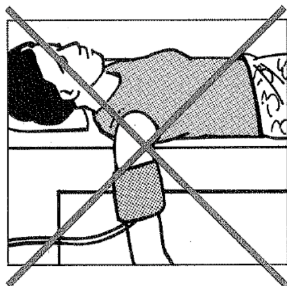
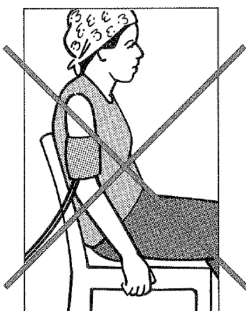
Lying down or standing during the blood pressure reading is unacceptable.

Position of the arm:



The arm must be supported so that the muscles are relaxed. The height of the upper arm where the cuff is to be worn should be at heart-level. If the table is too low, use extra support (e.g. books)

Avoid letting the arm hang down either in a sitting or lying position.



Fitting the cuff:

1. For the purposes of the study we will use the **RIGHT** arm.
2. Remove all tight clothing from around the arm.
3. The rubber bladder inside the cuff should go at least 80% of the way around the arm. If the patient has a large upper arm, use a larger cuff. Using a small cuff on a large arm can result in artificially raised blood pressure.
4. Wrap the cuff around the upper arm. The cuff must be at least 2-3cm (1 inch) above the elbow. Do not kink or twist the tubes or allow them to be tucked or caught under the cuff.
5. Make sure the patient is relaxed and comfortable. Explain that the cuff will become tight and may be mildly uncomfortable.

Measuring Procedure:

1. Press the start button. The pump begins to inflate the cuff. The rising pressure in the cuff is shown on the display.
2. After reaching the inflation pressure, the pump stops and the pressure gradually falls. The cuff pressures are displayed. In case that the inflation pressure is not sufficient, the monitor automatically re-inflates to a higher level.
3. When the instrument detects a pulse, the heart symbol in the display starts to flash and a beep is heard for every heartbeat.
4. A longer beep is sounded when the measurement has been completed. The systolic, and diastolic blood pressures and pulse rate now appear in the display.
5. The measurement results are displayed, until you switch the device off. If no button is pressed for 5 minutes, the device switches off automatically, to save the batteries

Recording the Results:

Record both the systolic and diastolic values in the corresponding data collection form in mmHg.

If this is the Maternal Study Entry visit, the form looks like this:

13. Blood Pressure	
Systolic	<input type="text"/> <input type="text"/> <input type="text"/> mmHg
Diastolic	<input type="text"/> <input type="text"/> <input type="text"/> mmHg

If this is the Pregnancy Follow-up visit, the form looks like this:

6. Blood pressure	Systolic	<input type="text"/> <input type="text"/> <input type="text"/> mmHg
	Diastolic	<input type="text"/> <input type="text"/> <input type="text"/> mmHg

Appendix 3. Measurement of Symphysis Fundal Height

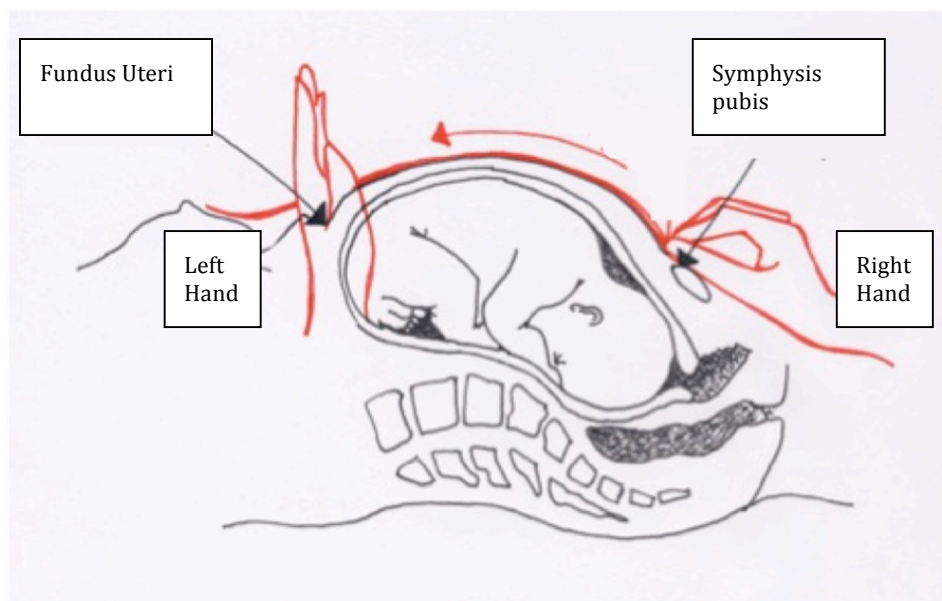
Position of the patient

The patient should lie in the **supine** position and should have an **empty bladder**. Therefore the measurement is best done after the ultrasound scan when the woman has voided the bladder.

Technique for measuring uterine height:

1. Uterine height should be measured only using the **metric** tape of **non-elastic** material provided by the study.
2. Measurements are to be **blinded**, by turning the tape measure so that no numbers are visible during the measurement.
3. Hold the 0 cm marking of the tape with one hand, securing it over the upper border of the symphysis pubis bone.
4. With the palm of the other hand on the abdomen, pass the tape in a straight line from the symphysis pubis over the uterus to the fundus uteri until you feel a resistance in the abdominal wall. **DO NOT HOLD THE TAPE BETWEEN THE FINGERS.**
5. Use the cubital edge of the hand to sustain the tape in place at the point of the fundus uteri.
6. Carefully fold the paper at the level of the fundus. The tape should then be turned so that the numbers are visible and the value can be recorded. Please be aware that the tape has both cm and inches but that values should be recorded in cm only.

Figure 1. Tape measure technique from the symphysis pubis to the fundus uteri



7. Record the measurements in question 14 of the Ultrasound Follow-up form, to the nearest complete millimeter. Repeat the whole process a **second time** and record the second measurement.

Section 2: Symphysis Fundal Height	
15. Symphysis Fundal Height	
1 st Measurement	2 nd Measurement
<input type="text"/> <input type="text"/> . <input type="text"/> cm	<input type="text"/> <input type="text"/> . <input type="text"/> cm

Ref. Belizan J, Villar J et al. Diagnosis of intrauterine growth retardation by a simple clinical method: Measurement of uterine height. Am J Obstet Gynecol 1978 131:6: 643-646