

**PROBIT IV**

**Promotion of Breastfeeding Intervention Trial IV**

**MANUAL OF PROCEDURES**

ISRCTN37687716

## Contact details

Natalia Bogdanovich  
Position: Head of Information Department  
Address: ul Orlovskaja, Bld. 8, app. 12, Minsk  
Telephone number: (017)-233-32-85  
Mobile: +375297079825  
Fax: (017)-233-55-84  
Email: [magicienne@tut.by](mailto:magicienne@tut.by)  
[Omd12@tut.by](mailto:Omd12@tut.by)  
[sevenhos@belpak.by](mailto:sevenhos@belpak.by)

\*\*\*\*\*

## Frequently asked questions

### **At what age range should I see the PROBIT child for PROBIT IV?**

Please try to see all the oldest children first, so that as many as possible are seen before they leave school (aim for an age range of 15 to 15.5 years; try not to let any child reach the age of 16 before seeing them for this study).

### **Can I perform the examination on children who were not recruited to PROBIT I?**

No; we only want data on those children who were in PROBIT I. But you can see children who were not seen in PROBIT II or PROBIT III

### **What do I do with the consent form?**

Please keep the consent form at your polyclinic. However it is vital that you also fill in the appropriate part of the Interview Questionnaire to record that you have a copy of the consents/assent.

### **Is the order of the questions/measurements in the Interview Questionnaire important?**

The order of the Interview Questionnaire is deliberate - Please answer the questions and take the measurements in the order they are printed.

### **Do the children have to fast like in PROBIT III?**

There is no need for the children to fast for this phase of PROBIT (IV), they can eat as normal and have a snack before the visit if required.

### **Do we examine the mother like in PROBIT III?**

No, we only examine the child not the mother or father in PROBIT IV.

## Helpful Tips

- It is useful to say all values out loud until you record them. This tip includes numbers that you measure (e.g. height, visual acuity) as well as those you read from a machine (e.g. weight, bioimpedance, blood pressure and spirometry measures). Repeating the measurements out loud helps to ensure you write down the correct values.
- Label the three blood pressure cuffs small, medium and large. This will make writing the cuff size on the Interview Questionnaire easier.

**Index:**

PROBIT IV ..... 1  
Promotion of Breastfeeding Intervention Trial IV ..... 1  
MANUAL OF PROCEDURES ..... 1  
Contact details ..... 2  
Frequently asked questions ..... 2  
Helpful Tips ..... 2  
Index: ..... 3  
    A. DESCRIPTION OF THE STUDY ..... 4  
    B. ORGANIZATION OF THE STUDY ..... 5  
    C. DURING THE VISIT ..... 5  
    D. RULES FOR COMPLETING THE DATA FORMS ..... 6  
Interview Questionnaire ..... 7  
    SECTION 1: Child identifying information ..... 7  
    SECTION 2: Height and waist circumference ..... 8  
    SECTION 3: Weight and bioelectrical impedance (Tanita) ..... 9  
    SECTION 4: Measurement of vision ..... 12  
    SECTION 5: Child’s sitting blood pressure (1) ..... 13  
    SECTION 6: Child’s sitting blood pressure (2) ..... 15  
    SECTION 7: Skin questions ..... 15  
    SECTION 8: Lung function ..... 16  
    SECTION 9: Medications ..... 20  
    SECTION 10: School performance and *Mindstream* test ..... 21  
    SECTION 11: To be filled in by the doctor ..... 22  
Child self-complete questions ‘Life of a 15+ Teenager’ ..... 22  
    SECTION 12: Contact details ..... 22  
    SECTION 13: Respiratory questions ..... 22  
    SECTION 14: Female teenage questionnaire ..... 22  
    and ..... 22  
    SECTION 15: Male teenage questionnaire ..... 22  
  
END OF INTERVIEW ..... 22  
Appendix 1: Teenagers and parent’s information, assent/consent form ..... 24  
Appendix 2: Blood pressure for girls/boys age and height percentile ..... 24  
Appendix 3: Skin conditions ..... 25  
Appendix 4: Predicted average\* normal values for lung function ..... 28  
Appendix 5: Inventory of equipment for each centre ..... 29  
Appendix 6: Quality assurance Protocols ..... 30

## A. DESCRIPTION OF THE STUDY

### A1 Overview

Children from 31 maternity hospitals were randomly selected and followed for 12 months from time of birth (PROBIT I) and again when the children were 6½ years of age (PROBIT II) and at 11½ years (PROBIT III) at a polyclinic affiliated with each study maternity hospital. PROBIT IV is a follow-up of these children at 15-16 years of age.

**Objective of the study:** The principal objective of the proposed study is to examine whether the experimental breastfeeding promotion intervention introduced in Belarus in 1996-98 has effects on obesity, vision, blood pressure, eczema, lung function and cognitive development, detectable at 15-16 years of age. The comparison of the experimental and control groups, when analyzed by intention to treat, will allow the most rigorous examination to date of the causal relationship between the duration and exclusivity of breastfeeding and these important health outcomes. PROBIT also provides valuable data for observational analyses of early life factors such as infant growth and feeding with later health outcomes.

### A2 Information to be collected

During the interview, the information collected will include:

1. Measurement of child's standing height and waist circumference
2. Weight and bioelectrical impedance.
3. Visual acuity
4. Measurements of child's blood pressure
5. Eczema
6. Lung function
7. Cognitive development
8. Self reported- Respiratory questions, pubertal development and other questions about the life of a teenager

### A3 Logistics and roles

#### Polyclinic paediatrician(s):

In each clinic, the participating polyclinic paediatrician(s) will be responsible for:

1. Verifying that each child included in the study is followed up according to the protocol. The main role will consist of contacting parents and children and asking them to come to the polyclinic. This task is very important for the study. The paediatrician's clinical responsibilities are listed in detail in section B.
2. Making sure that for each study child seen for a visit, and the following information is collected and sent by driver every 4 weeks to the Data Centre in Minsk:
  - (i) PROBIT IV Interview Questionnaire
  - (ii) Life of a teenager questionnaire
  - (iii) memory stick/portable hard drive containing cognitive test results
3. Arranging all paper work according to the child's Subject number before collection by the driver.
4. Correcting errors and completing missing information identified by the Data Centre.

#### Data Centre:

The Data Centre is responsible for data entry and management. It will receive the forms on a 4-weekly basis on average from each of the participating polyclinics and proceed to data entry. The Data Centre will generate, every four weeks, a list of errors identified on the forms that

have been entered. There are two types of errors: missing values and incorrect values (incompatible with what is expected).

The polyclinic paediatricians will be contacted to correct the errors. The corrections will then be sent back to the Data Centre to be entered into the database.

#### Polyclinic patient representative:

Each polyclinic will identify a polyclinic patient representative to address any ethical or other concerns raised by the study children or their parents.

## **B. ORGANIZATION OF THE STUDY**

### **B1 Locating the Children and scheduling the study visit**

Within 1 month after the initial PROBIT IV training workshop, each participating polyclinic paediatrician will attempt to locate each PROBIT child and document if the child is willing to participate in PROBIT IV. It is essential that the oldest children (i.e. those around 15.5 years) are located and examined first, so that as many as possible are examined before they leave school.

The paediatrician will telephone the parents of the children in the study; he/she will obtain verbal consent for the child to take part in the PROBIT IV, record this consent on a specially designed form (See Appendix 1). Inform the parents that there is no need for the child to fast, they can have a snack before the visit if required.

### **B2 The Visit**

The polyclinic paediatrician will receive the blank Interview Questionnaires after the training workshop in Minsk.

The polyclinic paediatrician will:

1. Ensure that children come to the polyclinic visit.
2. Ensure that the parental phone consent has been administered and signed.
3. Ensure that the parent consent and child assent forms are signed.
4. Ensure that the PROBIT IV data forms are completed.
5. Every 4 weeks, send copies of the data forms and computerised cognitive function data (stored on a memory stick) to the Republican Centre for Maternal and Child Health in Minsk.
6. Correct or complete information when errors are detected.
7. Attend PROBIT IV workshops.
8. Participate in audit and quality assurance monitoring (see Appendix 6).

## **C. DURING THE VISIT**

1. Ask the accompanying parent to sign the consent form and the child to sign the assent form (Appendix 1); record the relationship of the adult to the child. If the parent has not accompanied the child, then the paediatrician must check that the telephone consent sheet obtaining verbal consent from the parent is fully completed. If not, please phone the parent to obtain consent and record this on the telephone consent sheet.
2. Examine the child and complete the data form.
3. Take the child to the laptop to complete the Mindstreams test.
4. Please tear out Section 14 (Female Teenager questionnaire) for boys and Section 15 (Male Teenager questionnaire) for girls and give the child the appropriate 'Life of a 15+ Teenager' self-completion questionnaire.

5. When the interview and examination have been completed, give the child the gift.
6. Every 4 weeks: send the data and memory stick by driver to the Republican Centre for Maternal and Child Health in Minsk.
7. If vision or lung function are lower than expected or the child's blood pressure is higher than expected, please notify the parents and offer necessary follow-up and/or referral.

#### **D. RULES FOR COMPLETING THE DATA FORMS**

1. Write the responses in the designated areas or tick the appropriate boxes.
2. Dates should be written in Arabic figures starting with day, then month and year.
3. Use a 24-hour clock for recording times.
4. All figures should be entered by filling the provided spaces on the right, and zeroes entered in the empty cells on the left.
5. If it is not possible to obtain data on certain questions, write 'unknown' or cross out the question and write 'unknown.'
6. All corrections made to data in the questionnaires should be initialled by the examining paediatrician.
7. Please complete the questions in the order they are printed.

# **Interview Questionnaire**

## **SECTION 1: Child identifying information**

### **1.01 Hospital number**

Each polyclinic has a specific number from 01 to 34. The hospital number for each child is the number that was originally assigned in PROBIT I. This number is also part of the identifier that serves to uniquely identify each child during the study. It is therefore necessary to report this number on all data forms. It is also crucial to keep the original hospital number to ensure a link between the four databases (PROBIT I, PROBIT II, PROBIT III and PROBIT IV). This number will already have been stamped onto the questionnaire by the research staff in Minsk. Please verify that the identification details are correct for each child and inform the data centre if they are not.

### **1.02 Subject number**

Each child at each polyclinic has a subject number from 0001 to 9999, which was assigned at the maternity hospital for all children whose mothers originally agreed to participate in PROBIT. This number is also part of the identifier that serves to uniquely identify each child during the study. It is therefore necessary to report this number on all data forms. It is crucial to keep the same subject number to ensure a link between the four databases (PROBIT I, PROBIT II, PROBIT III and PROBIT IV). This number will already have been stamped onto the questionnaire by the research staff in Minsk. Please verify that the identification details are correct for each child and inform the data centre if they are not.

Example: **32\_0010** would be the identifier for child number 10 at polyclinic 32

### **1.03 First name**

Write the Child's first name.

### **1.04 Last name**

Then write child's last name

### **1.05 Child's date of birth**

Write the day, month and year of birth: Day Month Year.

### **1.06-1.08 Consent and assent**

Please tick the appropriate boxes. In order to proceed with the visit, the telephone consent must have been given and recorded and the assent form must be signed by the child (Items 1.06 and 1.08 both ticked "Yes"). Item 1.07 may be "No", but ONLY if the parent or legal guardian did not accompany the child and 1.06 (telephone consent is ticked) "Yes." See Appendix 1.

### **1.09 Number of Examiner**

Please enter your Pediatrician number that we provided to you at the training workshop

### **1.10 Date physical examination completed**

This is the date on which the physical examination is completed: Day Month Year.

### **1.11 Number of younger siblings**

Record the number of younger siblings (or half-siblings) living at home.

### 1.12-1.13

Record the date and time of the child's last main meal.

## SECTION 2: Height and waist circumference

It is important to use standardized procedures consistently. Remove heavy clothing, shoes and socks before taking the measurements.

### Standing height

Standing height is measured with a stadiometre with a movable headboard. Hair ornaments, jewellery, and braids should be removed from the top of the head in order to measure height properly. The child stands with the heels of both feet together so the medial malleoli are touching (unless the child has knock knees), and the backs of the heels are touching the base of the wall. Feet should be flat, so the undersides of the heels are in contact with the ground. The toes are pointing slightly outward at an approximately 60-degree angle.

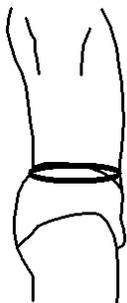
The paediatrician should check the position of several points of body contact with the wall. The first contact point is the heels, then calves, followed by the buttocks, the scapula or shoulder blades, and finally the back of the head. Depending upon the overall body shape of the child, all points may not touch. The trunk of the body should be positioned vertically above the waist with the arms and shoulders relaxed and arms loose with palms facing medially. The head should be aligned in a Frankfort horizontal plane. The head is in a Frankfort plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the wall. Many children will assume this position naturally, but for some it might be necessary to make a minor adjustment. If required, the paediatrician may gently tilt the head up or down until a proper alignment is achieved with the eyes looking straight ahead. Once correctly positioned, the headboard is lowered, and the child is instructed to take a deep breath and stand as tall as possible. A deep breath allows the spine to straighten, yielding a more consistent and reproducible height measurement. Ask the child to 'relax the shoulders and stretch up but keep the heels on the ground'. Assist this stretching by applying gentle upwards pressure beneath the mastoid processes. Check that the heels are still touching the ground. The headboard is positioned firmly on top of the head with sufficient pressure to compress the hair. The measurement is read in centimetres and recorded to the nearest millimetre (0.1cm). The child then relaxes and steps away from the stadiometre.

### 2.01

Measure the child's height twice. If the measurements differ by more than 0.5 cm, check technique and take a third and fourth measurement. Record all readings.

### Child's waist circumference

This should be measured with the subject standing with feet together and weight evenly balanced on both feet. The arms should hang loosely at the sides. The paediatrician, who is positioned to the right of the child, locates the right ilium. Just above the uppermost lateral border of the right ilium, a horizontal mark is drawn and then crossed with a vertical mark on the mid-axillary line. The paediatrician places the measuring tape around the trunk at the level of the mark on the right side. The paediatrician then inspects all sides to make sure the measuring tape is at a level horizontal plane.



The tape is then tightened slightly, but without compressing the skin and underlying subcutaneous tissues. The measure is made at end expiration and is recorded to the nearest millimetre (0.1cm). Ask the child look straight ahead, be relaxed, and not to pull the tummy in.

## 2.02

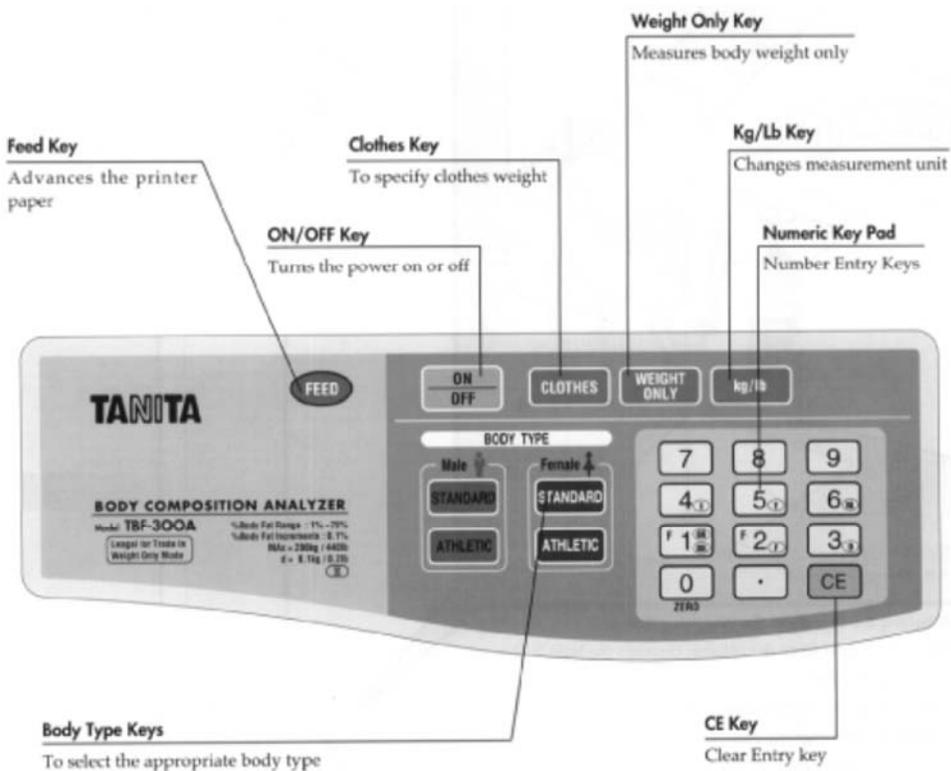
Record waist circumference twice to the nearest 0.1 cm. If the measures differ by more than 0.5 cm, check technique and take a third and fourth measurement. Record all readings.

NOTE: The measuring tape should be placed around the trunk, just above the iliac crest. Please note that the tape should NOT be placed on the bone. The tape should have a gentle tension, and should be horizontal around the waist.

## SECTION 3: Weight and bioelectrical impedance (Tanita)

**Background:** The Tanita TBF 300GS body-fat analyser, which provides a measure of bioelectrical impedance from foot to foot, will be used to measure weight, total body water, % body fat, fat mass and fat free mass. This bioelectrical impedance system consists of two main units. The first is a platform scale on which two subdivided stainless steel foot pad electrodes are mounted. While the subject stands with bare feet making pressure contact with the foot pads, a small current (50 KHz/0.8 mA) is transmitted through the anterior part of the foot pad electrodes and the difference in voltage across the legs is measured by the posterior (heel) electrodes. The second unit is a tabletop indicator with a digital keyboard through which height and sex can be entered into a microcomputer. The unit measures body weight and impedance simultaneously and the measured impedance (W) is converted into the output of total body water, % body fat, fat mass and fat-free mass

WEIGHT	ВЕС		кг	Kg
CLOTHES	ОДЕЖДА	<input type="checkbox"/>	фунты/стоуны, фунты	lb/st.lb
MALE	МУЖЧИНА		см	Cm
FEMALE	ЖЕНЩИНА		футы, дюймы	ft. in
ATHLETIC	СПОРТСМЕН		ВОЗРАСТ	AGE
STEP ON	СТАНЬТЕ НА ПРИБОР		ЖИР, %	%FAT



<b>Feed key</b> Advances the printer paper	<b>Клавиша загрузки</b> Подает бумагу в принтер
<b>ON/OFF key</b> Turns the power on and off	<b>Клавиша ВКЛ/ВЫКЛ</b> Включает и выключает питание
<b>Clothes key</b> To specify clothes weight	<b>Клавиша «одежда»</b> Для указания веса одежды
<b>Weight only key</b> Measures body weight only	<b>Клавиша «только вес»</b> Измеряет только вес тела
<b>Kg/Lb key</b> Changes measurement unit	<b>Клавиша «кг/фунты»</b> Выбирает единицу измерения
<b>Numeric key pad</b> Number entry keys	<b>Клавиатура нумерации клавиш</b> Номера клавиш ввода
<b>Body type keys</b> To select the appropriate body type	<b>Клавиши выбора типа тела</b> Для выбора типа тела
Standard Athletic Male Female	Стандартный Атлетическо Мужчин Женщин
<b>CE key</b> Clear entry key	<b>Клавиша очистки</b> Клавиша очистки ввода

**Procedure:** Place the platform of the Tanita machine on a stable flat surface, clean with a disinfecting wipe, and switch on. The paediatrician asks the child to pass urine (if possible) and remove heavy clothes, shoes and socks before taking the measurements. The first prompt asks for the weight of the child’s clothing, enter 0.0 for **ALL** subjects. Now select either STANDARD MALE or STANDARD FEMALE. Enter the child’s age in years. Record the child’s standing height in centimetres to the nearest centimetre (up to 0.4 is rounded down and 0.5 is rounded up). The child steps slowly on the metal sole plates of the machine without touching anything else. It is essential that the child stands on the metal plate with clean bare feet. Heels should be placed directly on the posterior electrodes and the front part of the foot should be in contact with the anterior electrodes, with feet parallel. The child should stand reasonably straight if possible – leaning to one side (or forwards) can affect the weight recorded. Once the printer prints out the results, the child steps off the machine.

**The Tanita scale sometimes reads an error with very thin boys when using the ‘male standard’ setting. If this occurs please take a reading using the ‘female standard’ setting. Record this information on the interview questionnaire.**

### 3.01-3.10 Bioelectrical Impedance results for child

Using the results from the printout, record the child’s weight, impedance, % fat, fat mass, fat free mass and total body water onto the data form. In addition, staple the printout onto the data sheet; make sure the printout is readable, if not, correct any printer problems and repeat the measurement. One measurement is taken.

If the child exceeds the maximum weight registering on the scales (200kg) do not attempt to weigh them but code as “weight not attempted”. If the child has a pacemaker or internal medical device, code as “weight not attempted”. Do not attempt to weigh them using the Tanita machine. If the Tanita machine cannot be used, measure weight using the standard clinic scales.

ТАНИТА АНАЛИЗАТОР ТЕЛА ТБФ – 300GS	
ТИП ТЕЛА	СТАНДАРТНЫЙ
ПОЛ	МУЖСКОЙ
ВОЗРАСТ	26 лет
РОСТ	182 см
ВЕС	82,0 кг
ИМТ	24,8
ИОО	10810 кДж 1932 ккал
ИМПЕДАНС	449
ЖИР, %	16,1%
ВЕС ЖИРА	13,2 кг
ВБЖ	68,8 кг
ОВО	50,4 кг
ЖЕЛАТЕЛЬНЫЙ ДИАПАЗОН	
ЖИР, %	14-20%
ВЕС ЖИРА	11,2-17,2 кг

TANITA BODY COMPOSITION ANALYZER TBF - 300GS	
BODY TYPE	STANDARD
GENDER	MALE
AGE	26
HEIGHT	182cm
WEIGHT	82.0 kg
BMI	24.8
BMR	10810 kJ 1932 kcal
IMPEDANCE	449
FAT%	16.1 %
FAT MASS	13.2 kg
FFM	68.8 kg
TBW	50.4 kg
DESIRABLE RANGE	
FAT%	14 - 20 %
FAT MASS	11.2 - 17.2 kg

## SECTION 4: Measurement of vision

### Equipment:

- LogMAR crowded test
- Eye patches
- Hand held occluders with pinhole
- Masking tape
- Tape measure

The following outlines the eye measurements to be recorded. **Questions 4.01-4.04** need to be filled in for everybody, Questions 4.05-4.07 need to be completed in specific circumstances (outlined below).

### 4.01

Ask the child if they wear spectacles.

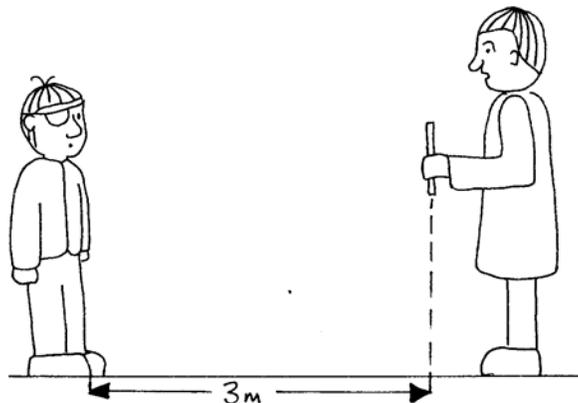
### 4.02

If YES, ask the child if they have their spectacles with them.

### 4.03

Look through each lens of the child's spectacles at the data sheet, holding the spectacles 30 cm from you with a further 30 cm to the page. Indicate whether the lens is positive (+), or negative (-). Positive lenses will magnify the page, negative lenses will minimise the page. If it is not clear if the lenses are positive or negative tick 'unsure'.

### 4.04-4.06



1. Measure a distance of 3 metres on the floor (use masking tape and the tape measure to indicate a distance of 1 and 3 metres). You may want to mark out these distances ahead of time, and use the same marks for all children you see.
2. Position the child at one end without spectacles.
3. Have the child place the patch over the left eye. Ensure the eye is covered and that there is no way the child can peek around the patch by turning his/her head.
4. Test the vision using the 'LogMAR Acuity Cards' at 3 metres.

5. Start with line 6 (in the red book) and go smaller if the line is read correctly until letters are misread or you reach line 9. NOTE: Lower numbers=worse vision.
6. If line 6 is not seen go bigger until you reach line 1. If the letters are still not seen at 3 metres, retest at 1 metre beginning again at line 6.
7. Record the line and numbers of letters seen in the boxes accordingly (indicate with a tick only if the test is done at 1 metre) **(4.04)**.
8. Repeat for the other eye but ask child to read letters in reverse order.
9. If the child wears spectacles, test each eye again with the spectacles on **(4.05)**.
10. If the best vision recorded (either unaided or with spectacles) is lines 1 to 6 in either eye, retest with pinhole occluder in front of the eye. Be sure to encourage the child to read as much as possible **(4.06)**.
11. If you are concerned that the child may be remembering the letters from the other eye, rather than reading them, change the order of chart presentation and/or ask the child to read the letters in reverse order.

#### **4.07**

If the vision is lines 1 to 6 in either eye and acuity does not improve with spectacles or with use of the pinhole, ask the child if they are aware of having reduced vision. If the child indicates that they are not aware of having reduced vision and are not in touch with health services about their eyes, tick 'No, unknown problem' and ensure that the parents are notified. If the child is aware of having reduced vision and have been under health services about their eyes either now or in the past, then tick 'Yes, known problem'.

### **SECTION 5: Child's sitting blood pressure (1)**

***Before taking the child's blood pressure, allow the child to rest for 5 minutes. Allow the child to empty their bladder if needed (a full bladder will affect blood pressure readings).***

#### **5.01**

Record the time at which the blood pressure measurement is taken.

#### **5.02**

Record the temperature of the room with the thermometer we provided to you.

#### **5.03-5.04**

The child's systolic and diastolic blood pressure is measured twice during the examination on the right arm in the sitting position using the fully automated (digital read-out) OMRON 705IT device. It is important to select the correct blood pressure cuff size. **The appropriately sized blood pressure cuff should be used i.e. the bladder of the cuff should encircle at least 80% of the upper arm (but NOT more than 100%).** The following protocol for child blood pressure should be followed:

1. The subject should sit down; rest their right arm on the table, palm of hand facing upwards and upper arm at chest level. Ensure that the subject is sitting with their feet on the ground and that the legs are not crossed.
2. The cuff should be airless and the air tube inserted into the right side of the OMRON 705IT device.
3. The cuff should be placed around the **bare** right upper arm. Avoid rolling sleeves up as this can cause a constriction to the upper arm.
4. The cuff should be at the same level as the heart. The green marker on the cuff should lie over the brachial artery on the inside of the arm. The air tube should run down the side of the arm. The lower end of the cuff should be 2 cm above the antecubital fossa (elbow crease). There should be a two-finger gap between the antecubital fossa and the bottom edge of the cuff.
5. Pull the cuff so that the top and bottom edges are tightened evenly around the arm. When the cuff is positioned correctly, close the Velcro fastener firmly. Make certain the cuff fits snugly around the arm. The cuff should make good contact with the skin. Do not place the cuff too tightly as bruising may occur on inflation. Ideally, it should be possible to insert one finger between the cuff and arm, but the cuff should not be applied too loosely, as this will result in an inaccurate measurement.
6. Check that subject is familiar with having her/his blood pressure taken.
7. Explain that you will inflate the cuff, which will then slowly deflate automatically.
8. Be sure there are no kinks in the air tubing.
9. Press the 'on' button. Then press the 'start' button.
10. As the cuff begins to inflate, the monitor automatically determines the ideal inflation level. Because the monitor detects the pulse even during inflation, ask the subject not to move the arm or talk, but remain still until the entire measurement completes. Do not put your hand on the cuff, as this will interfere with the readings.
11. Inflation stops automatically and blood pressure measurement is started. As the cuff slowly deflates, decreasing numbers appear on the display and the heart symbol flashes at every heartbeat. In rare circumstances, a higher inflation may be necessary. In those cases the monitor automatically reinflates the cuff up to 30mmHg higher than initial inflation and restarts the measurement.
12. Encourage the child to keep the arm still and not to talk during measurement. Arm movement is a very common cause of error readings on the blood pressure machine and talking will distort the blood pressure reading.
13. When the measurement is complete, the cuff completely deflates and the blood pressure (and pulse rate) is displayed.
14. Record the systolic and diastolic blood pressure readings exactly as on the machine (DO NOT ROUND THE FIGURES UP OR DOWN).
15. Clear the memory by pressing the 'M' button and the start button simultaneously.
16. Repeat this process for the second blood pressure reading.

### 5.05

Tick the appropriate box for which arm the measurement was taken on. Note that measurements should be taken in the **right** arm. If the right arm cannot be used or you are unable to obtain a reading in the right arm after two attempts using the OMRON 705IT, then move to left arm and make two further attempts using the OMRON 705IT. If this fails, use a mercury sphygmomanometer on the right arm.

## 5.06

Tick the appropriate box for which BP measurement device was used. Note that measurements should be taken using the OMRON 705IT. The main reasons why blood pressure readings using this device fail are:

- Positioning the cuff incorrectly
- Not keeping the arm still or child is talking
- Using an incorrectly sized cuff
- Placing a hand on the cuff while pumping
- Arrhythmia (rare)

If there are difficulties obtaining readings with the OMRON 705IT, repeat having checked that you are not making one of the mistakes listed above. As a last resort, a mercury sphygmomanometer may be used, but only after multiple unsuccessful attempts with the OMRON 705IT. (See 5.05).

We recommend that standard nomograms are used to determine if the child's blood pressure (averaged over 2 readings) is in excess of current recommendations and that standard protocols for their investigation and management are followed (see Appendix 2).

## 5.07

Tick the appropriate box to record the size of the cuff used to measure the child's blood pressure.

## **SECTION 6: Child's sitting blood pressure (2)**

**Repeat blood pressure readings after waiting 1 minute between measurements.**

See Section 5

## **SECTION 7: Skin questions**

### 7.01-7.08

Ask the child the questions and fill in each response.

### 7.09-7.13

Your task is to record as consistently as possible the presence/absence of physical signs of atopic eczema - "visible flexural dermatitis" for all children.

See Appendix 3

## SECTION 8: Lung function

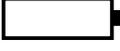
### Equipment:

- MicroMedical Micro Spirometer
- 3 litre (3L) Calibration Syringe
- Disposable Mouthpieces
- Nose Clips

The first time you use the spirometer, you will need to assemble the parts by gently pushing the turbine into the body of the spirometer: there are three small lugs that need to be located in the slots in the spirometer body. The turbine section is then twisted clockwise ( $\frac{1}{8}$ -turn) to lock it in place. Then place the mouthpiece adapter (small plastic tube) over the top of the turbine so that it looks like the picture below.



The spirometer needs to be charged before using it. Follow the instruction in the user manual. Plug the charger into an electrical socket and connect the charger to the spirometer using the USB cable supplied.

The battery icon will display  when fully charged. When the battery icon shows  the spirometer must be plugged into the charger. As charging takes up to 5 hours, it is important that the battery is checked before the start of each testing session.

When the battery has finished charging, you must carry out a calibration procedure.

### Calibration procedure

#### 8.01

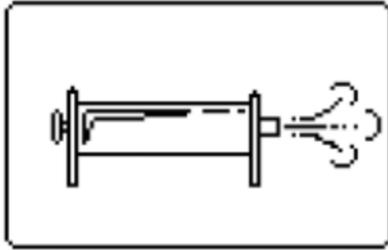
Check the calibration of the Micro Spirometer with a 3L calibration syringe at the start of each testing day.

1. Switch on the Micro Spirometer using the switch at the top of the instrument marked

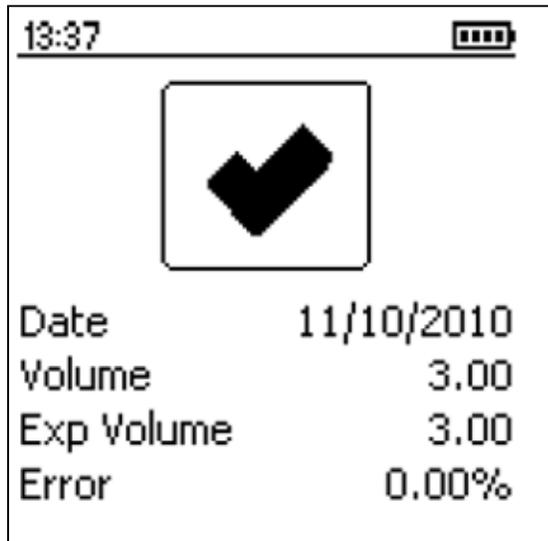


(if the display doesn't light up, charge the battery as above)

2. Click 'Settings' > 'Calib check' Display will show:



3. Attach the 3L calibration syringe to the Micro Spirometer
4. Inject the syringe volume evenly into the Micro Spirometer without pausing.
5. If the calibration is correct (within +/- 3.5% (0.11 L), the following will be displayed:



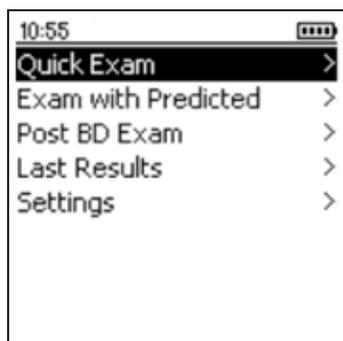
6. If the calibration is outside this range, the tick (√) will be replaced with a cross (X). Check the syringe and connection to make sure there is no leak and repeat steps 4 & 5.
7. If calibration is not achieved, notify the Minsk coordinating centre who will discuss with Professor John Henderson.

### Measurement of lung function by spirometry <sup>1</sup>

#### **8.02-8.09**

1. Seat child comfortably on a chair. Show the child the noseclip (but don't apply it until you're ready to start testing).
2. Explain the procedure:
  - i. You will have the noseclip on.
  - ii. You will hold the device (show the child the Micro Spirometer) in your hand.
  - iii. You will be asked to sit up, and take a deep breath in to fill your lungs to maximum capacity.
  - iv. You will put your mouth around the mouthpiece so your lips form a tight seal around it.

- v. You will then blow **as hard and as fast as you can** into the mouthpiece and try to keep blowing until you empty your lungs completely. The tester will count to 6 as you blow – try to keep blowing for 6 seconds.
  - vi. You will be asked to repeat the blowing in exactly the same way another 2-7 times.
  - vii. You can rest in between each blow and remove the noseclip if it's uncomfortable.
3. Tell the child: *“Try to blow as hard as you can every time. If it makes you cough, you can stop and try again. However, it is very important to try to keep blowing for as long as you can.”*
- i. Demonstrate the technique of blowing using a cardboard mouth piece.
  - ii. Sit up. Fill your lungs to maximum capacity.
  - iii. Hold your breath and put your lips around the tube – showing the child how to make a seal with your lips.
  - iv. Blow as hard and as fast as you can and continue blowing for at least 6 seconds –count down on your fingers to demonstrate this as you blow.
  - v. Once you complete the blow, remove the mouthpiece from your mouth and relax.
4. Perform the lung function measurements:
- i. Make sure the child is comfortably seated in an upright posture.
  - ii. Insert a new mouthpiece into the Spirometer, ensuring it is tightly connected.
  - iii. Switch on the Micro Spirometer. From the display select ‘Quick Exam’. If there is no display, check the battery is charged.



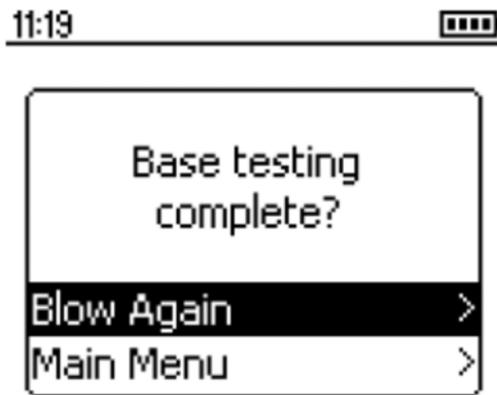
- iv. Give the Spirometer to the child and instruct them to hold it still until they are ready to blow. Apply the nose clip.
- v. Ask the child to take a deep breath in. Give the following instructions:
  - “Fill your lungs until you can’t get any more air in.”*
  - “Now put your lips around the mouthpiece and blow as hard and as fast as you can.”*
  - “Keep blowing, keep blowing!”*
 Encourage the child to continue until you have counted to 6 seconds
  - “Great effort. Now relax!”*

- vi. The results for that blow will be displayed with a statement 'Good Blow' at the bottom if the test was performed properly\*.

10:56		[Battery Icon]	
<b>Current Blow Results</b>			
Base Blow 1		%Pred	
FEV1	4.15L	96%	
FVC	4.91L	97%	
FEV1/FVC	85%	102%	
PEF	566L/m	96%	
Predicted:		FCCS	
Quality:		Good Blow	

\* Each manoeuvre is quality checked for a slow start, abrupt end, short blow, poor effort or cough according to ATS/ERS 2005 guidelines.

- vii. Record FEV<sub>1</sub>, FVC, and FEF<sub>25-75</sub> on the questionnaire
5. Tell them they did great and that you're going to ask them to do that again.
  6. Press 'Enter' to display:



7. Select 'Blow Again' and repeat steps 4-iii to vii. After each reading check the values of FEV<sub>1</sub> and FVC against the previous. The difference from the highest value should be less than 0.15L.
8. Continue to repeat steps 4-iii to vii until you have **three** good blows that are within 0.15L of the child's highest FEV<sub>1</sub> and FVC. You can allow up to a maximum of **eight blows** to achieve this.
9. Stop the test when **either** (1) the child has achieved three blows with FEV<sub>1</sub> and FVC within 0.15L of the child's highest value from a 'Good blow' **or** (2) eight blows have been completed without meeting this criterion.
10. For each blow, record on the form one of the following responses so we can understand the validity of the measurement:
  1. *Good blow*
  2. *Child coughed*
  3. *Child's noseclip came off/leakage of air form the nose*

4. *Child stopped blowing early*
  5. *Child did not appear to use maximal effort*
  6. *Child did not make a good seal around the mouthpiece*
  7. *Child inhaled before they finished the blow*
  8. *Child didn't start blowing immediately after they put their mouth to the Spirometer*
  9. *Other reason for inadequate blow*
11. Once you have finished the test, switch off the spirometer using the switch at the top of the device marked  to conserve the battery charge.
12. When the child has finished the test, it is possible they will complain of tight chest or difficult breathing and you may hear an audible wheeze when the exhale, especially if they are known to have asthma. If these symptoms persist or are bothersome, you can give the child 4 puffs of albuterol from a metered aerosol with a spacer. The symptoms should settle within 10 minutes.

Forced Expiratory Volume in 1 second (FEV<sub>1</sub>) measured in liters is the maximum amount of air that someone can blow out of their lungs in the first 1 second. If the air passages are narrowed, FEV<sub>1</sub> is reduced. Average values for FEV<sub>1</sub> in healthy people depend mainly on sex and age. Values of between 80% and 120% of the average value is considered normal.

Forced Vital Capacity (FVC) is the volume of air that can forcibly be blown out after full inspiration, measured in liters.

These are approximate ranges of expected lung function values in adolescents. Values outside these ranges may be normal for individuals and do not signify disease.

These are a guide to the expected values. See Appendix 4 for more detail:

	FEV <sub>1</sub>	FVC	FEF <sub>25-75</sub>
Girls	2.04 - 3.66	2.33 - 4.20	2.06 - 4.09
Boys	2.34 - 4.43	2.78 - 5.29	2.12 - 4.57

#### **8.10-8.12**

Ask the child the questions and record the responses.

If a child's values fall outside the predicted values for their age or height (Appendix 4), please arrange for clinical follow-up and/or referral.

## **SECTION 9: Medications**

### **9.01**

Ask if the child has taken any medicine in the last week. If 'No' then go to Section 10.

#### **If Yes continue to 9.02-9.10**

Please indicate if the child has taken any of the medications listed and the last time it was taken. Tick ONE BOX ONLY in each row. Please make sure that each row has a ticked box.

## **SECTION 10: School performance and *Mindstream* test**

***Before taking the child to the laptop, allow the child to rest for 5 minutes.***

### **10.01**

Ask the child the number of years of schooling they have completed.

### **10.02**

Ask the child if they attend school now. Record 'yes' or 'no'

### **10.03-10.04b**

Record the grade the child is in either now or when they last attended school.

**Please take the child to the laptop to do the 'Mindstream' test.**

**Carefully select the child's ID number, initials and date of birth from the list of ID's, initials and dates of birth on the 'Mindstreams'.**

### **10.05**

Carefully record the computer test number

### **10.06-10.07**

Record one (main) reason when the *Mindstream* test was not able to be done.

NEED TO ADD IN INSTRUCTIONS ABOUT COMPLETING MINDSTREAMS

**Please go back and check you have answered all the questions.**

**Fill in the identifying details on the next page.**

**Please tear out Section 14 (Female Teenager questionnaire) for boys and Section 15 (Male Teenager questionnaire) for girls.**

**Give the child the ‘Life of a 15+ Teenager’ self-completion questionnaire.**

**Please assist the child if they have reading difficulties.**

**If the child does not want to answer any particular questions they can skip the question and go on.**

**SECTION 11: To be filled in by the doctor**

Carefully fill in the identification number for the child.

**11.01 Hospital number/ Subject number/ Child’s date of birth**

Write the child’s hospital number, subject number and the day, month and year of birth: Day Month Year DD/MM/YY

**11.02 Date of visit**

This is the date on which the physical examination is completed: Day Month Year DD/MM/20YY.

**Child self-complete questions ‘Life of a 15+ Teenager’**

Give the questionnaire to the child to fill the following sections:

**SECTION 12: Contact details**

**SECTION 13: Respiratory questions**

**SECTION 14: Female teenage questionnaire**

**and**

**SECTION 15: Male teenage questionnaire**

**END OF INTERVIEW**

Give a small gift (provided) to say thank you. Remember to follow-up any unexpected findings on measurements of blood pressure, vision, or lung function.

A list of equipment required in the clinic is listed in Appendix 5.

The PROBIT IV quality assurance protocol is listed in Appendix 6.

**Check all forms have been filled in clearly. Sort all paper work into subject number order and backup memory stick before collection by driver**

## Appendix 1: Teenagers and parent's information, assent/consent form

## Appendix 2: Blood pressure for girls/boys age and height percentile <sup>2,3</sup>

### Blood pressure for girls age and height percentile

Age years Blood Pressure percentile	Systolic Blood Pressure, mmHg							Diastolic Blood Pressure, mmHg						
	5	10	25	50	75	90	95	5	10	25	50	75	90	95
<b>Percentile of height</b>														
<b>14</b>														
<b>Height (cm)</b>	<b>151</b>	<b>153</b>	<b>157</b>	<b>161</b>	<b>166</b>	<b>170</b>	<b>172</b>	<b>151</b>	<b>153</b>	<b>157</b>	<b>161</b>	<b>166</b>	<b>170</b>	<b>172</b>
50th	106	106	107	109	110	111	112	63	63	63	64	65	66	66
90th	119	120	121	122	124	125	125	77	77	77	78	79	80	80
95th	123	123	125	126	127	129	129	81	81	81	82	83	84	84
99th	130	131	132	133	135	136	136	88	88	89	90	90	91	92
<b>15</b>														
<b>Height (cm)</b>	<b>152</b>	<b>154</b>	<b>158</b>	<b>162</b>	<b>167</b>	<b>171</b>	<b>173</b>	<b>152</b>	<b>154</b>	<b>158</b>	<b>162</b>	<b>167</b>	<b>171</b>	<b>173</b>
50th	107	108	109	110	111	113	113	64	64	64	65	66	67	67
90th	120	121	122	123	125	126	127	78	78	78	79	80	81	81
95th	124	125	126	127	129	130	131	82	82	82	83	84	85	85
99th	131	132	133	134	136	137	138	89	89	90	91	91	92	93
<b>16</b>														
<b>Height (cm)</b>	<b>152</b>	<b>154</b>	<b>158</b>	<b>163</b>	<b>167</b>	<b>171</b>	<b>173</b>	<b>152</b>	<b>154</b>	<b>158</b>	<b>163</b>	<b>167</b>	<b>171</b>	<b>173</b>
50th	108	108	110	111	112	114	114	64	64	65	66	66	67	68
90th	121	122	123	124	126	127	128	78	78	79	80	81	81	82
95th	125	126	127	128	130	131	132	82	82	83	84	85	85	86
99th	132	133	134	135	137	138	139	90	90	90	91	92	93	93
<b>17</b>														
<b>Height (cm)</b>	<b>152</b>	<b>155</b>	<b>159</b>	<b>163</b>	<b>167</b>	<b>171</b>	<b>174</b>	<b>152</b>	<b>155</b>	<b>159</b>	<b>163</b>	<b>167</b>	<b>171</b>	<b>174</b>
50th	108	109	110	111	113	114	115	64	65	65	66	67	67	68
90th	122	122	123	125	126	127	128	78	79	79	80	81	81	82
95th	125	126	127	129	130	131	132	82	83	83	84	85	85	86
99th	133	133	134	136	137	138	139	90	90	91	91	92	93	93

### Blood pressure for boys age and height percentile

Age years Blood Pressure percentile	Systolic Blood Pressure, mmHg							Diastolic Blood Pressure, mmHg						
	5	10	25	50	75	90	95	5	10	25	50	75	90	95
<b>Percentile of height</b>														
<b>14</b>														
<b>Height (cm)</b>	<b>154</b>	<b>157</b>	<b>162</b>	<b>167</b>	<b>173</b>	<b>177</b>	<b>180</b>	<b>154</b>	<b>157</b>	<b>162</b>	<b>167</b>	<b>173</b>	<b>177</b>	<b>180</b>
50th	106	107	109	111	113	114	115	60	61	62	63	64	65	65
90th	120	121	123	125	126	128	128	75	76	77	78	79	79	80
95th	124	125	127	128	130	132	132	80	80	81	82	83	84	84
99th	131	132	134	136	138	139	140	87	88	89	90	91	92	92
<b>15</b>														
<b>Height (cm)</b>	<b>159</b>	<b>162</b>	<b>167</b>	<b>172</b>	<b>177</b>	<b>182</b>	<b>184</b>	<b>159</b>	<b>162</b>	<b>167</b>	<b>172</b>	<b>177</b>	<b>182</b>	<b>184</b>

50th	109	110	112	113	115	117	117	61	62	63	64	65	66	66
90th	122	124	125	127	129	130	131	76	77	78	79	80	80	81
95th	126	127	129	131	133	134	135	81	81	82	83	84	85	85
99th	134	135	136	138	140	142	142	88	89	90	91	92	93	93
<b>16</b>														
<b>Height (cm)</b>	<b>162</b>	<b>165</b>	<b>170</b>	<b>175</b>	<b>180</b>	<b>184</b>	<b>186</b>	<b>162</b>	<b>165</b>	<b>170</b>	<b>175</b>	<b>180</b>	<b>184</b>	<b>186</b>
50th	111	112	114	116	118	119	120	63	63	64	65	66	67	67
90th	125	126	128	130	131	133	134	78	78	79	80	81	82	82
95th	129	130	132	134	135	137	137	82	83	83	84	85	86	87
99th	136	137	139	141	143	144	145	90	90	91	92	93	94	94
<b>17</b>														
<b>Height (cm)</b>	<b>164</b>	<b>166</b>	<b>171</b>	<b>176</b>	<b>181</b>	<b>185</b>	<b>187</b>	<b>164</b>	<b>166</b>	<b>171</b>	<b>176</b>	<b>181</b>	<b>185</b>	<b>187</b>
50th	114	115	116	118	120	121	122	65	66	66	67	68	69	70
90th	127	128	130	132	134	135	136	80	80	81	82	83	84	84
95th	131	132	134	136	138	139	140	84	85	86	87	87	88	89
99th	139	140	141	143	145	146	147	92	93	93	94	95	96	97

We recommend investigating those children whose blood pressure is equal to or above the 99<sup>th</sup> percentile. We recommend the guidelines of the National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. Pediatrics 2004; 114(2 Suppl 4th Report):555-576

### Appendix 3: Skin conditions

To decide whether this sign is present or not, there are two components to consider:

#### Step 1

#### What dermatitis looks like?

Definition of dermatitis: Poorly demarcated erythema (redness) with surface change. "Surface change" can mean fine scaling, vesicles, oozing, crusting or lichenification.

Here are some photographs to help you.



1. This is dermatitis. Note it is red, has an indistinct margin and there is a surface change (in this case fine scaling)



2. This is dermatitis showing another type of surface change, in this case oozing (clear fluid leaking from the skin) and crusting (scabs).



3. These are vesicles (tiny clear "water" blisters).



4. This is lichenification... Lichenification means a thickening of the skin in response to scratching. The skin markings are exaggerated and the skin feels thickened.

## Step 2. Where to look?

"Flexural" in this study means just the following five areas.

Get into the habit of working from top to bottom when examining subjects.



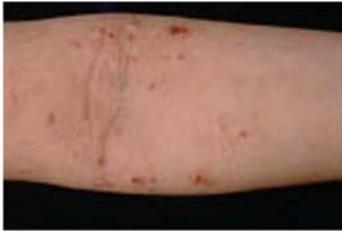
### 1. Around the eyes.

Any area of dermatitis within the confines of the orbital cavity affecting one or both eyes. Notice the redness, scaling and prominent skin creases on this child's eyelids.



### 2. Around the sides or front of the neck

Any patch of dermatitis larger than 1 cm in diameter in an area defined by the jaw bone above and clavicles below, and a line drawn vertically downwards from the ears with the head in an upright position looking directly forward. It may affect all the neck as in the first photograph (notice the redness, fine scaling, indistinct margins and prominent skin creases) or it may be patchy as in the second photograph.



### 3. Front of elbows

Any patch of dermatitis larger than 1 cm in diameter affecting one or both elbow creases within an area marked out by the subject's palm. Note the subtle redness, prominent skin markings and scratch marks in this child's elbow crease.



### 4. Behind the knees

Any patch of dermatitis larger than 1 cm in diameter affecting one or both areas behind the knee within an area marked out by the subject's palm.



### 5. Front of ankles

Any patch of dermatitis larger than 1 cm in diameter affecting one or both fronts of ankles within an area marked out by the subject's palm.

## Ah! but what if ...



### ... the dermatitis is only on the side of the limb?

Since limbs are round, deciding where the front and back begins can be difficult. As a general rule, if you can see the dermatitis with an arm facing directly forward or leg facing backwards, then you may consider it as "visible flexural dermatitis present". ...



### ...all of the limb is affected?

This does not matter - as long as the skin crease is involved as we have defined, you must record "visible flexural dermatitis present".



**... there is only one spot?**

If it is a tiny pimple, then ignore it. Any patch of dermatitis larger than 1 cm at its minimum diameter counts, however, so this child's arm should be recorded as "visible flexural dermatitis present".



**... there is a small group of spots in a skin crease?**

When there is a small group of spots behind the knees or in front of the elbow as shown above, you may count it as "visible flexural dermatitis" only if

1. the spots are confined to the skin crease as opposed to all over the limb, and
2. they cover an area greater than 1 cm in diameter.

**Appendix 4: Predicted average\* normal values for lung function**

FEV1 (L) Girls (<18 years)						FVC (L) Girls (<18 years)					
Age		12	14	16	18	Age		12	14	16	18
	125 cm	1.71	1.84	1.97	2.10		125 cm	1.82	1.93	2.05	2.17
	130 cm	1.86	1.99	2.12	2.25		130 cm	2.01	2.12	2.24	2.36
	135 cm	2.01	2.14	2.27	2.40		135 cm	2.20	2.32	2.44	2.56
	140 cm	2.17	2.30	2.43	2.56		140 cm	2.41	2.52	2.64	2.76
	145 cm	2.33	2.46	2.59	2.72		145 cm	2.62	2.73	2.85	2.97
	150 cm	2.50	2.63	2.76	2.89		150 cm	2.84	2.95	3.07	3.19
	155 cm	2.68	2.81	2.94	3.07		155 cm	3.06	3.18	3.30	3.42
	160 cm	2.86	2.99	3.12	3.25		160 cm	3.29	3.41	3.53	3.65
	165 cm	3.04	3.17	3.30	3.44		165 cm	3.54	3.65	3.77	3.89
	170 cm	3.24	3.37	3.50	3.63		170 cm	3.78	3.90	4.02	4.14
	175 cm	3.43	3.56	3.70	3.83		175 cm	4.04	4.16	4.28	4.39
	180 cm	3.64	3.77	3.90	4.03		180 cm	4.30	4.42	4.54	4.66
	185 cm	3.85	3.98	4.11	4.24		185 cm	4.57	4.69	4.81	4.93

FEV1 (L) Boys (<18 years)						FVC (L) Boys (<18 years)					
Age		12	14	16	18	Age		12	14	16	18
	125 cm	1.61	1.76	1.95	2.17		125 cm	1.66	1.78	1.98	2.26
	130 cm	1.79	1.94	2.13	2.35		130 cm	1.90	2.02	2.22	2.50
	135 cm	1.98	2.13	2.31	2.54		135 cm	2.15	2.27	2.47	2.75
	140 cm	2.17	2.32	2.51	2.73		140 cm	2.40	2.52	2.72	3.00
	145 cm	2.37	2.52	2.71	2.93		145 cm	2.67	2.79	2.99	3.27
	150 cm	2.58	2.73	2.92	3.14		150 cm	2.95	3.06	3.26	3.54
	155 cm	2.79	2.94	3.13	3.35		155 cm	3.23	3.35	3.55	3.83
	160 cm	3.02	3.17	3.35	3.58		160 cm	3.52	3.64	3.84	4.12
	165 cm	3.24	3.40	3.58	3.80		165 cm	3.83	3.94	4.14	4.43
	170 cm	3.48	3.63	3.82	4.04		170 cm	4.14	4.26	4.46	4.74
	175 cm	3.72	3.87	4.06	4.28		175 cm	4.46	4.58	4.78	5.06
	180 cm	3.97	4.13	4.31	4.53		180 cm	4.79	4.91	5.11	5.39
	185 cm	4.23	4.38	4.57	4.79		185 cm	5.13	5.25	5.45	5.73

\*Note : there is considerable normal variation around these values and an individual result above or below these values does not necessarily signify disease.

### Appendix 5: Inventory of equipment for each centre

<b>Anthropometry:</b>	1	Stadiometre
	1	Harpenden cloth tape measure
<b>Bio impedance:</b>	1	Tanita TBF 300GS Body Fat analyser
	1	Boxes of Cleaning wipes
	3	Printer rolls
<b>Vision</b>	1	LogMAR crowded test
	6	Eye patches
	6	Hand held occluders with pinhole
	1	Masking tape
	(1	Tape measure)
<b>Blood Pressure:</b>	1	Omron 705IT blood pressure monitor
	3	Omron cuffs (small, medium and large)
	1	Thermometer for room temp
<b>Skin Examination</b>	3	Laminated cards Appendix 3
<b>Spirometry</b>	1	MicroMedical Micro Spirometer

	1	3 litre Calibration Syringe
		Disposable Mouthpieces
	10	Nose Clips
	4	PP3 alkaline batteries
<b>Mindstreams</b>	1	Laptop
	3	Memory sticks

## Appendix 6: Quality assurance Protocols

### 1 Monitoring & test-retest protocol

1. Monitoring Visits will occur in first 3 months after the rollout of the PROBIT IV. We will also consider repeating the monitoring visits half-way through the recruitment period to ensure compliance with the protocol is being maintained.
2. On a specified day, specifically trained monitors will observe the paediatricians to check adherence to the examination protocols.
3. During the observed visits, monitors will repeat the pediatrician's measurements. These measurements will be recorded on the Monitoring Report Form.
4. Monitors will provide feedback to the paediatricians at the end of the monitoring visit.
5. Monitors will also provide a feedback report to the study investigators who will collate the reports to see if a generic problem requires a further specific retraining day in Minsk.
6. In total 190 children will be retested in the first 3 months and possibly half-way through the recruitment period (5 children per paediatrician = 38X5 = 190 children).

### 2 Audit

1. Audits will be carried out at the end of the study recruitment period as in PROBIT II and III.
2. Approximately 5 children per paediatrician (n = 190) will be randomly selected for repeat visits including re-examination, administration of the questionnaire and Mindstream test by trained auditors.
3. Repeat examination should only be undertaken with the parent's consent and child's assent. This will require second consent and assent forms labelled AUDIT to be signed.
4. Recording sheets for the monitoring visits must be clearly marked 'AUDIT' to avoid confusion with the main study data.
5. Provide the child with an additional gift for the extra test.

#### References:

<sup>1</sup> Standardisation of Spirometry M.R Miller et al. ATS/ERS Task Force: Standardisation of Lung Function Testing. Eur Respir J 2005; 26: 319-338.

<sup>2</sup> National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. Pediatrics 2004; 114(2 Suppl 4th Report):555-576.

---

<sup>3</sup> National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. A Pocket Guide to Blood Pressure Measurement in Children. 2007. Available from: [http://www.nhlbi.nih.gov/health/public/heart/hbp/bp\\_child\\_pocket/](http://www.nhlbi.nih.gov/health/public/heart/hbp/bp_child_pocket/)