

INTERBIO-21st

The Functional Classification of Abnormal Fetal and Neonatal Growth Phenotypes



NEONATAL STUDY APPLICATION INSTRUCTIONS

July 2012 (version 1.0)



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

These instructions for the INTERBIO-21st Neonatal Study are based on the INTERBIO-21st protocol.

www.intergrowth21.org.uk

The INTERBIO-21st Neonatal 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 with the procedures for subject selection using the study application.

Neonatal Screening: General Guidelines

Every day the midwife/researcher uses the INTERBIO-21st application ('app') to screen **all** women on the Labour & Delivery suite or those scheduled for Caesarean section. The researcher should enter the required information into the app and the app will inform them if the woman meets all the inclusion criteria and is eligible for the study.

Multiple women can be screened at any one time. All unfinished forms will automatically be saved and can be accessed again at a later time e.g. when required information becomes available.

The infant's birth weight should be entered as soon as possible after birth as this will determine whether the woman is eligible for the study or not. It is essential that biological samples are sent to the lab for processing as soon as possible after collection. To ensure that all biological samples are collected and processed within the timeframe, the researcher should be aware of all women delivering.

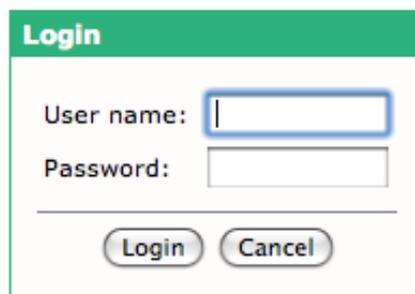
Neonatal Screening

Logging in to the App

To log in to the app, go to the website:

<https://www.medscinet.net/interbio/mobile>

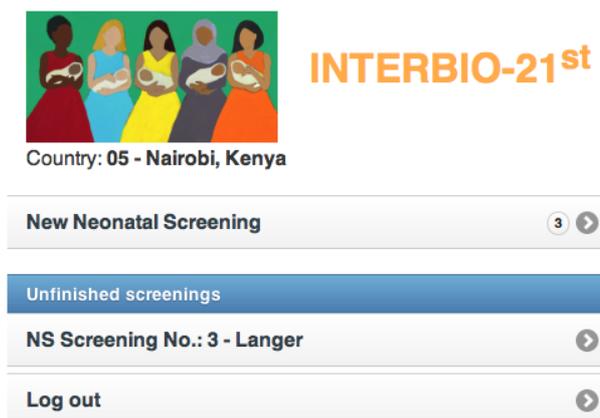
Once a login for the user has been set up (this is done by the INTERBIO-21st Data Manager), a user can log in by entering their username and password at the login screen.



Lost your password? Please, contact Administrator.
stephen.ash@obs-gyn.ox.ac.uk

Logging in and out of the application requires access to the internet. However, once logged into the app, screening can be carried out offline. If there is no access to the internet to log into the app there is no way to screen women. If working in an area with poor or no internet connection, someone should remain logged into the app at all times to ensure women can be screened.

App Homepage



Once logged in, the above screen will appear. The number in the circle on the right-hand side records how many women have been screened. To start screening a new woman, touch the 'New Neonatal Screening' button.

If a woman's screening cannot be completed, an incomplete form will be saved and can be accessed again later. To re-identify women that have been partially screened, a list of unfinished screens will appear on the homepage displaying both the woman's screening number and name (N.B. the woman's name will not be transferred to the database once screening is complete). To complete unfinished forms, touch the button corresponding to the woman's name and continue screening.

Screen 1: New Neonatal Screening

When screening a new woman, this screen will appear:

The screenshot shows a mobile application interface for neonatal screening. At the top, there is a blue header with a back arrow and the text 'Home' and 'Neonatal Screening for Cases/Controls'. Below the header, a grey bar displays 'NS Screening No.: 4 | Country: 05 - Nairobi, Kenya | Date: 21 June 2012'. The main form area contains several questions with corresponding input fields: 'Woman's name:' with a text box; 'What is the woman's age? (in full years)' with a text box and a slider; 'How many previous births has she had? (include all births after 24 weeks' gestation, regardless of outcome)' with a text box and a slider; 'Highest level of education attended:' with a dropdown menu showing '--Select--'; 'Is this a singleton pregnancy?' with a toggle switch set to 'Yes'; 'Was this pregnancy conceived with fertility treatment?' with a toggle switch set to 'No'; 'Where does the woman live?' with a dropdown menu showing '--Select--'; and 'Is she already taking part in the INTERBIO-21st Fetal Study?' with a toggle switch set to 'No'. At the bottom, there are two buttons: 'Cancel' and 'Next'.

1. **Woman's name:**

Touch in the box and using the keyboard, type in the woman's name.

2. **What is the woman's age? (in full years)**

Using the slider to the right of the box, enter the woman's age.

N.B. You may have to calculate the woman's age from her date of birth.

3. **How many previous births has she had? (include all births after 24 weeks' gestation, regardless of outcome)**

Using the slider to the right of the box, enter the number of previous births she has had.

4. **Highest level of education attended:**

Touch the '--Select--' box and a dropdown list will appear. Select from the options:

- No school attended;
- Primary;
- Secondary;
- Professional/Technical training;
- University.

If the answer to this question is unknown, do not answer and continue to Question 5.

5. **Is this a singleton pregnancy?**

If this is a singleton pregnancy, leave the slider on 'Yes'.

If this is not a singleton pregnancy, touch the slider and change the answer to 'No'.

6. **Was this pregnancy conceived with fertility treatment?**

If the pregnancy was not conceived with fertility treatment, leave the slider on 'No'.

If the pregnancy was conceived with fertility treatment, touch the slider and change the answer to 'Yes'.

7. **Where does the woman live?**

Touch the '--Select--' box and a dropdown list will appear. Select from the options (these are site-specific).

8. **Is she already taking part in the INTERBIO-21st Fetal Study?**

If the woman is not taking part in the INTERBIO-21st Fetal Study, leave the slider on 'No'.

If the woman is taking part in the INTERBIO-21st Fetal Study, touch the slider and change the answer to 'Yes'.

You can cancel this screen at any time by touching the 'Cancel' button.

You can return to the homepage at any time by touching the 'Home' button in the top right corner of the screen. However, note that returning to the homepage **before** completing screen 1 will result in **the loss of all information that has been entered**. You can return to the homepage **after** completing screen 1 - i.e. once you have proceeded to screen 2 (the next page) - and **all information will be saved**.

Once all the questions have been answered, touch the 'Next' button. The app will then inform the user if the woman is eligible or not. For instructions as to how to proceed if she is not eligible for the study see [Screen 5a: Eligibility](#).

If she is eligible for the study, the following screen will appear:

Screen 2: Estimation of gestational age

← Home Neonatal Screening for Cases/Controls

NS Screening No.: 5 | Country: 11 - Mae Sot, Thailand | Date: 24 May 2012

Was a crown-rump length (CRL) measurement taken before 14 weeks? No

Was a head circumference (HC) measurement taken before 24 weeks? No

Back Next

N.B. To be eligible for this study, either a CRL or HC measurement must be entered.

9. **Was a crown-rump length (CRL) measurement taken before 14 weeks?**

If the woman has a CRL measurement after or at 14 weeks, or not at all, leave the slider on 'No'. Proceed to the next question.

If the woman has a CRL measurement before 14 weeks, touch the slider and change the answer to 'Yes'.

- a) **If the woman does have a CRL measurement taken before 14 weeks' gestation the following additional questions will appear:**

- b) **What was the date of the earliest CRL measurement?**

Touch the box and a wheel will appear. Use this to scroll up and down to enter the date the CRL measurement was obtained.

- c) **Is the exact CRL measurement known?**

If the exact CRL measurement (in mm) is known, leave the slider on 'Yes'. Enter the CRL measurement in mm into the box '**What was the CRL measurement at that time?**'

If the exact CRL measurement is not known, touch the slider and change the answer to 'No'. The screen will then change and the question '**Based on this CRL, what was the estimated gestational age?**' will appear. Using the sliders, enter the estimated gestational age at the time of the scan in weeks and days.

If a CRL measurement has been entered, a HC measurement does not need to be entered. To proceed to the next page touch the 'Next' button.

10. Was a head circumference (HC) measurement taken before 24 weeks?

If the woman has a HC measurement after or at 24 weeks, or not at all, leave the slider on 'No'. Press the 'Next' button to proceed.

If the woman has a HC measurement before 24 weeks, touch the slider and change the answer to 'Yes'.

- a) **If the woman has a head circumference (HC) measurement taken before 24 weeks' gestation the following additional questions will appear:**

Was a crown-rump length (CRL) measurement taken before 14 weeks? No

Was a head circumference (HC) measurement taken before 24 weeks? Yes

What was the date of the earliest HC measurement?

Is the exact HC measurement known? Yes

b) What was the date of the earliest HC measurement?

Touch the box and a wheel will appear. Use this to enter the date the HC measurement was obtained.

c) Is the exact HC measurement known?

If the exact HC measurement (in cm) is known, leave the slider on 'Yes'. Enter the HC measurement in cm into the box **'What was the HC measurement at that time?'**

If the exact HC measurement is not known, touch the slider and change the answer to 'No'. The screen will then change and the question **'Based on this HC, what was the estimated gestational age?'** will appear. Using the sliders, enter the estimated gestational age at the time of the scan in weeks and days.

Is the exact HC measurement known? No

Based on this HC, what was the estimated gestational age?

weeks

days

To proceed to the next page touch the 'Next' button.

If neither a CRL nor HC measurement has been taken before 14 or 24 weeks respectively, touch the 'Next' button. This woman will not be eligible for the study. For instructions as to how to proceed, see [Screen 5a: Eligibility](#).

Screen 3: Date of delivery

Once you have entered the CRL or HC measurement information, the following screen will appear:

11. Date of delivery

Touch the box and using the wheel, enter the date of delivery.

The estimated age at delivery will appear on the screen.

Touch the 'Next' button to proceed.

If the woman is selected you will be directed to the recruitment screen (see [Screen 5a: Eligibility](#)). If the woman is no longer eligible for the study, see [Screen 5a: Eligibility](#) for instructions as to how to proceed.

If the woman is not selected but is still eligible, the app will continue to screen the woman.

Screen 4: Birth weight

12. Birth weight

Take birth weight measurements as soon after delivery as possible. Enter the birth weight in grams.

Screen 5a: Eligibility

The app will calculate whether the woman and her baby are eligible for the study.

Ineligible

If the woman is not eligible for the study for any reason, the following screen will appear:

Home Neonatal Screening for Cases/Controls
NS Screening No.: 5 | Country: 11 - Mae Sot, Thailand | Date: 24 May 2012

This woman is not eligible for the INTERBIO-21st Neonatal Study. No further questions need to be answered and no samples need to be taken.

Name of Researcher/Midwife:

Researcher Code: XX

The researcher's name and code should be entered into the boxes and the form completed by touching the 'Submit' button. The following screen will appear:

Home Neonatal Screening for Cases/Controls
NS Screening No.: 3 | Country: 11 - Mae Sot, Thailand | Date: 23 May 2012

You have successfully screened this woman

The woman has been successfully screened. Return to the homepage by touching the 'Home' button.

Eligible

If the woman is eligible the following screen will appear:

Home Neonatal Screening for Cases/Controls
NS Screening No.: 2 | Country: 11 - Mae Sot, Thailand | Date: 23 May 2012

This woman is eligible for the INTERBIO-21st Neonatal Study.

Has she given informed consent to participate in the study? No

Name of Researcher/Midwife:

Researcher Code: XX

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

If she has not given informed consent to participate, leave the slider on 'No', complete your name and researcher code and touch 'Submit'.

If she has given informed consent to participate, touch the slider and change the answer to 'Yes'.

14. Will you collect samples for this woman?

If biological samples will be collected for this woman, leave the slider on 'Yes'. Then continue to enrol the woman.

If biological samples will not be collected from this woman, touch the slider and change the answer to 'No'. If you cannot collect samples the following question will appear:

a) Reasons why samples have not been taken

Touch the button and a dropdown list will appear. Select from the options:

- Clinical event prevented sample collection;
- Research staff unable to collect biological samples;
- Laboratory staff unable to process biological samples.

Enter the researcher's name and code into the boxes and complete the form by touching the 'Submit' button.

Screen 5b: Recruitment

Ensure that the woman has given her consent to participate in the study and that biological samples can be collected and processed, then enrol the woman.

Home Neonatal Screening for Cases/Controls
NS Screening No.: 2 | Country: 11 - Mae Sot, Thailand | Date: 23 May 2012

This woman is eligible for the INTERBIO-21st Neonatal Study.

Has she given informed consent to participate in the study? Yes

Will you collect samples for this woman? Yes

Enrol this woman into the INTERBIO-21st Neonatal Study.

INTERBIO-21st PTID Number (XX-XXXXX)

Maternal Hospital Record Number

Affix PTID labels to sample collection kits. Collect biological samples.

Name of Researcher/Midwife:

Researcher Code: XX

Back Submit

15. INTERBIO-21st PTID Number (XX-XXXXX)

Collect a new sheet of Patient Identification (PTID) labels and type in the PTID Number. This assigns the PTID (a unique identifier) to the woman – ***it is essential to ensure that no other woman has already been assigned this particular PTID.***

16. Maternal Hospital Record Number

Enter the woman's local Maternal Hospital Record Number.

To complete recruitment, enter the researcher's name and code and touch the 'Submit' button. The following screen will appear to signal that screening and recruitment of the woman has been successfully completed:

Home Neonatal Screening for Cases/Controls
NS Screening No.: 5 | Country: 11 - Mae Sot, Thailand | Date: 24 May 2012

You have successfully screened this woman

Once a woman has been recruited:

- Collect maternal blood, maternal faeces, cord blood and placental samples, according to the Biological Sample Collection Operations Manual. Affix a matching PTID label to each specimen and to the front of the sample collection pack.
- For each used kit, complete the **Sample Collection Slip** and affix a PTID label to the header. Place the **Sample Collection Slip** and all remaining PTID labels in the sample collection pack. Send the completed sample collection pack(s) to the lab.

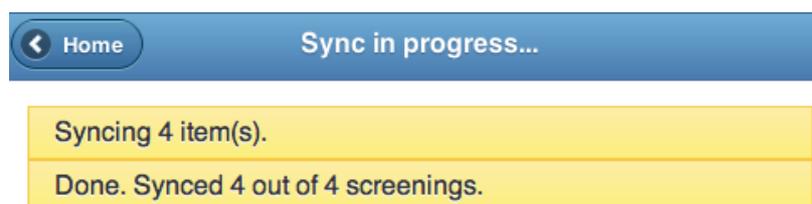
Syncing Data to the Database

To transfer the data from the app to the database (MedSciNet) the app needs to be synchronised with the database. In order to 'sync' data an internet connection is required; without the internet the data cannot be synced.

Only completed screening forms can be transferred to the database; if incomplete screening forms are saved on the app, these will not be transferred to the database. If there are data that can be synced to the database, a 'Sync' button will appear on the homepage. The circled number on the button indicates how many forms are ready to be transferred.



Touch the 'Sync' button and the app will transfer all these data into the database. The following screen will appear when the data transfer is complete:



Ideally data should be synced at the end of every day or first thing in the morning before screening starts for the day. Once data have been transferred to the database you will no longer be able to see any of these records in the app; however, they can be accessed by logging into the online database.