

INTERBIO-21st

The Functional Classification of Abnormal Fetal and Neonatal Growth Phenotypes



FETAL STUDY INSTRUCTIONS FOR FORMS

February 2013
(version 1.2)



Please read these instructions carefully and refer to them throughout the study if any clarification is needed.

This Instructions Manual for the INTERBIO-21st Fetal Study is based on the INTERBIO-21st protocol, the INTERGROWTH-21st protocol and the FGLS operations manual produced by the International Fetal and Newborn Growth Consortium.

www.intergrowth21.org.uk

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

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INTERBIO-21st Fetal Study (FS) Summary

INTERBIO-21st is a study within the INTERGROWTH-21st project. The aim of the study is to establish a biobank of maternal blood, maternal faeces, umbilical cord blood, and placental samples from healthy and complicated pregnancies to allow nutritional, epigenetic and other biomarker studies to be performed. For this study, detailed information will also be acquired about gestational age and fetal growth patterns starting at <14 weeks' gestation.

The INTERBIO-21st Fetal Study (within INTERBIO-21st) will provide detailed phenotypic information based on fetal growth patterns and biological samples in pregnancies with optimal outcomes, as well as those complicated by a range of factors in resource-poor settings.

The ultimate aim of INTERBIO-21st is to integrate all the pregnancy-related, clinical and biomarker data to improve the phenotypic characterisation of newborns so as to facilitate the development of targeted interventions and screening strategies in pregnancy and early infant life.

The INTERBIO-21st Fetal Study will follow a similar protocol to the INTERGROWTH-21st Fetal Growth Longitudinal Study (FGLS).

Approximately 3,500 pregnancies (500 per centre) will be included in the INTERBIO-21st Fetal 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 3D ultrasound examinations every five weeks, i.e. up to six times during a term pregnancy.

Subject Flow

Subject flow for the Fetal Study is presented in Figure 1. The text below describes the recruitment process.

Recruitment

All women attending antenatal care from <14 weeks' gestation, irrespective of their risk profile for adverse pregnancy/neonatal outcomes, should be provided with a patient information leaflet and helped to understand what the study entails.

If the woman is interested, a **Baseline Information Form** should be completed by the research staff or assistant/nurse/midwife. Information for this form is to be extracted from the medical records or gained by conducting a direct interview with the potential study subject or their care provider (Figure 1).

In Section 1 of the Baseline Information Form, if the woman is found to be eligible and she is willing to participate, ask the woman to sign an **Informed Consent Form**. Once consent has been acquired, complete the rest of the Baseline Information Form. Then, if she has not already had one, the woman will be offered a dating scan to confirm the gestational age.

After the dating scan the **Ultrasound Dating Form** must be completed. If the woman is still eligible for the study then she should be enrolled.

The woman should then be assigned a Fetal Study Booklet. Complete the front cover of this booklet and the **Maternal Study Entry Form**. Adhesive patient identifier (PTID) labels (comprising a computer-readable barcode and a numeric identification code which match those pre-printed on the front of the booklet) will be located within the Fetal Study Booklet. A

PTID label should be affixed to each page of the completed Baseline Information and Ultrasound Dating Forms. The PTID number must then be linked to the woman by logging the required information onto a patient identifier list/database.

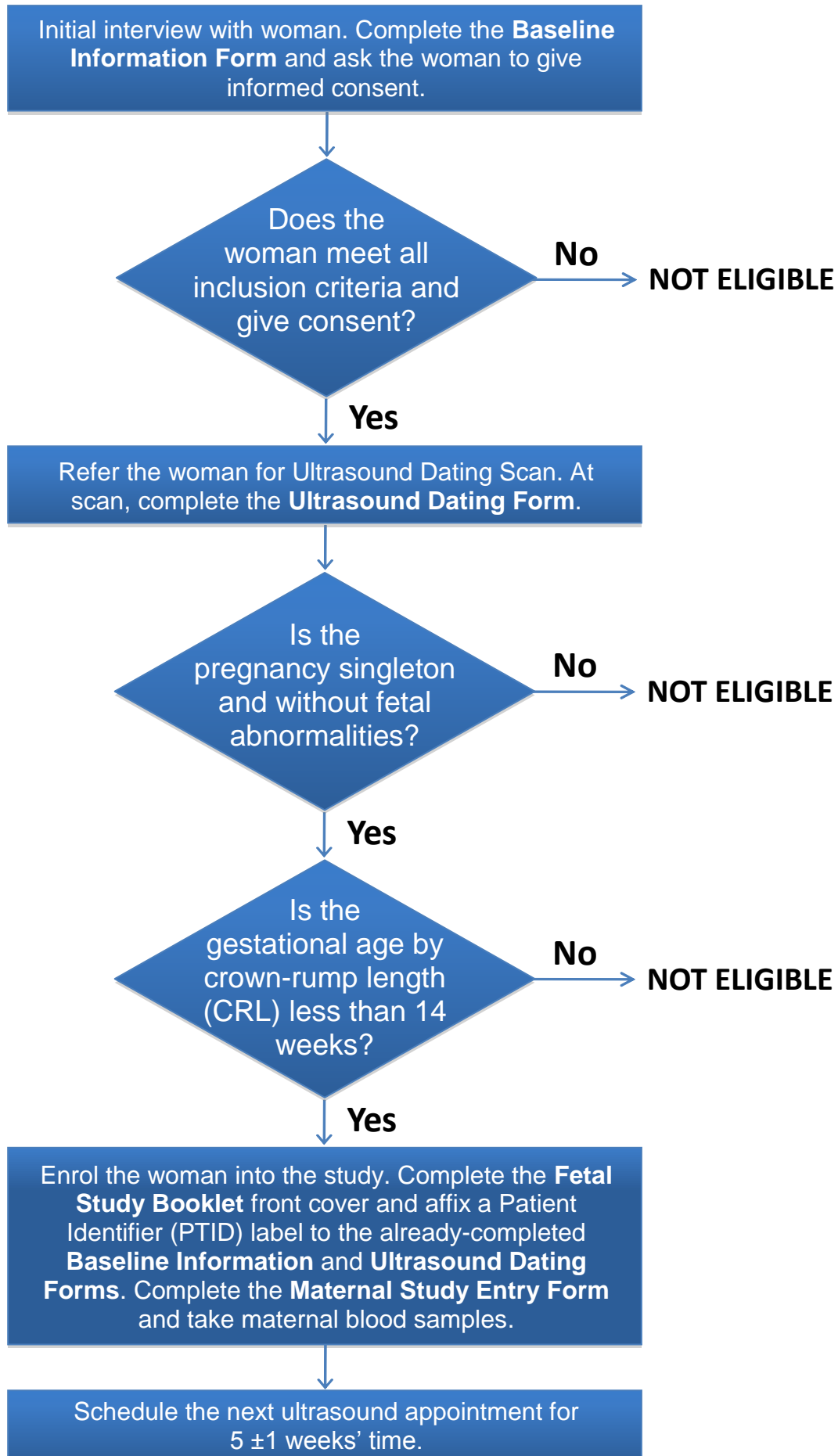
At the same time, a one-off set of maternal blood samples should be taken (following the guidelines laid out in the Biological Sample Collection Operations Manual), and – if your site is using the Study Appointment Cards – enrolled women should receive an **Appointment Card** with the dates and times of their follow-up appointments.

[Note: The sheet of PTID labels within the Fetal Study Booklet has been split into two sections, perforated down the middle. Those on the left-hand side are intended for use at recruitment and at the follow-up appointments; this half of the label sheet should remain attached within the booklet for the duration of the study. Those on the right-hand side are intended for use at delivery; at recruitment, please tear along the perforations, detach this half of the label sheet and place it in the woman's medical notes for use at delivery.]

The next ultrasound appointment should be scheduled 5 (± 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. FS subject flow: Recruitment.

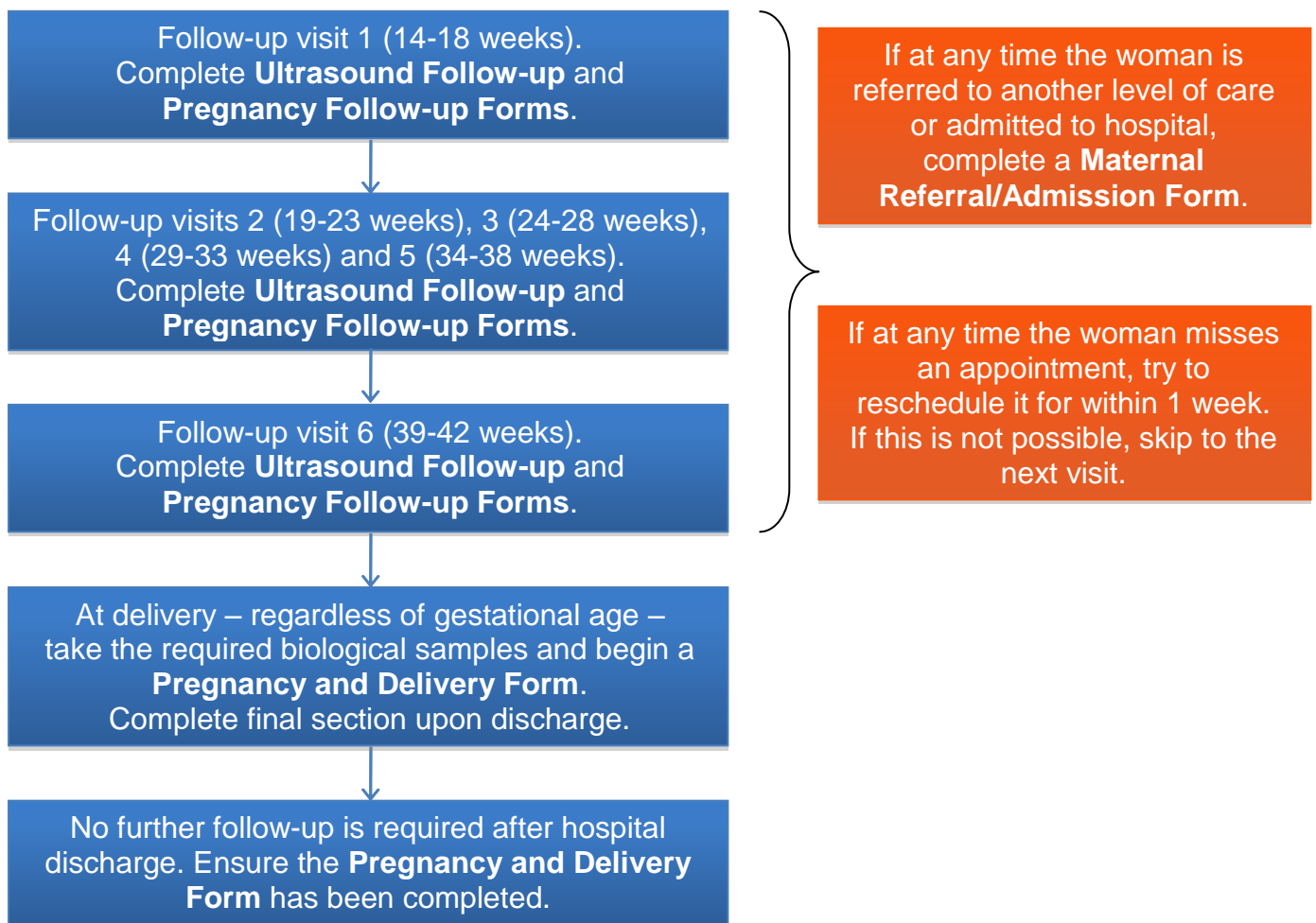


Follow-up

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 standardised 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/Admission Form** should be completed. Local medical or obstetrical protocols should be adhered to (Figure 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 measurements 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 the woman a few questions about her health, taking three required clinical measurements (weight, blood pressure and symphyseal-fundal 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 records.
- 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 by an INTERBIO-21st trained midwife/technician. A PTID label must be affixed to the front cover of this form.
- Furthermore at delivery, maternal blood (only if not already collected at study entry) maternal faeces (only if passed), umbilical cord blood, and placental samples should be collected, according to the guidelines laid out in the Biological Sample Collection Operations Manual. Affix a matching PTID label to each specimen, to the completed **Sample Collection Slip**, and to each sample collection kit.

Figure 2. FS subject flow: Follow-up.



The mechanism for the study process should be organised and coordinated by the local delivery hospitals. All women, whether enrolled in the study or not, will receive routine antenatal care. The content of this care will be standardised but local variability is to be expected.

All newborns during the study period, including those on NICU or special care, will be followed on a daily basis until hospital discharge to document severe morbidity and detect neonatal death. There is no follow-up of infants or their mothers after discharge from hospital.

General Instructions for Form Completion

1. Patient identifier (PTID) labels are only to be affixed to the form headers and booklet covers for women who are enrolled into the study.
2. A ballpoint pen should be used to complete the forms and the writing should be legible and in block capitals where appropriate.
3. Do not write on the forms except in the white 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 and fill all boxes, using leading zeros if required (e.g. if required to enter a diastolic blood pressure of '90' in the 3 boxes provided, a '0' should be added to the front of the number, writing the response as '090'). All dates should be written in the format dd-mm-yy; for example, '20th May 2010' should be written '20-05-10'.
4. If there is an error made in writing, it must be crossed out, and the correct answer written outside the box and initialled. Correction fluids should not be used.
5. The person completing the form should fill in his/her name, signature and researcher code (provided by the Coordinating Unit) at the bottom of each form.
6. After completion, each white top copy should be separated out and forwarded on to the Data Management Unit at regular intervals (to be decided locally) for data entry. The study subject booklet containing the duplicate (yellow) forms should be kept in a separate filing system within the facility.
7. It is the responsibility of each institution to organise the local arrangements to facilitate this process.

Baseline Information Form (BAS)

Before completing this form, provide the woman with a patient information leaflet and make sure she understands what the study entails. If the woman is still eligible to be included in the study after completing the first section of the **Baseline Information Form** and she is willing to participate in the study, ask her to fill in and sign the **Informed Consent Form**.

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

If the woman is accepted into the study after completion of the Ultrasound Dating Form (which follows this form if all screening requirements are met), a patient identifier (PTID) label must be affixed to the header of this form for identification purposes.

If any sections of this form can be completed in full using information from accessible medical records then this information can be extracted for this purpose. However, any information which cannot be found in her medical records must be obtained during the interview with the woman.


In particular, questions in Section 2 regarding high-risk activities and diet will need to be asked directly to the woman. For questions marked 'see table', use the relevant flip-chart page (see [Appendix 1](#)) to prompt the woman for an appropriate answer.

For Section 1, weight will need to be taken using the Adult Scale (Seca 877 Portable Digital Scale) and height using the Adult Stadiometer (Seca 242 Digital Display). Remember to calibrate the machines regularly according to the instructions in the Anthropometry Manual. For Question 5, the Body Mass Index (BMI) calculator will also be required.

Once the form has been completed:

- Book her dating scan at the Study Ultrasound Centre for within 3 days.
- Sign the bottom of the form (completing also the researcher code and your name).
- Pass the completed form to the Data Management Unit for data entry.

Form Header

 UNIVERSITY OF OXFORD	INTERBIO-21st Fetal Study Baseline Information	BAS Page 1 of 3				
AFFIX PTID LABEL HERE	Country Code	<input type="text" value="0"/> <input type="text" value="7"/>	Hospital/Clinic Code	<input type="text"/>	<input type="text"/>	
	Screening Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	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"/>
Please answer all yes/no questions by placing a 'X' in the corresponding box						

PTID Label: If the woman is accepted into the study after completion of the Ultrasound Dating Form (which follows this form if all screening requirements are met), affix the woman's allocated patient identifier (PTID) label to the marked section. This is necessary to identify the woman.

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

Hospital/Clinic Code: Enter the code that corresponds to your hospital or clinic.

Screening Number: Assign the woman the next available number from your allocated batch. Ensure that you do not give her a duplicate number that has already been allocated – for example, by keeping a log-book in the clinic.

Interview Date: Enter the date of the interview in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Please answer all yes/no questions by placing a 'X' in the corresponding box.

Section 1: Fetal Study inclusion criteria

NB Information required for this section must be obtained from direct interview with the woman. For Questions 3 and 4, measurements should be taken using the equipment provided for this study; Question 5 requires the use of the Body Mass Index (BMI) calculator provided.

Section 1: Fetal Study inclusion criteria	
1. Age: (years) <input type="text"/> <input type="text"/> yrs	2. Is the woman aged 18 or over? <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. Weight: (kg) <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg
5. Is her Body Mass Index < 35 kg/m ² ? <input type="checkbox"/> yes <input type="checkbox"/> no	
6. Was this pregnancy conceived with fertility treatment? <input type="checkbox"/> yes <input type="checkbox"/> no	
7. Is she going to deliver at a hospital participating in the study? <input type="checkbox"/> yes <input type="checkbox"/> no	
8. Has she given informed consent to participate in the study? <input type="checkbox"/> yes <input type="checkbox"/> no	
9. Are all the shaded boxes (<input type="checkbox"/>) above marked with a 'X'?	<input type="checkbox"/> yes <input type="checkbox"/> no
<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 5px; width: 45%;"> <p><i>If yes, the woman is potentially eligible for the study. Please complete the rest of this form.</i></p> </div> <div style="border: 1px solid black; padding: 5px; width: 45%;"> <p><i>If no, the woman is <u>not</u> eligible for the study. Stop here.</i></p> </div> </div>	

1. Age (years)

Write the age of the woman in years. Obtain her age in completed years; that is, her 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 the woman aged 18 or over?

Place a 'X' in the box marked 'YES' if the woman has had her 18th birthday i.e. the woman's age is 18 complete years or older at the time of her last birthday.

Place a 'X' in the box marked 'NO' if the woman is still 17 or younger at the time of her last birthday.

3. Height (cm)

Take the woman's height using the Adult Stadiometer (Seca 242 Digital Display). Write the woman's height in centimetres (cm) to 1 decimal place. Example: A height of 152.9cm should be written as '152.9cm' – do not round up to 153cm.

4. Weight (kg)

Take the woman's weight using the Adult Scale (Seca 877 Portable Digital Scale). Write the woman's weight in kilograms (kg) to 1 decimal place. Example: A weight of 60.4kg should be written as '060.4kg' – do not round down to 60kg or up to 60.5kg.

5. Is her Body Mass Index < 35 kg/m²?

Calculate the woman's Body Mass Index (BMI) from her height (Question 3) and weight (Question 4) using the BMI calculator provided. Type in the woman's height and weight when prompted and the calculator will work out her BMI using the formula:

$$\text{BMI} = \frac{\text{Weight (kg)}}{\text{Height (m)} \times \text{Height (m)}} \quad \text{i.e. BMI} = \frac{\text{Question 4}}{\text{Question 3} \times \text{Question 3}}$$

Place a 'X' in the box marked 'YES' if the resulting answer (unrounded) is less than 35.

Place a 'X' in the box marked 'NO' if the resulting answer (unrounded) is greater than or equal to 35.

6. 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 conceived naturally, without any form of fertility treatment, ovulation stimulation injections or similar.

7. Is she going to deliver at a hospital participating in the study?

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

8. Has she given informed consent to participate in the study?

Place a 'X' in the box marked 'YES' if she gives informed consent to participate in the study.

Place a 'X' in the box marked 'NO' if she does not give informed consent to participate in the study.

A woman who has not given informed consent cannot take part in the study. If she does not give informed consent she will continue with her routine antenatal care.

9. Are all the shaded boxes above marked with a 'X'?

The shaded boxes correspond to Questions 2, 5, 6, 7 and 8.

Place a 'X' in the box marked 'YES' if all the shaded boxes have been marked with a 'X'.

Place a 'X' in the box marked 'NO' if any of the non-shaded boxes have been marked with a 'X'.

If the answer to Question 9 was YES, the woman is potentially eligible for the study. Continue completing the rest of this form.

If the answer to Question 9 was NO, the woman is not eligible for the study. Stop completing the form here – no further information is required from her or her medical records. Sign the bottom of the form and pass it to the Data Management Unit for data entry. Continue with routine antenatal care.

Section 2: Demographic and nutritional characteristics

NB Information required for this section must be obtained from direct interview with the woman. Questions 13-16 require the use of the supplementary flip-chart as a visual aid.

Section 2: Demographic and nutritional characteristics			
In the last 3 months:			
10. Has she smoked?	<input type="checkbox"/> yes	<input type="checkbox"/> no	If yes, how many cigarettes/cigars per day? <input type="text"/> <input type="text"/>
11. Has she sniffed/chewed tobacco?	<input type="checkbox"/> yes	<input type="checkbox"/> no	If yes, how many times per day? <input type="text"/> <input type="text"/>
12. Has she chewed betelnut?	<input type="checkbox"/> yes	<input type="checkbox"/> no	If yes, how many nuts per day? <input type="text"/> <input type="text"/>

In the last 3 months:

10. Has she smoked?

Place a 'X' in the box marked 'YES' if the woman reports smoking cigarettes, cigars (including cheroots) or shisha any time in the last 3 months.

Place a 'X' in the box marked 'NO' if the woman has not smoked cigarettes, cigars (including cheroots) or shisha in the last 3 months.

If yes, how many cigarettes/cigars per day?

If she has smoked cigarettes or cigars (including cheroots), write the average number of cigarettes or cigars that she smoked on a typical day. If her smoking habits have changed during the course of the last 3 months, write the maximum that she was smoking at any time point. 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.

For shisha, one puff = ½ cigarette. A whole pipe = 15.

11. Has she sniffed/chewed tobacco?

Place a 'X' in the box marked 'YES' if the woman reports sniffing or chewing tobacco any time in the last 3 months.

Place a 'X' in the box marked 'NO' if the woman has not sniffed or chewed tobacco in the last 3 months.

If yes, how many times per day?

If she has sniffed or chewed tobacco, write the average number of times that she sniffed or chewed it on a typical day. If her habits have changed during the course of the last 3 months, write the maximum that she was sniffing/chewing at any time point. For example, if she was chewing tobacco 20 times per day but has cut down to 10 in the last 2 weeks, write '20' for this visit.

12. Has she chewed betelnut?

Place a 'X' in the box marked 'YES' if the woman reports chewing betelnut any time in the last 3 months.

Place a 'X' in the box marked 'NO' if the woman has not chewed betelnut in the last 3 months.

If yes, how many nuts per day?

If she has chewed betelnut, write the average number of nuts that she chewed on a typical day. If her habits have changed during the course of the last 3 months, write the maximum that she was chewing at any time point. For example, if she was chewing 20 nuts per day but has cut down to 10 in the last 2 weeks, write '20' for this visit.

13. Since discovering she was pregnant, on average, how many units of alcohol per week has she had? (1 unit = small glass (125ml) of wine or one bottle/can (330ml) of beer; see table)	<input type="text"/>	<input type="text"/>			
14. Has she used any of the following recreational drugs in the last 3 months? (cross all that apply; see table)					
Heroin	<input type="checkbox"/>	Amphetamines	<input type="checkbox"/>	Benzodiazepines	<input type="checkbox"/>
Methadone	<input type="checkbox"/>	Hallucinogens	<input type="checkbox"/>	Inhalants/Solvents	<input type="checkbox"/>
Crack/Cocaine	<input type="checkbox"/>	Cannabis	<input type="checkbox"/>	Other recreational drugs	<input type="checkbox"/>
15. Is she involved in any of the following high-risk occupations or activities? (cross all that apply; see table)					
Frequent exposure to chemical/toxic substances		<input type="checkbox"/>			
Frequent physically demanding work		<input type="checkbox"/>			
Frequent high-risk sports/vigorous exercise		<input type="checkbox"/>			
16. Does she follow any of the following special diets? (cross all that apply; see table)					
Vegetarian with no animal products		<input type="checkbox"/>	Gluten-free	<input type="checkbox"/>	
Weight loss programme		<input type="checkbox"/>	Malabsorption treatment	<input type="checkbox"/>	

13. Since discovering she was pregnant, on average, how many units of alcohol per week has she had?

Show the woman the relevant page on the flip-chart (see [Appendix 1](#)) and write the number of units of alcohol she has consumed in a typical week (to the nearest whole number).

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

14. Has she used any of the following recreational drugs in the last 3 months?

Show the woman the relevant page on the flip-chart (see [Appendix 1](#)). Place a 'X' in the corresponding box if in the last 3 months she has used heroin, methadone, crack/cocaine, amphetamines (including ya ba and khat), hallucinogens, cannabis (in South Africa, also called 'dugga'), benzodiazepines (including diazepam), inhalants/solvents, or any other recreational drugs.

If the woman is unsure but thinks she may have used one or more of these recreational drugs, still place a 'X' in the corresponding box(es).

Cross all that apply.

15. Is she involved in any of the following high-risk occupations or activities?

Show the woman the relevant page on the flip-chart (see [Appendix 1](#)) and place a 'X' in the corresponding box if she is involved in one or more of the high-risk occupations or activities shown in the table on a frequent basis.

If she is unsure but thinks she may have been involved in one or more of these activities, still place a 'X' in the corresponding box(es).

NB If she frequently walks for several hours per day (i.e. more than 4 times per week in the 2nd half of pregnancy), this could be considered 'vigorous exercise' and the third option 'Frequent high-risk sports/vigorous exercise' should be crossed. Do not include in this category the occasional long walk (e.g. to the hospital for an appointment once a month).

Cross all that apply.

16. Does she follow any of the following special diets?

Show the woman the relevant page on the flip-chart (see [Appendix 1](#)) and place a 'X' in the corresponding box if she follows one or more of these special diets.

Special diets include: vegetarian with no animal products (sometimes known as 'vegan', meaning that the woman eats no meat, fish, milk, cheese, yoghurt, eggs or gelatin); gluten-free diets (the woman eats no wheat, oats, barley or rye products – bread, pasta, breakfast cereals, etc.); weight-loss programmes; and malabsorption treatments.

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

Cross all that apply.

Section 3: Medical history

Section 3: Medical history					
Has she ever been diagnosed with or treated for any of the following medical conditions?					
17. Diabetes	<input type="checkbox"/>	<input type="checkbox"/>	28. Lupus erythematosus	<input type="checkbox"/>	<input type="checkbox"/>
18. Thyroid disease	<input type="checkbox"/>	<input type="checkbox"/>	29. HIV or AIDS	<input type="checkbox"/>	<input type="checkbox"/>
19. Other endocrinological condition	<input type="checkbox"/>	<input type="checkbox"/>	30. Hepatitis B or C	<input type="checkbox"/>	<input type="checkbox"/>
20. Any type of malignancy/cancer (including leukaemia or lymphoma)	<input type="checkbox"/>	<input type="checkbox"/>	31. Malaria - <i>within past 5 years</i>	<input type="checkbox"/>	<input type="checkbox"/>
21. Cardiac disease	<input type="checkbox"/>	<input type="checkbox"/>	32. Tuberculosis	<input type="checkbox"/>	<input type="checkbox"/>
22. Epilepsy	<input type="checkbox"/>	<input type="checkbox"/>	33. Thalassaemia	<input type="checkbox"/>	<input type="checkbox"/>
23. Mental illness e.g. Clinical depression	<input type="checkbox"/>	<input type="checkbox"/>	34. Sickle-cell anaemia	<input type="checkbox"/>	<input type="checkbox"/>
24. Hypertension/chronic hypertension with treatment	<input type="checkbox"/>	<input type="checkbox"/>	35. Thrombophilia	<input type="checkbox"/>	<input type="checkbox"/>
25. A chronic respiratory disease (including chronic asthma)	<input type="checkbox"/>	<input type="checkbox"/>	36. Glucose-6-phosphate dehydrogenase deficiency	<input type="checkbox"/>	<input type="checkbox"/>
26. Proteinuria, kidney disease or chronic renal disease	<input type="checkbox"/>	<input type="checkbox"/>	37. Any congenital abnormality or genetic disease	<input type="checkbox"/>	<input type="checkbox"/>
27. Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition	<input type="checkbox"/>	<input type="checkbox"/>	38. Any other clinically relevant condition	<input type="checkbox"/>	<input type="checkbox"/>

Has she ever been diagnosed with or treated for any of the following medical conditions?

For each condition:

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

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

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

17. **Diabetes** (any type)

18. **Thyroid disease** (Examples: hypo- or hyper-thyroidism, parathyroidism (PTH)). Malignant thyroid nodules should be classed as a type of malignancy/cancer (Question 20).

19. **Other endocrinological condition** (Examples: Addison's disease, adrenal gland disorders, hypophysitis)

20. **Any type of malignancy/cancer (including leukaemia or lymphoma)**

21. **Cardiac disease** (Examples: arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, sarcoma, pericarditis, cardiomyopathy, etc.)

22. **Epilepsy** (any type)

23. **Mental illness e.g. Clinical depression** (excluding mild depression without treatment). Include all forms of mental illness requiring treatment. Examples: clinical depression, schizophrenia, bipolar disorder, obsessive-compulsive disorder (OCD), generalised anxiety disorder.

24. **Hypertension/chronic hypertension with treatment.** Defined as 140/90 mmHg or greater. Include in this category any woman who has ever been treated for hypertension.

25. **A chronic respiratory disease** (including chronic asthma during adult life). Do not include childhood asthma that is no longer present or very mild cases/allergies. Other examples: chronic bronchitis, emphysema.

26. **Proteinuria, kidney disease or chronic renal disease.** Proteinuria is defined as the presence of excessive protein substance (chiefly albumin) in the urine.

27. **Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition** (requiring special diet)

28. **Lupus erythematosus** (a chronic inflammatory collagen disease affecting connective tissue)

29. **HIV or AIDS**

30. **Hepatitis B or C**

31. **Malaria – within past 5 years** (any episode within the past 5 years)

32. **Tuberculosis**

33. **Thalassaemia** (a quantitative haematological disorder affecting the production of the globin chains that make up haemoglobin)
34. **Sickle-cell anaemia** (if a woman has been diagnosed as a carrier only, do not consider this as a diagnosis for having the condition itself – place a 'X' in the box marked 'NO').
35. **Thrombophilia** (an abnormality of blood coagulation that increases the risk of thrombosis)
36. **Glucose-6-phosphate dehydrogenase deficiency** (abnormally low levels of the G6PD enzyme especially important in red blood cell metabolism)
37. **Any congenital abnormality or genetic disease** (Examples: cystic fibrosis, congenital heart defects). Do not include very mild abnormalities such as extra digits, skin tags, hare lips, or colobomas.
38. **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 4: Gynaecological history

NB Information required for this section must be obtained from direct interview with the woman. Question 42 requires the use of a laminated calendar as a visual aid.

Section 4: Gynaecological history	
39. Has she had regular (24-32 day) menstrual cycles in the 3 months prior to this pregnancy?	<input type="checkbox"/> yes <input type="checkbox"/> no
40. What is the average length of her menstrual cycle?	<input type="text"/> <input type="text"/> days
41. Has she used hormonal contraceptives or been breastfeeding in the 2 months prior to this pregnancy?	<input type="checkbox"/> yes <input type="checkbox"/> no
42. Is the first day of the last menstrual period (LMP) known?	<input type="checkbox"/> yes <input type="checkbox"/> no
43. If yes, date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	44. Was she certain of the date of her LMP? <input type="checkbox"/> yes <input type="checkbox"/> no

39. Has she had regular (24-32 day) menstrual cycles in the 3 months prior to this 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.

40. What is the average length of her menstrual cycle?

Enter the average length of her menstrual cycle, in days. Length is measured from the first day of bleeding during one cycle to the first day of bleeding during the next cycle.

If she gives a range of values, take the average of the top and bottom figures. Round up to the nearest whole number if necessary. Examples: (i) A range of '26 to 28' days should

be entered as '27' days; (ii) A range of '27 to 28' days (which yields an average of 27.5 days) should be entered as '28' days.

41. Has she used hormonal contraceptives or been breastfeeding in the 2 months prior to this 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'.

42. Is the first day of the last menstrual period (LMP) known?

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.

Place a 'X' in the box marked 'YES' if she knows the date of her LMP.

Place a 'X' in the box marked 'NO' if the first day of LMP is unknown.

43. If yes, date

If the answer to Question 42 is 'YES', enter the date of the first day of her last menstrual period (LMP) in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

44. Was she certain of the date of her LMP?

Place a 'X' in the box marked 'YES' if the woman was certain of the first day of her last menstrual period.

Place a 'X' in the box marked 'NO' if she was not certain or expresses any doubt over this date.

Section 5: Obstetric history

NB Information required for this section can be obtained from direct interview with the woman or from her medical records. Please be aware that this section contains questions which some women may find distressing – you may prefer to extract information for miscarriage, termination or stillbirth-related questions from her medical records.

Section 5: Obstetric history	
45. Number of previous pregnancies, excluding this pregnancy (if 0, skip to Question 66):	<input type="text"/> <input type="text"/>
46. Date of last delivery, miscarriage or termination:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
47. Has she ever had a molar pregnancy or choriocarcinoma?	<input type="text"/> yes <input type="text"/> no
48. Has she ever had an extrauterine or ectopic pregnancy?	<input type="text"/> yes <input type="text"/> no
49. Number of previous miscarriages:	<input type="text"/> <input type="text"/>
50. Number of previous terminations:	<input type="text"/> <input type="text"/>

45. Number of previous pregnancies, excluding this pregnancy (if 0, skip to Question 66)

Enter the number of previous pregnancies in the box (IMPORTANT: Do not include this pregnancy). If this is her first pregnancy, enter '00' and skip to Question 66 at the beginning of Section 6: 'Current pregnancy'. If she has had one previous pregnancy, enter '01'; if two, '02', etc.

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

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

46. Date of last delivery, miscarriage or termination

Enter the date on which her last pregnancy ended, regardless of whether it resulted in delivery, miscarriage or termination, in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Make every effort to obtain this date in full. Where possible extract this information from the medical records. If it is not at all possible to do so, ask the question directly bearing in mind that the date of miscarriage or termination may be a sensitive subject for some women. If the woman knows only the year or month-and-year for this event, enter this known information and replace the unknown details with 'xx'.

47. Has she ever had a molar pregnancy or choriocarcinoma?

Place a 'X' in the box marked 'YES' if she has ever had a molar pregnancy or choriocarcinoma.

Place a 'X' in the box marked 'NO' if she has never had a molar pregnancy or choriocarcinoma.

48. Has she ever had an extrauterine or ectopic pregnancy?

Place a 'X' in the box marked 'YES' if she has ever had an extrauterine or ectopic pregnancy.

Place a 'X' in the box marked 'NO' if she has never had an extrauterine or ectopic pregnancy.

49. Number of previous miscarriages

Enter the number of previous miscarriages in the box. For 0, enter '00'; for 1, enter '01', etc.

50. Number of previous terminations

Enter the number of previous terminations in the box. For 0, enter '00'; for 1, enter '01', etc.

Section 5: Obstetric history (continued)

51. Number of previous births (if 0, skip to Question 58):	<input type="text"/>	<input type="text"/>			
52. Birthweight of the immediately previous newborn:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	g
53. Gestational age at birth of the immediately previous newborn:	<input type="text"/>	<input type="text"/>	weeks	<input type="text"/>	days
54. Have ANY of her babies weighed less than 2500g?	<input type="text"/>	yes	<input type="text"/>	no	
55. Have ANY of her babies been born preterm (<37 ⁺⁰ weeks' gestation)?	<input type="text"/>	yes	<input type="text"/>	no	
56. Has she had ANY previous stillbirths?	<input type="text"/>	yes	<input type="text"/>	no	
57. Has she had ANY previous neonatal deaths?	<input type="text"/>	yes	<input type="text"/>	no	

51. Number of previous births (if 0, skip to Question 58)

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

Enter the number of previous births in the box. For 0, enter '00'; for 1, enter '01', etc. If she has had any multiple births, count each baby as 1.

If the woman has had no previous births, do not complete Questions 52 to 57. Skip to Question 58.

52. Birthweight of the immediately previous newborn

Enter the birthweight (in grams, without any decimal places) of the last baby she delivered, prior to this one. If not known, consult the medical records. If still not available, leave blank.

53. Gestational age at birth of the immediately previous newborn

Enter the gestational age at birth (in completed weeks and days) of the last baby she delivered, prior to this one.

54. Have ANY of her babies weighed less than 2500g?

2500g is approximately the equivalent of 5.5lb (5lb 8oz).

Place a 'X' in the box marked 'YES' if she has had a low birthweight (<2500g) baby.

Place a 'X' in the box marked 'NO' if she has never had a low birth weight (<2500g) baby.

If she is unsure, check her medical records or those of her children. If the birthweights are not available on the medical records, place a 'X' in the box marked 'NO'.

55. Have ANY of her babies been born preterm (<37⁺⁰ weeks' gestation)?

<37⁺⁰ 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 previously had a preterm baby.

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

If she is unsure, check her medical records or those of her children. If the gestational ages are not available on the medical records, place a 'X' in the box marked 'NO'.

56. Has she had ANY previous stillbirths?

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

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

Place a 'X' in the box marked 'NO' if she has had no previous pregnancies resulting in stillbirth.

57. Has she had ANY previous neonatal deaths?

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 neonatal death.

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

During any previous pregnancy, has she been diagnosed with or treated for any of the following conditions?					
58. Gestational diabetes	<input type="checkbox"/> yes	<input type="checkbox"/> no	62. Abruptio placentae	<input type="checkbox"/> yes	<input type="checkbox"/> no
59. Preeclampsia/Eclampsia/HELLP syndrome	<input type="checkbox"/> yes	<input type="checkbox"/> no	63. Postpartum depression	<input type="checkbox"/> yes	<input type="checkbox"/> no
60. Rhesus disease or anti-Kell antibodies	<input type="checkbox"/> yes	<input type="checkbox"/> no	64. Pyelonephritis or renal condition requiring bed rest >1 week or hospitalisation	<input type="checkbox"/> yes	<input type="checkbox"/> no
61. Severe anaemia that required hospitalisation	<input type="checkbox"/> yes	<input type="checkbox"/> no	65. Any other pregnancy-related condition requiring bed rest >1 week or hospitalisation (excluding delivery)	<input type="checkbox"/> yes	<input type="checkbox"/> no

During any previous pregnancy, has she been diagnosed with or treated for any of the following conditions?

For each condition:

Place a 'X' in the box marked 'YES' if she has ever been diagnosed with or taken any medication for that condition during any previous pregnancy.

Place a 'X' in the box marked 'NO' if she has never been diagnosed with or taken any medication for that condition during any previous pregnancy.

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

58. Gestational diabetes (defined as any degree of glucose intolerance with onset or first recognition during pregnancy)

59. Pre-eclampsia/Eclampsia/HELLP syndrome

Pre-eclampsia is defined as high blood pressure 140/90 mmHg or greater, or an increase of 30mmHg systolic or 15mmHg 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: **Haemolysis**, **EL** (elevated) liver enzymes and **LP** (low platelet) count.

60. **Rhesus disease or anti-Kell antibodies.** Rhesus disease – also known as isoimmunisation or RH – can occur when the mother is Rh negative and the baby is Rh positive. The transfer of anti-Kell antibodies from the mother to the fetus across the placental barrier can cause severe anaemia by interfering with the early proliferation of red blood cells.
61. **Severe anaemia that required hospitalisation** – severe anaemia is clinically defined as a haemoglobin level <7g/dl during pregnancy. For this question, an outpatients or day appointment to receive intravenous iron does constitute hospitalisation.
62. **Abruptio placentae** (i.e. placental abruption) refers to the partial or complete separation of the normally located placenta after the 20th week of gestation and prior to birth. The normal placenta separates from the uterus prematurely and blood collects between the placenta and the uterus.
63. **Postpartum depression** – a form of clinical depression, typically following childbirth.
64. **Pyelonephritis or renal condition requiring bed rest >1 week or hospitalisation** – 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.
65. **Any other pregnancy-related condition requiring bed rest >1 week or hospitalisation (excluding delivery)**

Do not include miscarriage as this is covered in Question 48.

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 was not admitted to hospital for a serious pregnancy-related condition during a previous pregnancy.

Section 6: Current pregnancy

Section 6: Current pregnancy			
During this pregnancy, has she been diagnosed with or treated for any of the following conditions?			
66. Threatened miscarriage	<input type="checkbox"/>	<input type="checkbox"/>	72. Any genital tract or sexually transmitted infection
67. Mental illness e.g. Clinical depression	<input type="checkbox"/>	<input type="checkbox"/>	73. Severe vomiting requiring hospitalisation
68. Malaria	<input type="checkbox"/>	<input type="checkbox"/>	74. Hypertension
69. Pyelonephritis or kidney disease	<input type="checkbox"/>	<input type="checkbox"/>	75. Rhesus disease or anti-Kell antibodies
70. Lower urinary tract infection requiring antibiotic treatment	<input type="checkbox"/>	<input type="checkbox"/>	76. Anaemia
71. HIV or AIDS	<input type="checkbox"/>	<input type="checkbox"/>	77. Other infection/febrile illness

During this pregnancy, has she been diagnosed with or treated for any of the following conditions?

For each condition:

Place a 'X' in the box marked 'YES' if any signs or symptoms of that condition have been clinically diagnosed or treated.

Place a 'X' in the box marked 'NO' if no signs or symptoms of that condition have been clinically diagnosed or treated.

If she is uncertain whether she has one or more of the conditions listed, check 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'.

66. 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.

67. Mental illness e.g. Clinical depression (excluding mild depression without treatment). Include all forms of mental illness requiring current treatment. Examples: clinical depression, schizophrenia, bipolar disorder, obsessive-compulsive disorder (OCD), generalised anxiety disorder.

68. Malaria (any episode)

69. Pyelonephritis or kidney disease – 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.

70. Lower urinary tract infection requiring antibiotic treatment (e.g. cystitis)

71. HIV or AIDS

72. Any genital tract or sexually transmitted infection (e.g. syphilis, gonorrhoea, trichomoniasis, genital warts, condyloma acuminata, candidiasis)

73. Severe vomiting requiring hospitalisation

74. Hypertension (systolic blood pressure >140 and/or diastolic blood pressure >90)

75. Rhesus disease or anti-Kell antibodies. Rhesus disease – also known as isoimmunisation or RH – can occur when the mother is Rh negative and the baby is Rh

positive. The transfer of anti-Kell antibodies from the mother to the fetus across the placental barrier can cause severe anaemia by interfering with the early proliferation of red blood cells.

76. **Anaemia** – a haemoglobin level <11g/dl during the current pregnancy. If the woman has not yet had any blood tests during this pregnancy, and has no symptoms of anaemia, tick 'NO'.

77. **Other infection/febrile illness**

Section 7: Next appointment

Section 7: Next appointment							
Please now arrange an ultrasound dating appointment for within the next 3 days.							
78. Date of the ultrasound dating appointment:	<table border="1"><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	Y	Y
D	D	M	M	Y	Y		

Please now arrange an ultrasound dating appointment for within the next 3 days.

78. **Date of the ultrasound dating appointment**

Enter the date of the scheduled ultrasound dating appointment in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'. Ensure that the **Ultrasound Dating Form** is completed immediately after the ultrasound dating appointment or within that week.

Ultrasound Dating Form (USD)

Important: Complete ALL questions. If the woman is accepted into the study after the ultrasound dating appointment, a patient identifier (PTID) label must be affixed to the header of this form for identification purposes.

For all women for whom a **Baseline Information Form** was completed, an ultrasound dating appointment should be made within 3 days (if the scan has not already been performed).

The information required to complete this form should be obtained during the ultrasound dating scan. The form should be completed by the research midwife, who will abstract the relevant information from the woman's notes.


If the woman IS eligible after the dating scan:

1. Inform the woman that she is eligible for the study. Begin a **Fetal Study Booklet** for her. Complete the front cover and the **Maternal Study Entry Form** (see [p.32-38](#)). PTID labels, which match the PTID Number pre-printed on the front of the booklet, will be located within the Fetal Study Booklet. Affix a PTID label to all pages of the **Baseline Information** and **Ultrasound Dating Forms**.
2. If your site is using the Study Appointment Cards, give her an **Appointment Card**, with the dates and times of her follow-up appointments and the contact details of the ultrasound clinic filled in.
3. Take blood samples from her (completing the **Sample Collection Slip**) and send these to the lab.
4. Affix an INTERBIO-21st Fetal Study sticker to the front of the woman's medical notes.
5. Once all required forms are completed (Informed Consent; Baseline Information; Ultrasound Dating; and Maternal Study Entry) review them for inconsistencies and missing data; make corrections as necessary. Sign the bottom of each form (completing also the researcher code and your name).
6. Pass the completed forms to the Data Management Unit for data entry.

If the woman IS NOT eligible after the dating scan:

1. Inform her that she is not a candidate for the study and that she will proceed with her routine antenatal care.
2. Pass the completed **Baseline Information** and **Ultrasound Dating Forms** to the Data Management Unit for data entry. *Do not affix a PTID label to either of these forms.*

Form Header

 UNIVERSITY OF OXFORD	INTERBIO-21st Fetal Study Ultrasound Dating	USD Page 1 of 1
AFFIX PTID LABEL HERE	Country Code	<input type="text" value="0"/> <input type="text" value="7"/> Hospital/Clinic Code
	Screening Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Date of Ultrasound Dating	<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 answer all yes/no questions by placing a 'X' in the corresponding box		

PTID Label: If the woman is accepted into the study after completion of the Ultrasound Dating Form, affix the woman's allocated patient identifier (PTID) label to the marked section. This is necessary to identify the woman.

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

Hospital/Clinic Code: Enter the code that corresponds to your hospital or clinic.

Screening Number: Enter the Screening Number assigned to the woman when completing the Baseline Information Form. Double-check that the number is correct – for example, by checking it against the log-book kept in the clinic (see [page 11](#)).

Date of Ultrasound Dating: Enter the date that the ultrasound dating scan was conducted, in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Please answer all yes/no questions by placing a 'X' in the corresponding box.

Section 1: Last menstrual period (LMP)

Section 1: Last menstrual period (LMP)	
1. First day of the woman's last menstrual period (LMP):	<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. First day of the woman's last menstrual period (LMP)

Enter the date of the first day of the woman's last menstrual period (LMP) in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-2010'.

2. Estimated gestational age by LMP (using the wheel provided)

Use the Obdisk gestational age wheel provided to calculate the gestational age of the fetus, using the first day of the last menstrual period (as recorded in Question 1) as a starting point (see next page for instructions).

Write down the estimated gestational age by LMP in completed weeks and days (0 to 6 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.

Instructions for use of Obdisk

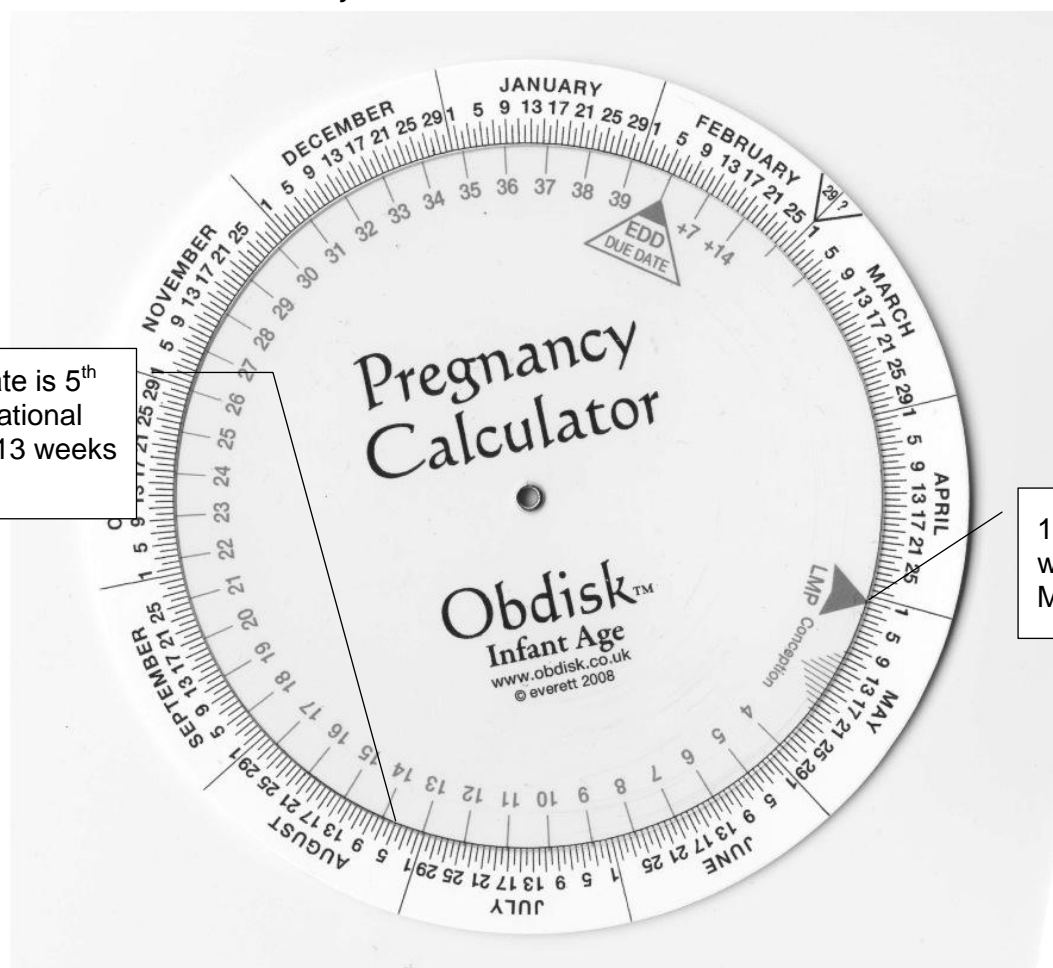
Turn the Obdisk to the side that reads 'Pregnancy Calculator'.

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

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

1. Determine the date of the LMP.
2. Turn the rotating disk so that the bold pink arrow labelled '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 1st May and today's date is 5th August. The pink arrow is turned to point exactly at 1st May. Follow the wheel round until you reach 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.



2. Today's date is 5th August. Gestational age today is 13 weeks and 5 days.

1. The LMP was on 1st May.

Section 2: Ultrasound observations

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

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

Place a 'X' in the box marked 'YES' if there is any evidence of fetal abnormality. Please refer to your local protocol for early congenital abnormality detection.

Section 3: Crown-rump length (CRL) measurements

Section 3: Crown-rump length (CRL) measurements	
7. 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. Is this less than 14 weeks?	<input type="checkbox"/> yes <input type="checkbox"/> no

7. CRL measurement

Write the value obtained for the crown-rump length (in millimetres).

Write the value to one decimal place. Example: If the CRL is 59.8mm, write '059.8mm' in the box – do not round up to 60mm.

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 age by CRL is 80 days, write '11' weeks and '3' days.

9. Is this less than 14 weeks?

Place a 'X' in the box marked 'YES' if the gestational age (as recorded in Question 8) is less than 14 weeks.

Place a 'X' in the box marked 'NO' if the gestational age (as recorded in Question 8) is more than or equal to 14 weeks.

Example: If the gestational age (by CRL) is 13 weeks and 6 days (97 days), place a 'X' in the box marked 'YES'; if it is 14 weeks (98 days), place a 'X' in the box marked 'NO'.

Section 4: Eligibility

Section 4: Eligibility	
10. Are all the shaded boxes (<input type="checkbox"/>) on this page marked with a 'X'?	<input type="checkbox"/> yes <input type="checkbox"/> no
<div style="border: 1px solid black; padding: 5px;"><p><i>If yes, the woman is eligible for the study. Continue to Section 5.</i></p><p><i>If no, the woman is <u>not</u> eligible for the study. No further action is required.</i></p></div>	

10. Are all the shaded boxes on this page marked with a 'X'?

The shaded boxes correspond to Questions 3, 4, 5, 6 and 9.

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

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

Section 5: How to proceed

Section 5: How to proceed
<p>If the woman is eligible for the study, please proceed as follows:</p> <ul style="list-style-type: none">(a) Complete the Maternal Study Entry Form in the Fetal Study Booklet.(b) Collect blood samples; complete the Sample Collection Slip.(c) Send samples to the lab.

If the woman is eligible for the study:

1. Inform the woman that she is eligible for the study. Begin a **Fetal Study Booklet** for her. Complete the front cover and the **Maternal Study Entry Form** (see [p.32-38](#)). PTID labels, which match the PTID Number pre-printed on the front of the booklet, will be located within the Fetal Study Booklet. Affix a PTID label to all pages of the **Baseline Information** and **Ultrasound Dating Forms**.
2. If your site is using the Study Appointment Cards, give her an **Appointment Card**, with the dates and times of her follow-up appointments and the contact details of the ultrasound clinic filled in.
3. Take blood samples from her (completing the **Sample Collection Slip**) and send these to the lab.
4. Affix an INTERBIO-21st Fetal Study sticker to the front of the woman's medical notes.
5. Once all required forms are completed (Informed Consent; Baseline Information; Ultrasound Dating; and Maternal Study Entry) review them for inconsistencies and missing data; make corrections as necessary. Sign the bottom of each form (completing also the researcher code and your name).
6. Pass the completed forms to the Data Management Unit for data entry.

If the woman IS NOT eligible for the study:

1. Inform her that she is not a candidate for the study and that she will proceed with her routine antenatal care.
2. Pass the completed **Baseline Information** and **Ultrasound Dating Forms** to the Data Management Unit for data entry. *Do not affix a PTID label to either of these forms.*

Maternal Study Entry Form (MSE)

This form can be found at the front of the **Fetal Study Booklet** (one booklet per woman).

Double-check that the woman has read the patient information leaflet and signed the **Informed Consent Form**.

The front cover of a new **Fetal Study 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 10 on the **Ultrasound Dating Form** is 'YES'). The stock of booklets should be easily accessible for when a subject is found to be eligible.

A sheet of adhesive patient identifier (PTID) labels (comprising a computer-readable barcode and a numeric identification code which match those pre-printed on the front of the booklet) will be located within the Fetal Study Booklet. Affix a PTID label to all pages of the completed **Baseline Information** and **Ultrasound Dating Forms**. It is important that the midwife responsible for recruitment keeps a log-book or database of participants' names, contact details and PTIDs in the centre.

[Note: The sheet of PTID labels within the Fetal Study Booklet has been split into two sections, perforated down the middle. Those on the left-hand side are intended for use at recruitment and at the follow-up appointments; this half of the label sheet should remain attached within the booklet for the duration of the study. Those on the right-hand side are intended for use at delivery; at recruitment, please tear along the perforations, detach this half of the label sheet and place it in the woman's medical notes for use at delivery.]

If any sections of this form can be completed in full using information from accessible medical records then this information can be extracted for this purpose. However, any information which cannot be found in her medical records must be obtained during the interview with the woman.

For Section 2, weight will need to be taken using the Adult Scale (Seca 877 Portable Digital Scale) and height using the Adult Stadiometer (Seca 242 Digital Display). Remember to calibrate the machines regularly according to the instructions in the Anthropometry Manual.

Blood pressure is to be taken using the Microlife Blood Pressure Monitor for Pregnant Women, following the manufacturer's guidelines and the instructions in [Appendix 3](#) of this document.


If lab tests for proteinuria, urine culture and haemoglobin are conducted for clinical purposes, please enter the results in the appropriate section. Do not especially take a urine or blood sample specifically to complete these fields.

Take blood samples for the biobank (completing the **Sample Collection Slip**) according to the guidelines laid out in the Biological Sample Collection Operations Manual. Send these with the completed slip to the lab.

If your site is using the Study Appointment Cards, before the woman leaves make sure that she has an **Appointment Card**, with the date and time of her next follow-up appointment filled in. Ensure she is provided with the appropriate contact details.

Once completed, all forms should be reviewed for missing values or inconsistencies and then passed to the Data Management Unit for data entry.

Form Header

 UNIVERSITY OF OXFORD		INTERBIO-21st Fetal Study Maternal Study Entry				MSE Page 1 of 1									
INTERBIO-21 st PTID Number	0	7	-	1	0	0	0	0	Hospital/Clinic Code						
Antenatal Record No.															
Screening Number															
Maternal Date of Birth	D	D	M	M	Y	Y			Visit Date	D	D	M	M	Y	Y
Please answer all yes/no questions by placing a 'X' in the corresponding box															

INTERBIO-21st PTID Number: This is the woman's patient identifier (PTID) number for the study and is pre-printed on the front of the booklet, on the labels attached within the booklet, and in all headers on each form within the booklet.

Hospital/Clinic Code: Enter the code that corresponds to the hospital or clinic where the woman receives her routine ANC care and was screened for the study.

Antenatal Record No.: This number is the hospital/clinic's own internal reference number for the woman; it can be used to help identify the woman and link the information on this form with her medical records.

Screening Number: Enter the Screening Number assigned to the woman when completing the Baseline Information Form. Double-check that the number is correct by checking it against the log-book/database kept in the clinic.

Maternal Date of Birth: Enter the woman's date of birth in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'. Make every effort to obtain her date of birth in full. If, however, she knows only the year or month-and-year of her birth, enter this known information and replace the unknown details with 'xx'.

Visit Date: Enter the date of this visit in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Please answer all yes/no questions by placing a 'X' in the corresponding box.

Section 1: Demography

NB Information required for this section must be obtained from direct interview with the woman.

Section 1: Demography	
<p>1. Marital status: (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 attended: (cross one box only)</p> <p>No school attended <input type="checkbox"/> Professional/technical training <input type="checkbox"/></p> <p>Primary <input type="checkbox"/> University <input type="checkbox"/></p> <p>Secondary <input type="checkbox"/></p>	<p>4. Which of the following best describes her occupational status? (cross one box only)</p> <p>Managerial/professional/technical <input type="checkbox"/> Skilled manual work <input type="checkbox"/></p> <p>Clerical support, service or sales <input type="checkbox"/> Unskilled manual work <input type="checkbox"/></p> <p>Housework <input type="checkbox"/> Other <input type="checkbox"/></p> <p>Student <input type="checkbox"/></p> <p>5. Father's age: <input type="text"/> <input type="text"/> years</p>

1. Marital status

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

- Place a 'X' next to **Single** if the woman has never been married and does not live with a partner;
- Place a 'X' next to **Married/Cohabiting** if the woman is married or living with a partner;
- Place a 'X' next to **Widowed** if the woman's partner has died;
- Place a '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 of formal education

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 the end total 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. Highest level of education attended

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

- **No school attended;**
- **Primary school** (age 5-11 or similar);
- **Secondary school** (age 11-16 or 11-18 in some cases);
- **Professional/technical training** (vocational training or 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 her occupational status?

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

See the occupational classification scheme in [Appendix 2](#) for clarification as to which occupations fall under each category.

5. Father’s age

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

Section 2: Current pregnancy

NB For Questions 6, 7 and 15, measurements should be taken using the equipment provided for this study.

Section 2: Current pregnancy	
6. Height: <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm	7. Weight (at this visit): <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg
8. Proteinuria (by dipstick): (cross one box only) 0 / trace <input type="checkbox"/> + <input type="checkbox"/> ++ <input type="checkbox"/> +++ <input type="checkbox"/> +++++ <input type="checkbox"/> No urine test available <input type="checkbox"/>	12. Urine culture: (cross one box only) Positive <input type="checkbox"/> Negative <input type="checkbox"/> No urine culture result <input type="checkbox"/>
and/or actual result (from urine sample) received from laboratory: <input type="text"/> <input type="text"/> <input type="text"/> mg/dl	13. If positive, was antibiotic treatment given? <input type="checkbox"/> yes <input type="checkbox"/> no
9. Has she had a syphilis test? <input type="checkbox"/> yes <input type="checkbox"/> no	14. Haemoglobin level: <input type="text"/> <input type="text"/> . <input type="text"/> g/dl <u>OR</u> Haematocrit: <input type="text"/> <input type="text"/> . <input type="text"/> %
10. If yes, was the result positive? <input type="checkbox"/> yes <input type="checkbox"/> no	15. Blood pressure: Systolic <input type="text"/> <input type="text"/> <input type="text"/> mmHg Diastolic <input type="text"/> <input type="text"/> <input type="text"/> mmHg
11. If positive, was treatment given? <input type="checkbox"/> yes <input type="checkbox"/> no	

6. Height

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

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’ – do not round up to 161cm.

7. Weight (at this visit)

Take the woman’s weight once using the Adult Scale (Seca 877 Portable Digital Scale).

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' – do not round down to 60kg or up to 60.5kg.

8. Proteinuria

Complete this question only if a urine sample was taken for clinical purposes – do not take an additional sample if this is not part of routine antenatal care.

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

If proteinuria is reported in the lab results, enter the actual value in milligrams/decilitre (mg/dl) in the corresponding box.

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

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

9. Has she had a syphilis test?

Place a 'X' in the box marked 'YES' if she has had a Venereal Disease Research Laboratory (VDRL) test.

Place a 'X' in the box marked 'NO' if she has not had a VDRL test. Leave the responses to Questions 10 and 11 blank, and skip to Question 12.

10. If yes, was the result positive?

Place a 'X' in the box marked 'YES' if she has had a positive VDRL test.

Place a 'X' in the box marked 'NO' if she has not had a positive VDRL test. Leave the response to Question 11 blank, and skip to Question 12.

11. If positive, was treatment given?

Place a 'X' in the box marked 'YES' if she received treatment for syphilis after the positive test result.

Place a 'X' in the box marked 'NO' if the positive syphilis test result was not treated.

12. Urine culture

Complete this question only if a urine sample was taken for clinical purposes – do not take an additional sample if this is not part of routine antenatal care. Cross one box only.

Place a 'X' next to 'Positive' if the urine culture showed evidence of a urinary tract infection.

Place a 'X' next to 'Negative' if the urine culture showed no evidence of a urinary tract infection.

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

If 'Negative' or 'No urine culture available', leave the response to Question 13 blank, and skip to Question 14.

13. If positive, was antibiotic treatment given?

Place a 'X' in the box marked 'YES' if antibiotic treatment was given after the positive test result.

Place a 'X' in the box marked 'NO' if the positive urine culture result was not treated.

14. Haemoglobin level OR Haematocrit

Complete this question only if a blood sample was taken for clinical purposes – do not take an additional sample if this is not part of routine antenatal care.

Obtain the results from the lab and – in the corresponding box – enter the haemoglobin level in grams/decilitre (g/dl) or the haematocrit result as a percentage (%) – whichever is usually assessed in your hospital/clinic.

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

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

15. Blood pressure

Take the blood pressure reading using the Microlife 'Blood Pressure Monitor for Pregnant Women', following the manufacturer's guidelines and the instructions in [Appendix 3](#) of this document.

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

Section 3: Nutritional supplements

Section 3: Nutritional supplements					
Does she routinely take any of the following nutritional supplements?					
16. Multi-vitamins/minerals	<input type="checkbox"/> yes	<input type="checkbox"/> no	19. Vitamin D	<input type="checkbox"/> yes	<input type="checkbox"/> no
17. Iron	<input type="checkbox"/> yes	<input type="checkbox"/> no	20. Calcium	<input type="checkbox"/> yes	<input type="checkbox"/> no
18. Folic acid	<input type="checkbox"/> yes	<input type="checkbox"/> no	21. Selenium	<input type="checkbox"/> yes	<input type="checkbox"/> no
			22. Food supplements	<input type="checkbox"/> yes	<input type="checkbox"/> no
			23. Cod liver oil	<input type="checkbox"/> yes	<input type="checkbox"/> no
			24. Other fish oil	<input type="checkbox"/> yes	<input type="checkbox"/> no

Does she routinely take any of the following nutritional supplements?

For each nutritional supplement:

Place a 'X' in the box marked 'YES' if she routinely takes that supplement.

Place a 'X' in the box marked 'NO' if she does not routinely take that supplement.

'Routinely' is defined as 'for more than one month'. Do not (for example) cross 'YES' for Question 21: 'Selenium' for a woman who has received a one-off supplement of selenium.

If she routinely takes multi-vitamins or minerals place a 'X' in the box marked 'YES' for Question 16. If this supplement includes any of the others listed, do not place a 'X' in the box marked 'YES' for the other supplement unless an additional preparation of that supplement, other than the multi-vitamins/minerals, is taken.

Example: If a woman takes a multi-vitamin/mineral supplement which includes iron, but she takes no other supplement of iron specifically, then place a 'X' in the box marked 'YES' for Question 16: 'Multi-vitamins/minerals' and a 'X' in the box marked 'NO' for Question 17: 'Iron'.

16. **Multi-vitamins/minerals** (see note above in cases where multi-vitamin/mineral supplement includes any of the other listed supplements)
17. **Iron**
18. **Folic acid**
19. **Vitamin D**
20. **Calcium**
21. **Selenium**
22. **Food supplements** e.g. high energy/calorie supplements for weight gain during pregnancy.
23. **Cod liver oil**
24. **Other fish oil** (i.e. a fish oil that is not cod liver oil)

Section 4: Next appointment

Section 4: Next appointment							
Please now arrange the next ultrasound appointment for within 5 weeks (\pm 1 week) of today.							
25. Date of the next ultrasound appointment:	<table border="1"><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	Y	Y
D	D	M	M	Y	Y		

Please now arrange the next ultrasound appointment for within 5 weeks (\pm 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 INTERBIO-21st study ultrasonographer.** Ensure that she has a written record of the date of her next visit in her **Appointment Card**.

25. Date of the next ultrasound appointment

Enter the date in the format dd-mm-yy, e.g. '20th May 2010' should be written '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 (± 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. *All scanning must be done by an INTERBIO-21st trained 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-21st Ultrasound Handbook and follow the advice 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, contact her as soon as possible to arrange another appointment *within the same week*. If this is not possible, skip to the next scheduled follow-up visit.

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

- Delivery of any kind (term or preterm);
- Miscarriage/Fetal death/Induced termination;
- Maternal death.

Form Header

 UNIVERSITY OF OXFORD	INTERBIO-21st Fetal Study Ultrasound Follow-up		UFU1 Page 1 of 1
	INTERBIO-21 st PTID Number	<input type="text" value="0"/> <input type="text" value="7"/> - <input type="text" value="1"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/>	Hospital/Clinic Code
Antenatal Record No.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
Maternal 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"/>	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"/>
Please answer all yes/no questions by placing a 'X' in the corresponding box			

INTERBIO-21st PTID Number: This is the woman's patient identifier (PTID) number for the study and is pre-printed on the front of the booklet, on the labels attached within the booklet, and in all headers on each form within the booklet.

Hospital/Clinic Code: Enter the code that corresponds to the hospital or clinic where the woman receives her routine ANC care and was screened for the study.

Antenatal Record No.: This number is the hospital/clinic's own internal reference number for the woman; it can be used to help identify the woman and link the information on this form with her medical records.

Maternal Date of Birth: Enter the woman's date of birth in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'. Make every effort to obtain her date of birth in full. If, however, she knows only the year or month-and-year of her birth, enter this known information and replace the unknown details with 'xx'.

Date of Ultrasound: Enter the date of this ultrasound scan in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Please answer all yes/no questions by placing a 'X' in the corresponding box.

Section 1: Ultrasound observations

Section 1: Ultrasound observations	
1. Are there any fetal abnormalities? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, please complete the Fetal Abnormality Form .	4. Placental localisation: (cross one box only)
2. Fetal presentation: (cross one box only)	Fundal <input type="checkbox"/> Low anterior <input type="checkbox"/> High anterior <input type="checkbox"/> Low posterior <input type="checkbox"/> High posterior <input type="checkbox"/> Low left lateral <input type="checkbox"/> High left lateral <input type="checkbox"/> Low right lateral <input type="checkbox"/> High right lateral <input type="checkbox"/>
3. Amniotic fluid volume: (cross one box only)	5. Can the uterine cervix be visualised transabdominally? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, length: <input type="text"/> <input type="text"/> mm
Cephalic <input type="checkbox"/> Transverse <input type="checkbox"/> Breech <input type="checkbox"/> Oblique <input type="checkbox"/>	
Normal <input type="checkbox"/> Moderately reduced <input type="checkbox"/> Moderately increased <input type="checkbox"/> Oligohydramnios <input type="checkbox"/> Polyhydramnios <input type="checkbox"/> Anhydramnios <input type="checkbox"/>	

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

1. Are there any fetal abnormalities?

Place a 'X' in the box marked 'YES' if there is any evidence of congenital abnormality. Complete a **Fetal Abnormality Form** to provide further information.

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

2. Fetal presentation

Place a 'X' in the box that best corresponds to the fetal presentation. Cross one box only.

3. Amniotic fluid volume

Place a 'X' in the box that best corresponds to the amniotic fluid volume. Cross one box only.

4. Placental localisation

Place a 'X' in the box that best corresponds to the localisation of the placenta. Cross one box only.

5. Can the uterine cervix be visualised transabdominally?

Place a 'X' in the box marked 'YES' if the uterine cervix can be visualised by transabdominal ultrasound. In the corresponding boxes, enter the cervical length in millimetres (mm). Round up to the nearest mm.

Place a 'X' in the box marked 'NO' if the uterine cervix cannot be visualised by transabdominal ultrasound. Continue to Question 6.

Section 2: Ultrasound measurements

Section 2: Ultrasound measurements				
Were the following measurements obtained from three separately generated images?				
	yes	no	Image quality rating	
6. Biparietal diameter (BPD)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> / 6	11. Abdominal circumference (AC)
7. Occipito-frontal diameter (OFD)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> / 6	12. Femur length (FL)
8. Head circumference (HC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> / 6	13. Was the Amniotic Fluid Index (AFI) measurement obtained?
9. Transverse abdominal diameter (TAD)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> / 6	<input type="checkbox"/> yes <input type="checkbox"/> no
10. Anterior-posterior abdominal diameter (APAD)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> / 6	

Were the following measurements obtained from three separately generated images?

For each measurement in Questions 6 to 12:

Place a X in the box marked 'YES' if the image was obtained 3 times from 3 separately generated images.

Place a X in the box marked 'NO' if the image was not obtained 3 times from 3 separately generated images.

Additionally, in the third column of boxes write down the maximum Image Quality score of the 3 images, using the criteria in the table below:

NB Each of the qualities outlined in the table above contributes 1 point towards the total Image Quality score for any given measurement.

BPD / OFD / HC	TAD / APAD / AC	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	Callipers placed correctly
Fetal head occupies at least 30% of the total image size	Abdomen occupies at least 30% of the total image size	
Callipers and dotted ellipse placed correctly	Callipers and dotted ellipse placed correctly	

6. **Biparietal diameter (BPD)**

7. **Occipito-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)** (NB The image quality rating for FL is rated out of 4 – not 6)

13. **Was the Amniotic Fluid Index (AFI) 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 a 'X' in the box marked YES if the measurement was successfully obtained.

Place a 'X' in the box marked NO if the measurement was not successfully obtained.

NB There is no image quality rating required for the AFI measurement.

Section 3: Doppler examinations

Section 3: Doppler examinations			
14. Were the Uterine Doppler measurements obtained? <i>If yes, continue to Question 15; if no, skip to Question 23.</i>			yes <input type="checkbox"/> no <input type="checkbox"/>
Uterine arteries	LEFT artery	RIGHT artery	Umbilical artery
15. Notch?	yes <input type="checkbox"/> no <input type="checkbox"/>	yes <input type="checkbox"/> no <input type="checkbox"/>	19. End diastolic flow: (cross one box only) Positive <input type="checkbox"/> Absent <input type="checkbox"/> Reversed <input type="checkbox"/>
16. Pulsatility index (PI):	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	20. Pulsatility index (PI): <input type="text"/> . <input type="text"/>
17. Resistance index (RI):	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	21. Resistance index (RI): <input type="text"/> . <input type="text"/>
18. Systolic/Diastolic (SD) ratio:	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	22. Systolic/Diastolic (SD) ratio: <input type="text"/> . <input type="text"/>

14. Were the Uterine Doppler measurements obtained?

Place a 'X' in the box marked 'YES' if the Uterine Doppler measurements were obtained. Continue to Question 15.

Place a 'X' in the box marked 'NO' if the Uterine Doppler measurements were not obtained. Leave the responses to Questions 15 to 22 blank, and skip to Question 23.

For Questions 15 to 18, take measurements for the left and right uterine arteries. Enter the requested information in the corresponding boxes.

15. Notch?

Place a 'X' in the box marked 'YES' if notch was seen in the Doppler trace.

Place a 'X' in the box marked 'NO' if no notch was seen in the Doppler trace.

16. Pulsatility index (PI)

Enter the value of the pulsatility index for each uterine artery, to two decimal places.

17. Resistance index (RI)

Enter the value of the resistance index for each uterine artery, to two decimal places.

18. Systolic/Diastolic (SD) ratio

Enter the value of the systolic/diastolic ratio for each uterine artery, to two decimal places.

For Questions 19 to 22, take measurements for the umbilical artery only if the estimated gestational age is 24 weeks or above. If the estimated gestational age is below 24 weeks, leave the responses to Questions 19 to 22 blank, and skip to Question 23.

19. End diastolic flow

Place a 'X' in the box which best describes the end diastolic flow. Cross one box only.

20. Pulsatility index (PI)

Enter the value of the pulsatility index for the umbilical artery, to two decimal places.

21. Resistance index (RI)

Enter the value of the resistance index for the umbilical artery, to two decimal places.

22. Systolic/Diastolic (SD) ratio

Enter the value of the systolic/diastolic ratio for the umbilical artery, to two decimal places.

Section 4: Next appointment

Section 4: Next appointment	
If not already done, please now arrange the next ultrasound appointment for within 5 weeks (\pm 1 week) of today.	
23. 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 not already done, please now arrange the next ultrasound appointment for within 5 weeks (\pm 1 week) of today.

23. Date of next ultrasound appointment

Enter the date of the next scheduled ultrasound appointment in the format dd-mm-yy, e.g. '20th May 2010' should be written '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 (± 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, contact her as soon as possible to arrange another appointment *within the same week*. If this is not possible, skip to the next scheduled follow-up visit.

If any sections of this form can be completed in full using information from accessible medical records then this information can be extracted for this purpose. However, any information which cannot be found in her medical records must be obtained during the interview with the woman.

In particular, questions in Section 1 regarding high-risk activities and diet will need to be asked directly to the woman. For questions marked 'see table', use the relevant flip-chart page (see [Appendix 1](#)) to prompt the woman for an appropriate answer.

For Section 1, weight will need to be taken using the Adult Scale (Seca 877 Portable Digital Scale) and height using the Adult Stadiometer (Seca 242 Digital Display). Remember to calibrate the machines regularly according to the instructions in the Anthropometry Manual.

Blood pressure is to be taken using the Microlife Blood Pressure Monitor for Pregnant Women, following the manufacturer's guidelines and the instructions in [Appendix 3](#) of this document.


If lab tests for proteinuria, urine culture and haemoglobin have been conducted since the last visit and the results are available, please enter the results in the appropriate section. Do not especially take a urine or blood sample specifically to complete these fields.

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

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

- Delivery of any kind (term or preterm);
- Miscarriage/Fetal death/Induced termination;
- Maternal death.

Form Header

 UNIVERSITY OF OXFORD	INTERBIO-21st Fetal Study Pregnancy Follow-up		PFU1 Page 1 of 2	
	INTERBIO-21 st PTID Number	<input type="text" value="0"/> <input type="text" value="7"/> -	<input type="text" value="1"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/>	Hospital/Clinic Code
Antenatal Record No.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			
Maternal 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"/>	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"/>	
Please answer all yes/no questions by placing a 'X' in the corresponding box				

INTERBIO-21st PTID Number: This is the woman's patient identifier (PTID) number for the study and is pre-printed on the front of the booklet, on the labels attached within the booklet, and in all headers on each form within the booklet.

Hospital/Clinic Code: Enter the code that corresponds to the hospital or clinic where the woman receives her routine ANC care and was screened for the study.

Antenatal Record No.: This number is the hospital/clinic's own internal reference number for the woman; it can be used to help identify the woman and link the information on this form with her medical records.

Maternal Date of Birth: Enter the woman's date of birth in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'. Make every effort to obtain her date of birth in full. If, however, she knows only the year or month-and-year of her birth, enter this known information and replace the unknown details with 'xx'.

Visit Date: Enter the date of this visit in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Please answer all yes/no questions by placing a 'X' in the corresponding box.

Section 1: Pregnancy status

NB Information required for the second part of this section (Questions 9-16) must be obtained from direct interview with the woman. For Questions 1-3 and 8, measurements should be taken using the equipment provided for this study.

Section 1: Pregnancy status	
1. Weight (at this visit): <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg	5. Urine culture: (cross one box only) Positive <input type="checkbox"/> Negative <input type="checkbox"/> No urine culture result <input type="checkbox"/>
2. Father's height: (if it can be obtained at this visit) <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm	6. If positive, was antibiotic treatment given? <input type="checkbox"/> yes <input type="checkbox"/> no
3. Symphyseal-fundal height: <input type="text"/> <input type="text"/> . <input type="text"/> cm	7. Haemoglobin level: <u>OR</u> Haematocrit: <input type="text"/> <input type="text"/> . <input type="text"/> g/dl <input type="text"/> <input type="text"/> . <input type="text"/> %
4. Proteinuria (by dipstick): (cross one box only) 0 / trace <input type="checkbox"/> + <input type="checkbox"/> ++ <input type="checkbox"/> +++ <input type="checkbox"/> ++++ <input type="checkbox"/> No urine test available since last visit <input type="checkbox"/> and/or actual result (from urine sample) received from laboratory: <input type="text"/> <input type="text"/> <input type="text"/> mg/dl	8. Blood pressure: Systolic <input type="text"/> <input type="text"/> <input type="text"/> mmHg Diastolic <input type="text"/> <input type="text"/> <input type="text"/> mmHg

1. Weight (at this visit)

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

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' – do not round down to 60kg or up to 60.5kg.

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

If the father is available to be measured, take his height once using the Adult Stadiometer (Seca 242 Digital Display).

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

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

3. Symphyseal-fundal height

Take the symphyseal-fundal height measurement, following the instructions in [Appendix 4](#) 'Measurement of Symphyseal-fundal Height'. Enter the value obtained in centimetres (cm) in the corresponding box, to 1 decimal place.

4. Proteinuria

Complete this question only if a test for proteinuria has been conducted since the last visit. Do not especially take a urine sample specifically to complete this field.

Check the woman's medical records to see if a test for proteinuria has been conducted since the last visit; obtain the results of the most recent urinalysis.

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

If proteinuria is reported in the lab results, enter the actual value in milligrams/decilitre (mg/dl) in the corresponding box.

If the results are not available and are not in the medical records, leave the field blank.

5. **Urine culture**

Complete this question only if a test for urine culture has been conducted since the last visit. Do not especially take a urine sample specifically to complete this field.

Check the woman's medical records to see if a test for urine culture has been conducted since the last visit; obtain the most recent results. Cross one box only.

Place a 'X' next to 'Positive' if the urine culture showed evidence of a urinary tract infection.

Place a 'X' next to 'Negative' if the urine culture showed no evidence of a urinary tract infection.

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

If 'Negative' or 'No urine culture result', leave the response to Question 5 blank, and skip to Question 6.

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

Place a 'X' in the box marked 'YES' if antibiotic treatment was given after the positive test result.

Place a 'X' in the box marked 'NO' if the positive urine culture result was not treated.

7. **Haemoglobin level OR Haematocrit**

Complete this question only if a test for haemoglobin levels or a haematocrit has been conducted since the last visit. Do not especially take a blood sample specifically to complete this field.

Check the woman's medical records to see if a test for haemoglobin levels or a haematocrit has been conducted since the last visit.

Obtain the most recent results from the lab and – in the corresponding box – enter the haemoglobin level in grams/decilitre (g/dl) or the haematocrit as a percentage (%) – whichever is usually assessed in your hospital/clinic.

If the results are not available and are not in the medical records, leave the field blank.

8. **Blood pressure**

Take the blood pressure reading using the Microlife 'Blood Pressure Monitor for Pregnant Women', following the manufacturer's guidelines and the instructions in [Appendix 3](#) 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, leave these boxes blank.

Since her last visit:	
9. Has she smoked?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, how many cigarettes/cigars per day?	<input type="text"/> <input type="text"/>
10. Has she lived in the same household as someone who smokes?	<input type="checkbox"/> yes <input type="checkbox"/> no
11. Has she sniffed/chewed tobacco?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, how many times per day?	<input type="text"/> <input type="text"/>
12. Has she chewed betelnut?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, how many nuts per day?	<input type="text"/> <input type="text"/>
13. On average, how many units of alcohol per week has she had? (1 unit = small glass (125ml) of wine or one bottle/can (330ml) of beer; see table)	<input type="text"/> <input type="text"/>
14. Has she taken any recreational drugs? (see table)	<input type="checkbox"/> yes <input type="checkbox"/> no
15. Has she been involved in any of the following high-risk occupations or activities? (cross all that apply; see table)	
Frequent exposure to chemical/toxic substances	<input type="checkbox"/>
Frequent physically demanding work	<input type="checkbox"/>
Frequent high-risk sports/vigorous exercise	<input type="checkbox"/>
16. Has she followed any of the following special diets? (cross all that apply; see table)	
Vegetarian with no animal products	<input type="checkbox"/>
Gluten-free	<input type="checkbox"/>
Weight loss programme	<input type="checkbox"/>
Malabsorption treatment	<input type="checkbox"/>

Since her last visit:

9. Has she smoked?

Place a 'X' in the box marked 'YES' if she has smoked cigarettes, cigars (including cheroots) or shisha since her last visit.

Place a 'X' in the box marked 'NO' if she has not smoked cigarettes, cigars (including cheroots) or shisha since her last visit.

If yes, how many cigarettes/cigars per day?

If she has smoked cigarettes or cigars (including cheroots), write the average number of cigarettes or cigars that she smoked on a typical day. If her smoking habits have changed during the course of the last 5 weeks, write the maximum that she was smoking at any time point. 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.

For shisha, one puff = ½ cigarette. A whole pipe = 15.

10. Has she lived in the same household as someone who smokes?

Place a 'X' in the box marked 'YES' if since her last visit she has lived in the same household as someone who smokes.

Place a 'X' in the box marked 'NO' if since her last visit she has not lived in the same household as someone who smokes.

11. Has she sniffed/chewed tobacco?

Place a 'X' in the box marked 'YES' if the woman reports sniffing or chewing tobacco since her last visit.

Place a 'X' in the box marked 'NO' if the woman has not sniffed or chewed tobacco since her last visit.

If yes, how many times per day?

If she has sniffed or chewed tobacco, write the average number of times that she sniffed or chewed it on a typical day. If her habits have changed during the course of the last 5 weeks, write the maximum that she was sniffing/chewing at any time point. For example, if she was chewing tobacco 20 times per day but has cut down to 10 in the last 2 weeks, write '20' for this visit.

12. Has she chewed betelnut?

Place a 'X' in the box marked 'YES' if the woman reports chewing betelnut since her last visit.

Place a 'X' in the box marked 'NO' if the woman has not chewed betelnut since her last visit.

If yes, how many nuts per day?

If she has chewed betelnut, write the average number of nuts that she chewed on a typical day. If her habits have changed during the course of the last 5 weeks, write the maximum that she was chewing at any time point. For example, if she was chewing 20 nuts per day but has cut down to 10 in the last 2 weeks, write '20' for this visit.

13. On average, how many units of alcohol per week has she had?

Show the woman the relevant page on the flip-chart (see [Appendix 1](#)) and write the number of units of alcohol she has consumed in a typical week (to the nearest whole number).

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

14. Has she taken any recreational drugs?

Show the woman the relevant page on the flip-chart (see [Appendix 1](#)). Recreational drugs include heroin, methadone, crack/cocaine, amphetamines (including ya ba and khat), hallucinogens, cannabis (in South Africa, also called 'dugga'), benzodiazepines (including diazepam), inhalants/solvents, and any other recreational drugs.

Place a 'X' in the box marked 'YES' if the woman has taken (or cannot remember if she has taken) any of these recreational drugs since her last visit.

Place a 'X' in the box marked 'NO' if the woman has not taken any of these recreational drugs since her last visit.

15. Has she been involved in any of the following high-risk occupations or activities?

Show the woman the relevant page on the flip-chart (see [Appendix 1](#)) and place a 'X' in the corresponding box if she is involved in one or more of the high-risk occupations or activities shown in the table on a frequent basis.

If she is unsure but thinks she may have been involved in one or more of these activities, still place a 'X' in the corresponding box(es).

NB If she frequently walks for several hours per day (i.e. more than 4 times per week in the 2nd half of pregnancy, as above), this could be considered 'vigorous exercise' and the third option 'Frequent high-risk sports/vigorous exercise' should be crossed. Do not

include in this category the occasional long walk (e.g. to the hospital for an appointment once a month).

16. Has she followed any of the following special diets?

Show the woman the relevant page on the flip-chart (see [Appendix 1](#)) and place a 'X' in the corresponding box if she follows one or more of these special diets.

Special diets include: vegetarian with no animal products (sometimes known as 'vegan', meaning that the woman eats no meat, fish, milk, cheese, yoghurt, eggs or gelatin); gluten-free diets (the woman eats no wheat, oats, barley or rye products – bread, pasta, breakfast cereals, etc.); weight-loss programmes; and malabsorption treatments.

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

Section 2: Current health

Section 2: Current health			
Since her last visit has she been diagnosed with or treated for any of the following?			
17. Diabetes, thyroid disease or any other endocrinological condition	<input type="checkbox"/>	<input type="checkbox"/>	
18. Any type of malignancy/cancer (if yes, please complete an Adverse Event Form)	<input type="checkbox"/>	<input type="checkbox"/>	
19. Cardiac disease	<input type="checkbox"/>	<input type="checkbox"/>	
20. Epilepsy	<input type="checkbox"/>	<input type="checkbox"/>	
21. Mental illness e.g. Clinical depression	<input type="checkbox"/>	<input type="checkbox"/>	
22. Symptomatic malaria	<input type="checkbox"/>	<input type="checkbox"/>	
23. Symptomatic malaria with parasite count	<input type="checkbox"/>	<input type="checkbox"/>	
24. Respiratory disease (including asthma)	<input type="checkbox"/>	<input type="checkbox"/>	
25. Pyelonephritis or kidney disease	<input type="checkbox"/>	<input type="checkbox"/>	
26. Lower urinary tract infection requiring antibiotic treatment	<input type="checkbox"/>	<input type="checkbox"/>	
27. Respiratory tract infection requiring antibiotic/antiviral treatment	<input type="checkbox"/>	<input type="checkbox"/>	
28. Any other infection requiring antibiotic/antiviral treatment	<input type="checkbox"/>	<input type="checkbox"/>	
29. Group B streptococcus carrier	<input type="checkbox"/>	<input type="checkbox"/>	
30. Positive syphilis test	<input type="checkbox"/>	<input type="checkbox"/>	
31. HIV or AIDS	<input type="checkbox"/>	<input type="checkbox"/>	
32. Any genital tract or sexually transmitted infection	<input type="checkbox"/>	<input type="checkbox"/>	
33. Cholestasis	<input type="checkbox"/>	<input type="checkbox"/>	
34. Any other medical/surgical condition requiring treatment (if yes, please complete an Adverse Event Form)	<input type="checkbox"/>	<input type="checkbox"/>	

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

For each condition:

Place a 'X' in the box marked 'YES' if since her last visit she has been diagnosed with or treated for that condition.

Place a 'X' in the box marked 'NO' if since her last visit 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.

17. Diabetes, thyroid disease or any other endocrinological condition (Examples: any type of diabetes where the woman was previously known to be diabetic before this pregnancy; any type of thyroid disease, hypo- or hyper-thyroidism, parathyroidism (PTH), Addison's disease, adrenal gland disorders, hypophysitis). Malignant thyroid nodules should be classed as a type of malignancy/cancer (Question 18).

NB If the woman developed diabetes during this pregnancy and had no previous history of diabetes, do not cross 'YES' here but instead refer to Question 36 ('Gestational diabetes') in Section 3.

18. **Any type of malignancy/cancer** (including leukaemia or lymphoma). If yes, complete further information in an **Adverse Event Form**.
19. **Cardiac disease** (Examples: arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, sarcoma, pericarditis, cardiomyopathy, etc.)
20. **Epilepsy** (any episode)
21. **Mental illness e.g. Clinical depression** (excluding mild depression without treatment). Include all forms of mental illness requiring treatment. Examples: clinical depression, schizophrenia, bipolar disorder, obsessive-compulsive disorder (OCD), generalised anxiety disorder.
22. **Symptomatic malaria** (any episode)
23. **Symptomatic malaria with parasite count**. If she has shown symptoms of malaria, only select this option if the presence of malaria has been confirmed by means of a parasite count.
24. **Respiratory disease (including asthma)**. Other examples: chronic bronchitis, emphysema.
25. **Pyelonephritis or kidney disease** – 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.
26. **Lower urinary tract infection requiring antibiotic treatment** (e.g. cystitis)
27. **Respiratory tract infection requiring antibiotic/antiviral treatment** (e.g. bacterial pneumonia)
28. **Any other infection requiring antibiotic/antiviral treatment**
29. **Group B streptococcus carrier** – a diagnosis of carrying (but not necessarily being infected by) the group B streptococcus bacteria, infection with which can cause serious illness and even death in newborn infants.
30. **Positive syphilis test**
31. **HIV or AIDS**
32. **Any genital tract or sexually transmitted infection** (e.g. syphilis, gonorrhoea, trichomoniasis, genital warts, condyloma acuminata, candidiasis)
33. **Cholestasis** (a condition where bile cannot flow from the liver to the duodenum)
34. **Any other medical/surgical condition requiring treatment**. If yes, complete further information in an **Adverse Event Form**.

Section 3: Current pregnancy-related health

Section 3: Current pregnancy-related health			
Since her last visit has she been diagnosed with or treated for any of the following pregnancy-related conditions?			
35. Severe vomiting requiring hospitalisation	<input type="checkbox"/>	<input type="checkbox"/>	
36. Gestational diabetes	<input type="checkbox"/>	<input type="checkbox"/>	
37. Vaginal bleeding	<input type="checkbox"/>	<input type="checkbox"/>	
38. Pregnancy-induced hypertension (BP>140/90, no proteinuria)	<input type="checkbox"/>	<input type="checkbox"/>	
39. Preeclampsia (BP>140/90 <u>and</u> proteinuria)	<input type="checkbox"/>	<input type="checkbox"/>	
40. Severe preeclampsia/Eclampsia/HELLP syndrome	<input type="checkbox"/>	<input type="checkbox"/>	
41. Rhesus disease or anti-Kell antibodies	<input type="checkbox"/>	<input type="checkbox"/>	
42. Preterm labour without delivery	<input type="checkbox"/>	<input type="checkbox"/>	
43. Prelabour premature rupture of membranes (PPROM)	<input type="checkbox"/>	<input type="checkbox"/>	
44. Fetal anaemia	<input type="checkbox"/>	<input type="checkbox"/>	
45. Fetal distress (abnormal fetal heart rate [FHR] or biophysical profile [BPP])	<input type="checkbox"/>	<input type="checkbox"/>	
46. Suspected impaired fetal growth	<input type="checkbox"/>	<input type="checkbox"/>	
47. Oligohydramnios	<input type="checkbox"/>	<input type="checkbox"/>	
48. Polyhydramnios	<input type="checkbox"/>	<input type="checkbox"/>	
49. A condition requiring amniocentesis or fetal blood sampling (FBS)	<input type="checkbox"/>	<input type="checkbox"/>	
50. Abruption placentae	<input type="checkbox"/>	<input type="checkbox"/>	
51. Clinical chorioamnionitis	<input type="checkbox"/>	<input type="checkbox"/>	
52. Any other pregnancy-related infection or condition requiring treatment (if yes, please complete an Adverse Event Form)	<input type="checkbox"/>	<input type="checkbox"/>	

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

For each condition:

Place a 'X' in the box marked 'YES' if since her last visit she has been diagnosed with or treated for that condition.

Place a 'X' in the box marked 'NO' if since her last visit 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.

35. Severe vomiting requiring hospitalisation

36. **Gestational diabetes** (defined as any degree of glucose intolerance with onset or first recognition during pregnancy). NB If the woman was previously known to be diabetic before this pregnancy, do not cross 'YES' here but instead refer to Question 17 ('Diabetes') in Section 2.

37. Vaginal bleeding

38. **Pregnancy-induced hypertension** (blood pressure >140/90, no proteinuria; develops after 20 weeks' gestation in a previously normotensive pregnancy)

39. **Preeclampsia** (blood pressure >140/90 and proteinuria)

Preeclampsia is defined as high blood pressure 140/90 mmHg or greater, or an increase of 30mmHg systolic or 15mmHg diastolic over baseline values on at least two occasions 6 or more hours apart, that develops after 20 weeks' gestation in a previously normotensive pregnancy, and proteinuria (presence of excessive protein substance, chiefly albumin, in the urine).

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

Severe preeclampsia is diagnosed when blood pressure is ≥ 160 mmHg systolic and/or ≥ 110 mmHg diastolic on two occasions, between 4 and 168 hours apart, or if the first measurement was immediately followed by treatment with an antihypertensive, either of these scenarios being associated with the presence of proteinuria.

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: **Haemolysis**, **EL** (elevated) liver enzymes and **LP** (low platelet) count.

41. **Rhesus disease or anti-Kell antibodies.** Rhesus disease – also known as isoimmunisation or RH – can occur when the mother is Rh negative and the baby is Rh positive. The transfer of anti-Kell antibodies from the mother to the fetus across the placental barrier can cause severe anaemia by interfering with the early proliferation of red blood cells.
42. **Preterm labour without delivery.** Preterm labour is initiation of labour before 37⁺⁰ weeks. If there has been a delivery, place a 'X' in the box marked 'NO' and proceed to the **Pregnancy and Delivery Form**.
43. **Prelabour premature rupture of membranes (PPROM)** – rupture of the membranes before labour has begun. If there has been a delivery, proceed to the **Pregnancy and Delivery Form**.
44. **Fetal anaemia** (suggested by very low haematocrit or haemoglobin concentration for gestational age)
45. **Fetal distress** (abnormal fetal heart rate (FHR) or biophysical profile (BPP))
46. **Suspected impaired fetal growth**
47. **Oligohydramnios** (a decreased amount of amniotic fluid)
48. **Polyhydramnios** (an excessive amount of amniotic fluid)
49. **A condition requiring amniocentesis or fetal blood sampling (FBS)**
50. **Abruptio placentae** (i.e. placental abruption) refers to the partial or complete separation of the normally located placenta after the 20th week of gestation and prior to birth. The normal placenta separates from the uterus prematurely and blood collects between the placenta and the uterus.
51. **Clinical chorioamnionitis** (an inflammation of the fetal membranes – chorion and amnion – due to a bacterial infection)
52. **Any other pregnancy-related infection or condition requiring treatment.** If yes, complete further information in an **Adverse Event Form**.

Section 4: Nutritional supplements/Medications

Section 4: Nutritional supplements/Medications			
Since her last visit, has she routinely taken any of the following nutritional supplements?		Since her last visit, has she routinely taken any of the following medications?	
53. Multi-vitamins/minerals	<input type="checkbox"/> yes	<input type="checkbox"/> no	62. Aspirin
54. Iron	<input type="checkbox"/> yes	<input type="checkbox"/> no	63. Non-steroidal anti-inflammatories
55. Folic acid	<input type="checkbox"/> yes	<input type="checkbox"/> no	64. Antibiotics used for PPRM
56. Vitamin D	<input type="checkbox"/> yes	<input type="checkbox"/> no	65. Any other antibiotics/antivirals
57. Calcium	<input type="checkbox"/> yes	<input type="checkbox"/> no	66. Antihypertensives
58. Selenium	<input type="checkbox"/> yes	<input type="checkbox"/> no	67. Insulin
59. Food supplements	<input type="checkbox"/> yes	<input type="checkbox"/> no	68. Prophylactic steroids for preterm labour
60. Cod liver oil	<input type="checkbox"/> yes	<input type="checkbox"/> no	69. Progesterone
61. Other fish oil	<input type="checkbox"/> yes	<input type="checkbox"/> no	70. Any other treatment

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

For each nutritional supplement:

Place a 'X' in the box marked 'YES' if she has routinely taken that supplement in the time since her last visit.

Place a 'X' in the box marked 'NO' if she has not routinely taken that supplement in the time since her last visit.

'Routinely' is defined as 'for more than one month'. Do not (for example) cross 'YES' for Question 58: 'Selenium' for a woman who has received a one-off supplement of selenium.

If she has routinely taken multi-vitamins or minerals place a 'X' in the box marked 'YES' for Question 53. If this supplement includes any of the others listed, do not place a 'X' in the box marked 'YES' for the other supplement unless an additional preparation of that supplement, other than the multi-vitamins/minerals, is taken.

Example: If a woman has taken a multi-vitamin/mineral supplement which includes iron, but she has taken no other supplement of iron specifically, then place a 'X' in the box marked 'YES' for Question 53: 'Multi-vitamins/minerals' and a 'X' in the box marked 'NO' for Question 54: 'Iron'.

53. **Multi-vitamins/minerals** (see note above in cases where multi-vitamin/mineral supplement includes any of the other listed supplements)

54. **Iron**

55. **Folic acid**

56. **Vitamin D**

57. **Calcium**

58. **Selenium**

59. **Food supplements** e.g. high energy/calorie supplements for weight gain during pregnancy.

60. **Cod liver oil**

61. **Other fish oil** (i.e. a fish oil that is not cod liver oil)

Since her last visit, has she routinely taken any of the following medications?

For each medication:

Place a 'X' in the box marked 'YES' if she has routinely taken that medication in the time since her last visit.

Place a 'X' in the box marked 'NO' if she has not routinely taken that medication in the time since her last visit.

'Routinely' is defined as 'for more than one month'. Do not (for example) cross 'YES' for Question 62: 'Aspirin' for a woman who has taken aspirin for occasional headaches.

62. **Aspirin**

63. **Non-steroidal anti-inflammatories**

64. **Antibiotics used for PPROM** (e.g. prophylactic antibiotics)

65. **Any other antibiotics/antivirals** (e.g. penicillin) – excluding those used for PPROM

66. **Antihypertensives**

67. **Insulin**

68. **Prophylactic steroids for preterm labour**

69. **Progesterone**

70. **Any other treatment**

Section 5: Referral

Section 5: Referral	
71. Since her last visit, has the woman been referred to another level of care or 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/Admission Form .	

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

Place a 'X' in the box marked 'YES' if so. Complete a **Maternal Referral/Admission Form**, using information from the medical records and/or interview with the woman/physician.

Place a 'X' in the box marked 'NO' if not.

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.							
72. Date of the next ultrasound appointment:	<table border="1"><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	Y	Y
D	D	M	M	Y	Y		

If not already done, please now arrange the next ultrasound appointment for within 5 weeks (\pm 1 week) of today.

72. Date of the next ultrasound appointment

Enter the date of the next ultrasound appointment in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Maternal Referral/Admission Form (MRA)

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

NB This applies to all referrals and admissions, including those to hospitals other than that where she is normally seen for antenatal care.

One Maternal Referral/Admission Form is supplied in each Fetal Study Booklet. If any additional forms are required during pregnancy, please print as necessary from the electronic file provided. Make sure to affix a patient identifier (PTID) label to both sheets of any additional Maternal Referral/Admission Forms – the PTID number is not pre-printed on the template for additional forms.


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 has been completed:

- Sign the bottom of the form (completing also the researcher code and your name).
- Pass the completed form to the Data Management Unit for data entry.

Form Header

	INTERBIO-21st Fetal Study Maternal Referral/Admission		MRA Page 1 of 2
	INTERBIO-21 st PTID Number	0 7 - 1 0 0 0 0	Hospital/Clinic Code
Antenatal Record No.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
Maternal Date of Birth	D D M M Y Y	Visit Date	D D M M Y Y
Please answer all yes/no questions by placing a 'X' in the corresponding box			

INTERBIO-21st PTID Number: This is the woman’s patient identifier (PTID) number for the study and is pre-printed on the front of the booklet, on the labels attached within the booklet, and in all headers on each form within the booklet.

Hospital/Clinic Code: Enter the code that corresponds to the hospital or clinic where the woman receives her routine ANC care and was screened for the study.

Antenatal Record No.: This number is the hospital/clinic’s own internal reference number for the woman; it can be used to help identify the woman and link the information on this form with her medical records.

Maternal Date of Birth: Enter the woman’s date of birth in the format dd-mm-yy, e.g. ‘20th May 2010’ should be written ‘20-05-10’. Make every effort to obtain her date of birth in full. If, however, she knows only the year or month-and-year of her birth, enter this known information and replace the unknown details with ‘xx’.

Visit Date: Enter the date of this visit in the format dd-mm-yy, e.g. ‘20th May 2010’ should be written ‘20-05-10’.

Please answer all yes/no questions by placing a ‘X’ in the corresponding box.

If you require more than one **Maternal Referral/Admission Form**, print off a blank copy from the electronic file provided. You will need to affix a PTID label to the header of the extra form. If the woman’s labels cannot be located, please write in the PTID Number by hand, making sure that it matches the PTID Number on the front of the Fetal Study Booklet.

Section 1: Pregnancy status

Section 1: Pregnancy status			
1. Is this a referral to another level of outpatient care or admission to hospital? (cross one box only)			
Referral	<input type="checkbox"/>	Admission	<input type="checkbox"/>
2. To which department/unit/service has she been referred or admitted? (cross one box only)			
Gynaecology	<input type="checkbox"/>	Surgery	<input type="checkbox"/>
Obstetric/ High-risk clinic	<input type="checkbox"/>	Trauma/ Orthopaedics	<input type="checkbox"/>
Nephrology	<input type="checkbox"/>	Emergency room	<input type="checkbox"/>
Nutritional	<input type="checkbox"/>	Internal medicine	<input type="checkbox"/>
Physiotherapy	<input type="checkbox"/>	Other	<input type="checkbox"/>
Psychiatry	<input type="checkbox"/>		
If she has been referred or admitted for a <u>nutritional</u> problem, please indicate the diagnosis: (cross all that apply)			
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 admission to hospital?

Place a 'X' in the corresponding box. Cross one box only.

2. To which department/unit/service has she been referred or admitted?

Place a 'X' in the corresponding box. Cross one box only from the following list:

- Gynaecology;
- Obstetric/High-risk clinic;
- Nephrology;
- Nutritional;
- Physiotherapy;
- Psychiatry;
- Surgery;
- Trauma/Orthopaedics;
- Emergency room;
- Internal medicine;
- Other.

Select 'Other' if the department/unit/service cannot be classed as one of the first 10 options.

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

Indicate the relevant diagnoses by placing a 'X' in the box next to all that apply from the list below:

3. **Gestational diabetes** (defined as any degree of glucose intolerance with onset or first recognition during pregnancy)
4. **Overweight**
5. **Underweight**

- 6. **Anaemia**
- 7. **Food allergy**
- 8. **Heartburn**
- 9. **Malabsorption syndrome**
- 10. **Specific dietary requirement**

Section 2: Lab information (if requested during admission/referral)

Section 2: Lab information (if requested during admission/referral)	
11. Proteinuria (by dipstick): (cross one box only)	
0 / trace	<input type="checkbox"/>
+	<input type="checkbox"/>
++	<input type="checkbox"/>
+++	<input type="checkbox"/>
++++	<input type="checkbox"/>
No urine test performed at this referral/admission <input type="checkbox"/>	
and/or actual result (from urine sample) received from laboratory: <input type="text"/> <input type="text"/> <input type="text"/> mg/dl	
12. Urine culture: (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? <input type="checkbox"/> yes <input type="checkbox"/> no	
14. Lowest haemoglobin level: OR Lowest haematocrit:	
<input type="text"/> <input type="text"/> . <input type="text"/> g/dl	<input type="text"/> <input type="text"/> . <input type="text"/> %
15. Lowest blood glucose level: <input type="text"/> <input type="text"/> <input type="text"/> mmol/l	
16. Highest blood glucose level: <input type="text"/> <input type="text"/> <input type="text"/> mmol/l	
17. Highest serum creatinine level: <input type="text"/> . <input type="text"/> μ mol/l	

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

Obtain the results of the urinalysis from the lab report for this referral/admission.

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

If proteinuria is reported in the lab results, enter the actual value in milligrams/decilitre (mg/dl) in the corresponding box.

If the results are not available, leave the field blank.

12. Urine culture

Cross one box only.

Place a 'X' next to 'Positive' if the urine culture showed evidence of a urinary tract infection.

Place a 'X' next to 'Negative' if the urine culture showed no evidence of a urinary tract infection.

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

If 'Negative' or 'No urine culture available', leave the response to Question 13 blank, and skip to Question 14.

13. If positive, was antibiotic treatment given?

Place a 'X' in the box marked 'YES' if antibiotic treatment was given after the positive test result.

Place a 'X' in the box marked 'NO' if the positive urine culture result was not treated.

14. Lowest haemoglobin level OR Lowest haematocrit

If her haemoglobin level or haematocrit was measured during referral/admission, obtain the results from the lab. In the corresponding box enter the lowest haemoglobin level recorded during the referral/admission, in grams/decilitre (g/dl), or the lowest haematocrit result as a percentage (%), to 1 decimal place.

If not available, leave the field blank.

15. Lowest blood glucose level

If her blood glucose level was measured during referral/admission, obtain the results from the lab. In the corresponding box enter the lowest blood glucose level recorded during the referral/admission, in millimoles/litre (mmol/l), with no decimal places.

If not available, leave the field blank.

16. Highest blood glucose level

If her blood glucose level was measured during referral/admission, obtain the results from the lab. In the corresponding box enter the highest blood glucose level recorded during the referral/admission, in millimoles/litre (mmol/l), with no decimal places.

If not available, leave the field blank.

17. Highest serum creatinine level

If her serum creatinine level was measured during referral/admission, obtain the results from the lab. In the corresponding box enter the highest serum creatinine level recorded during the referral/admission, in micromoles/litre ($\mu\text{mol/l}$), to 1 decimal place.

If not available, leave the field blank.

Section 3: Clinical 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, see Section 4.

Section 3: Clinical diagnosis for this admission or referral			
Please provide the main diagnosis by referring to the medical records:			
18. Diabetes	<input type="checkbox"/>	<input type="checkbox"/>	
If yes, was there any evidence of diabetic ketoacidosis?	<input type="checkbox"/>	<input type="checkbox"/>	
19. Thyroid disease or any other endocrinological condition	<input type="checkbox"/>	<input type="checkbox"/>	
20. Any type of malignancy/cancer (if yes, please complete an Adverse Event Form)	<input type="checkbox"/>	<input type="checkbox"/>	
21. Cardiac disease	<input type="checkbox"/>	<input type="checkbox"/>	
22. Epilepsy	<input type="checkbox"/>	<input type="checkbox"/>	
23. Mental illness e.g. Clinical depression	<input type="checkbox"/>	<input type="checkbox"/>	
24. Symptomatic malaria	<input type="checkbox"/>	<input type="checkbox"/>	
25. Symptomatic malaria with parasite count	<input type="checkbox"/>	<input type="checkbox"/>	
26. Respiratory disease (including asthma)	<input type="checkbox"/>	<input type="checkbox"/>	
27. Pyelonephritis or kidney disease	<input type="checkbox"/>	<input type="checkbox"/>	
28. Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition	<input type="checkbox"/>	<input type="checkbox"/>	
29. Lower urinary tract infection requiring antibiotic treatment	<input type="checkbox"/>	<input type="checkbox"/>	
30. Respiratory tract infection requiring antibiotic/antiviral treatment	<input type="checkbox"/>	<input type="checkbox"/>	
31. Any other infection requiring antibiotic/antiviral treatment	<input type="checkbox"/>	<input type="checkbox"/>	
32. Non-septic shock requiring fluid replacement or pressor agents	<input type="checkbox"/>	<input type="checkbox"/>	
33. Maternal trauma	<input type="checkbox"/>	<input type="checkbox"/>	
34. Deep vein thrombosis	<input type="checkbox"/>	<input type="checkbox"/>	
35. Systemic lupus erythematosus	<input type="checkbox"/>	<input type="checkbox"/>	
36. HIV or AIDS	<input type="checkbox"/>	<input type="checkbox"/>	
37. Any genital tract or sexually transmitted infection	<input type="checkbox"/>	<input type="checkbox"/>	
38. Sickle-cell anaemia	<input type="checkbox"/>	<input type="checkbox"/>	
39. Cholestasis	<input type="checkbox"/>	<input type="checkbox"/>	
40. Any other medical/surgical condition requiring treatment or surgery (if yes, please complete an Adverse Event Form)	<input type="checkbox"/>	<input type="checkbox"/>	

Please provide the main diagnosis by referring to the medical records.

For each condition:

Place a 'X' in the box marked 'YES' if during this referral/admission she has been diagnosed with or treated for that condition.

Place a 'X' in the box marked 'NO' if during this referral/admission she has not been diagnosed with or treated for that condition.

18. Diabetes (any type, woman previously known to be diabetic before this pregnancy). If the woman developed diabetes during this pregnancy and had no previous history of diabetes, do not cross 'YES' here but instead refer to Question 42 ('Gestational diabetes') in Section 4.

If yes, was there any evidence of diabetic ketoacidosis?

Place a 'X' in the box marked 'YES' if there was any evidence of diabetic ketoacidosis.

Place a 'X' in the box marked 'NO' if there was no evidence of diabetic ketoacidosis.

19. Thyroid disease or any other endocrinological condition (Examples: hypo- or hyper-thyroidism, parathyroidism (PTH), Addison's disease, adrenal gland disorders, hypophysitis). Malignant thyroid nodules should be classed as a type of malignancy/cancer (Question 20).

20. Any type of malignancy/cancer (including leukaemia or lymphoma). If yes, complete further information in an **Adverse Event Form**.

21. Cardiac disease (Examples: arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, sarcoma, pericarditis, cardiomyopathy, etc.)

22. **Epilepsy** (any episode)
23. **Mental illness e.g. Clinical depression** (excluding mild depression without treatment). Include all forms of mental illness requiring treatment. Examples: clinical depression, schizophrenia, bipolar disorder, obsessive-compulsive disorder (OCD), generalised anxiety disorder.
24. **Symptomatic malaria** (any episode)
25. **Symptomatic malaria with parasite count**. If she has shown symptoms of malaria, only select this option if the presence of malaria has been confirmed by means of a parasite count.
26. **Respiratory disease (including asthma)**. Other examples: chronic bronchitis, emphysema.
27. **Pyelonephritis or kidney disease** – 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.
28. **Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition**
29. **Lower urinary tract infection requiring antibiotic treatment** (e.g. cystitis)
30. **Respiratory tract infection requiring antibiotic/antiviral treatment** (e.g. bacterial pneumonia)
31. **Any other infection requiring antibiotic/antiviral treatment**
32. **Non-septic shock requiring fluid replacement or pressor agents**
33. **Maternal trauma** (a serious or critical bodily injury, wound or shock)
34. **Deep vein thrombosis**
35. **Systemic lupus erythematosus** (a chronic inflammatory collagen disease affecting connective tissue)
36. **HIV or AIDS**
37. **Any genital tract or sexually transmitted infection** (e.g. syphilis, gonorrhoea, trichomoniasis, genital warts, condyloma acuminata, candidiasis)
38. **Sickle-cell anaemia**
39. **Cholestasis** (a condition where bile cannot flow from the liver to the duodenum)
40. **Any other medical/surgical condition requiring treatment or surgery**. If yes, 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, see Section 3.

Section 4: Pregnancy-related diagnosis for this admission or referral			
Please provide the main diagnosis by referring to the medical records:			
41. Severe vomiting requiring hospitalisation	<input type="checkbox"/> yes	<input type="checkbox"/> no	
42. Gestational diabetes	<input type="checkbox"/> yes	<input type="checkbox"/> no	
43. Vaginal bleeding	<input type="checkbox"/> yes	<input type="checkbox"/> no	
44. Pregnancy-induced hypertension (BP>140/90, no proteinuria)	<input type="checkbox"/> yes	<input type="checkbox"/> no	
45. Preeclampsia (BP>140/90 <u>and</u> proteinuria)	<input type="checkbox"/> yes	<input type="checkbox"/> no	
46. Severe preeclampsia/Eclampsia/HELLP syndrome	<input type="checkbox"/> yes	<input type="checkbox"/> no	
47. Fetal maternal haemorrhage	<input type="checkbox"/> yes	<input type="checkbox"/> no	
48. Rhesus disease or anti-Kell antibodies	<input type="checkbox"/> yes	<input type="checkbox"/> no	
49. Uterine rupture	<input type="checkbox"/> yes	<input type="checkbox"/> no	
50. Prelabour premature rupture of membranes (PPROM) or Preterm labour without delivery	<input type="checkbox"/> yes	<input type="checkbox"/> no	
51. PPRM or Preterm labour <u>and</u> delivery (if yes, please complete the Pregnancy and Delivery Form)	<input type="checkbox"/> yes	<input type="checkbox"/> no	
52. Miscarriage or fetal death (if yes, please complete the Pregnancy and Delivery Form)	<input type="checkbox"/> yes	<input type="checkbox"/> no	
53. Fetal anaemia	<input type="checkbox"/> yes	<input type="checkbox"/> no	
54. Fetal distress (abnormal fetal heart rate [FHR] or biophysical profile [BPP])	<input type="checkbox"/> yes	<input type="checkbox"/> no	
55. Suspected impaired fetal growth	<input type="checkbox"/> yes	<input type="checkbox"/> no	
56. Pelvic mass	<input type="checkbox"/> yes	<input type="checkbox"/> no	
57. Oligohydramnios	<input type="checkbox"/> yes	<input type="checkbox"/> no	
58. Polyhydramnios	<input type="checkbox"/> yes	<input type="checkbox"/> no	
59. A condition requiring amniocentesis or fetal blood sampling (FBS)	<input type="checkbox"/> yes	<input type="checkbox"/> no	
60. Abruptio placentae	<input type="checkbox"/> yes	<input type="checkbox"/> no	
61. Clinical chorioamnionitis	<input type="checkbox"/> yes	<input type="checkbox"/> no	
62. Any other pregnancy-related infection or condition (if yes, please complete an Adverse Event Form)	<input type="checkbox"/> yes	<input type="checkbox"/> no	

Please provide the main diagnosis by referring to the medical records.

For each condition:

Place a 'X' in the box marked 'YES' if during this referral/admission she has been diagnosed with or treated for that condition.

Place a 'X' in the box marked 'NO' if during this referral/admission she has not been diagnosed with or treated for that condition.

41. Severe vomiting requiring hospitalisation

42. **Gestational diabetes** (defined as any degree of glucose intolerance with onset or first recognition during pregnancy). NB If the woman was previously known to be diabetic before this pregnancy, do not cross 'YES' here but instead refer to Question 18 ('Diabetes, thyroid disease or any other endocrinological condition') in Section 3.

43. Vaginal bleeding

44. **Pregnancy-induced hypertension** (blood pressure >140/90, no proteinuria; develops after 20 weeks' gestation in a previously normotensive pregnancy)

45. **Preeclampsia** (blood pressure >140/90 and proteinuria)

Preeclampsia is defined as high blood pressure 140/90 mmHg or greater, or an increase of 30mmHg systolic or 15mmHg diastolic over baseline values on at least two occasions 6 or more hours apart, that develops after 20 weeks' gestation in a previously normotensive pregnancy, and proteinuria (presence of excessive protein substance, chiefly albumin, in the urine).

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

Severe preeclampsia is diagnosed when blood pressure is ≥ 160 mmHg systolic and/or ≥ 110 mmHg diastolic on two occasions, between 4 and 168 hours apart, or if the first measurement was immediately followed by treatment with an antihypertensive, either of these scenarios being associated with the presence of proteinuria.

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: **Haemolysis**, **EL** (elevated) liver enzymes and **LP** (low platelet) count.

47. **Fetal maternal haemorrhage**

48. **Rhesus disease or anti-Kell antibodies.** Rhesus disease – also known as isoimmunisation or RH – can occur when the mother is Rh negative and the baby is Rh positive. The transfer of anti-Kell antibodies from the mother to the fetus across the placental barrier can cause severe anaemia by interfering with the early proliferation of red blood cells.

49. **Uterine rupture.** Complete uterine rupture is a catastrophic event where a full-thickness tear develops, opening the uterus directly into the abdominal cavity; it requires rapid surgical attention to safeguard maternal and infant outcomes. Occult or incomplete rupture is where a surgical scar separates but the visceral peritoneum stays intact; it is usually asymptomatic and does not require emergency surgery.

50. **Prelabour premature rupture of membranes (PPROM) or Preterm labour without delivery** – PPRM is rupture of the membranes before labour has begun; preterm labour is initiation of labour before 37⁺⁰ weeks.

51. **PPROM or Preterm labour and delivery** – PPRM is rupture of the membranes before labour has begun; preterm labour is initiation of labour before 37⁺⁰ weeks. If yes, complete the **Pregnancy and Delivery Form**.

52. **Miscarriage or fetal death.** If yes, complete the **Pregnancy and Delivery Form**.

53. **Fetal anaemia** (suggested by very low haematocrit or haemoglobin concentration for gestational age)

54. **Fetal distress** (abnormal fetal heart rate (FHR) or biophysical profile (BPP))

55. **Suspected impaired fetal growth**

56. **Pelvic mass** (enlargement or swelling in the lower abdomen or pelvic region)

57. **Oligohydramnios** (a decreased amount of amniotic fluid)

58. **Polyhydramnios** (an excessive amount of amniotic fluid)

59. **A condition requiring amniocentesis or fetal blood sampling (FBS)**

60. **Abruptio placentae** (i.e. placental abruption) refers to the partial or complete separation of the normally located placenta after the 20th week of gestation and prior to birth. The normal placenta separates from the uterus prematurely and blood collects between the placenta and the uterus.
61. **Clinical chorioamnionitis** (an inflammation of the fetal membranes – chorion and amnion – due to a bacterial infection)
62. **Any other pregnancy-related infection or condition.** If yes, complete further information in an **Adverse Event Form**.

Section 5: Medications and treatment

Section 5: Medications and treatment					
Has she been prescribed any of the following medications or treatments?					
63. Aspirin	<input type="checkbox"/> yes	<input type="checkbox"/> no	67. Treatments for asthma	<input type="checkbox"/> yes	<input type="checkbox"/> no
64. Antibiotics/Antivirals	<input type="checkbox"/> yes	<input type="checkbox"/> no	68. Antipsychotics	<input type="checkbox"/> yes	<input type="checkbox"/> no
65. Antihypertensives	<input type="checkbox"/> yes	<input type="checkbox"/> no	69. Antidepressants	<input type="checkbox"/> yes	<input type="checkbox"/> no
66. Prophylactic steroids for preterm labour	<input type="checkbox"/> yes	<input type="checkbox"/> no	70. Magnesium sulphate	<input type="checkbox"/> yes	<input type="checkbox"/> no
			71. Blood transfusion	<input type="checkbox"/> yes	<input type="checkbox"/> no
			72. Just bed rest/observation	<input type="checkbox"/> yes	<input type="checkbox"/> no
			73. Any other treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no

Has she been prescribed any of the following medications or treatments?

For each medication or treatment:

Place a 'X' in the box marked 'YES' if she has been prescribed that medication or treatment during this referral/admission.

Place a 'X' in the box marked 'NO' if she has not been prescribed that medication or treatment during this referral/admission.

63. **Aspirin**

64. **Antibiotics/Antivirals** (e.g. penicillin)

65. **Antihypertensives**

66. **Prophylactic steroids for preterm labour**

67. **Treatments for asthma**

68. **Antipsychotics**

69. **Antidepressants**

70. **Magnesium sulphate**

71. **Blood transfusion**

72. **Just bed rest/observation** (no treatment required)

73. **Any other treatment**

Section 6: Final outcome

Section 6: Final outcome	
74. 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 (inform study coordinator) <input type="checkbox"/>	Left hospital or treatment against medical advice (inform study coordinator) <input type="checkbox"/>
Delivered/Miscarried (complete the Pregnancy and Delivery Form) <input type="checkbox"/>	
75. 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"/>

74. Final outcome of the admission

Place a 'X' in the corresponding box. Cross one box only from the following list:

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

75. Date of discharge from hospital

Enter the date that the woman left the hospital/referral clinic in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Section 7: Next appointment

Section 7: Next appointment	
If the woman is still pregnant (even if she is still in hospital) check the date of the next ultrasound appointment.	
76. 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 in hospital please inform the study coordinator.	

If the woman is still pregnant (even if she is still in hospital) check the date of the next ultrasound appointment.

76. Date of the next ultrasound appointment

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

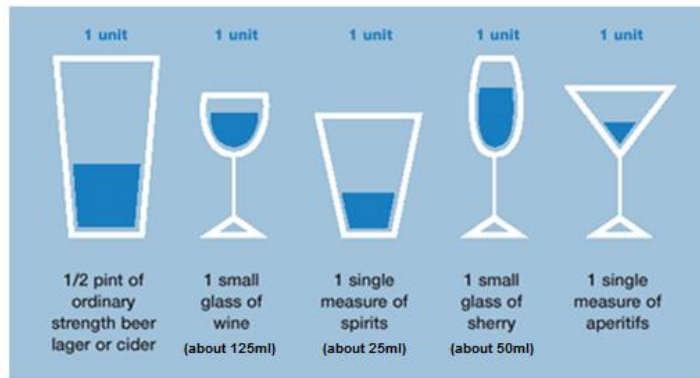
Refer to the last **Ultrasound Follow-up Form** or **Pregnancy Follow-up Form** in the **Fetal Study Booklet** for the date of the next ultrasound appointment.

Enter the date in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

If the woman is still in hospital please inform the study coordinator.

Appendix 1. Supplementary Flip-chart

Units of Alcohol



Recreational Drugs

Heroin	Amphetamines (including ya ba and khat)	Benzodiazepines (including diazepam)
Methadone	Hallucinogens	Inhalants/Solvents
Crack/Cocaine	Cannabis	Any other recreational drug...

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



Special Diets

Vegetarian with no animal products (vegan)

None of the following:

Gluten-free Diet

No wheat, oats, barley or rye products (bread, pasta, breakfast cereals etc.)

Malabsorption Treatment

Weight-loss Programme

Appendix 2. Occupational Classification Scheme

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 specialised services managers;
- ◆ Hospitality, retail and other services managers;
- ◆ Science and engineering professionals.

Clerical support, service or sales

- ◆ 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 e.g. care home worker;
- ◆ Protective services workers.

Housework (including child care/care of elderly relative)

Student

- ◆ School student;
- ◆ University student.

Skilled manual work

- ◆ 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 work

- ◆ 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

- ◆ Redundancy/unemployed.

Appendix 3. Blood Pressure Measurement Protocol

The equipment:

Microlife Blood Pressure Monitor for Pregnant Women¹
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-up visit of women in the Fetal Study. The blood pressure monitor should be placed in an accessible location, near to the ultrasound room.

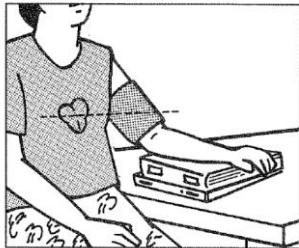
Blood pressure can rise if the woman has recently exercised or is nervous. In late pregnancy, even walking can be strenuous. Ensure that the woman has had time to rest (5-10 minutes) since arriving at the clinic. Put her at ease and make sure the temperature of the clinic is comfortable.

Position of the woman:

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

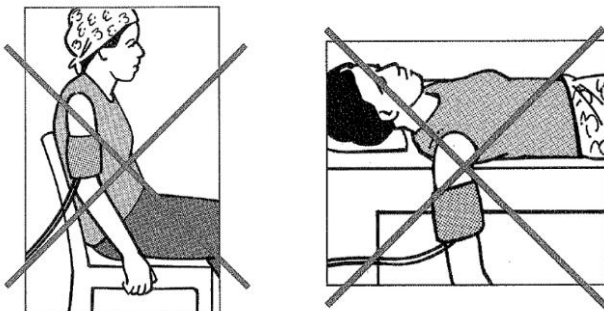
Lying down or standing during the blood pressure reading is unacceptable.

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 in either a sitting or a lying position.



¹ For any technical questions about the Microlife Blood Pressure Monitor for Pregnant Women consult the manufacturer's handbook that came with the product.

Fitting the cuff:

1. For the purposes of the study the **RIGHT** arm will be used.
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 woman 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. Make certain that the lower edge of the cuff lies approximately 2-3cm (1 inch) above the elbow, and that the rubber tube leaves the cuff on the inner side of the arm. Do not kink or twist the tubes or allow them to be tucked or caught under the cuff.
5. Make sure the woman 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 in the display.
2. After reaching the inflation pressure, the pump stops and the pressure gradually falls. The cuff pressures are displayed. In case 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 mmHg) in the corresponding data collection form².

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

15. 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:

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

² You may find it helpful to note that the Microlife Blood Pressure Monitor for Pregnant Women has a memory recall facility which automatically stores the last 30 measurement values. By pressing the 'M' button, previous measurements can be displayed one after the other. For more details, see the manufacturer's handbook that came with the product.

Appendix 4. Measurement of Symphyseal-fundal Height

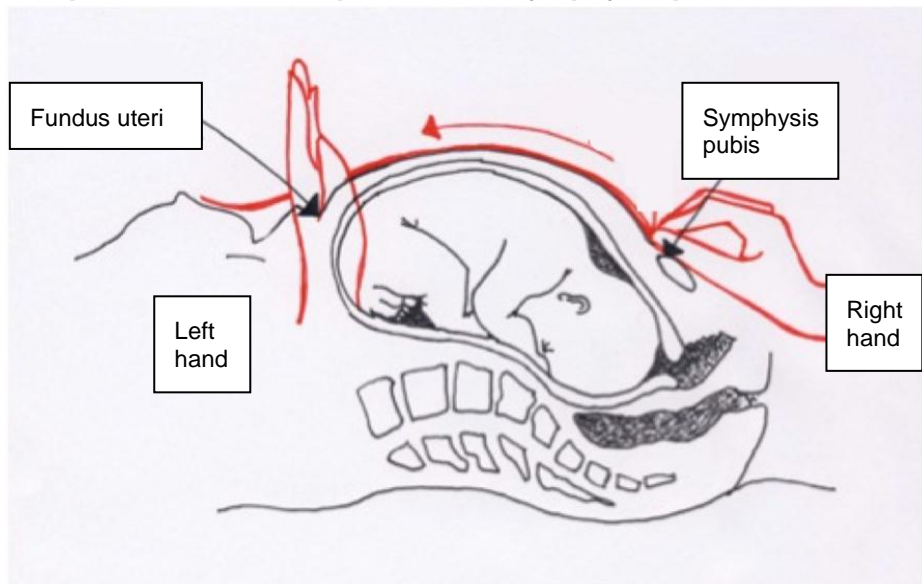
Position of the woman

The woman 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. Measurement is to be **blinded**, by turning the tape measure so that no numbers are visible during the measurement.
3. Hold the 0cm 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. Be aware that the tape has both centimetres and inches but that values should be recorded in centimetres (cm) only.

Figure: Tape measure technique from the symphysis pubis to the fundus uteri



7. Record the measurement in Question 3 of the **Pregnancy Follow-up Form**, in centimetres, to 1 decimal place (i.e. to the nearest complete millimetre).

Section 1: Pregnancy status	
1. Weight (at this visit):	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg
2. Father's height: (if it can be obtained at this visit)	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm
3. Symphyseal-fundal height:	<input type="text"/> <input type="text"/> . <input type="text"/> cm

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