

PROBIT V
Promotion of Breastfeeding Intervention Trial V
Associations of Maternal Health, Duration of Breastfeeding
with Offspring Health and Physical and Neurocognitive Development

MANUAL OF PROCEDURES
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A. DESCRIPTION OF THE STUDY

A1. Overview

The Promotion of Breastfeeding Intervention Trial (PROBIT) started in 1996-97 in 31 Belarusian maternity hospitals and their affiliated polyclinics. The main aim was to investigate the long-term effects of prolonged and exclusive breastfeeding on the development and health of the children in an experimental setting. We have been following the health of all those offspring who took part in PROBIT since they were babies (PROBIT I), with special medical research clinics when the children were 6½ years, 11½ years and 16 years (PROBIT II-IV).

The goal of this research project is to investigate associations of maternal and infant health and duration of breastfeeding with offspring health and physical and neurocognitive development.

This project will allow the preservation of a unique study group of mothers and their offspring in order to involve them in the future large-scale international research projects to study various aspects of their health, and procure and use medical equipment for testing and examinations.

The aims of this research are to:

- Abstract specific health, pregnancy and delivery data from the maternal delivery records from mothers whose children participated in PROBIT I, and who give consent for such data abstraction.
- Collect secondary school exam scores for the PROBIT offspring with the data from phases I, II, III and IV of PROBIT to help establish the effects of the duration and exclusivity of breastfeeding on school education outcomes.
- Update contact details of children and their mothers in order to keep a unique study group of mothers and their offspring in order to involve them in the future large-scale international research projects to study various aspects of their health.

Children who participated in the PROBIT project are now young adults, referred to hereinafter as “participants.”

A2. Logistics and roles

The following people contribute to PROBIT V:

Participating polyclinic pediatrician(s):

Most polyclinics have just one pediatrician; some larger polyclinics have two pediatricians. The pediatrician(s) at each study site will be responsible for:

- Verifying that each mother and participant included in the study is followed-up according to the protocol;
- Requesting and documenting consent from each mother and participant;
- Ensuring that the PROBIT V data forms are completed and sent to the Data Centre in Minsk for each study mother and participant
- Correcting errors and completing missing information identified by the Data Centre;
- Attending PROBIT V workshops.

Specialists at the State Institution “The Republican Scientific and Practical Centre Mother and Child” will:

- Help train the pediatricians from the polyclinics taking part in the PROBIT project;
- Supervise the schedules of contacts with the mothers and the delivery of all data forms from the polyclinics taking part in the PROBIT project;
- Support printing and delivery of all documents and forms to the polyclinics taking part in the PROBIT project;
- Organize and support operation of the computerized database, including the collection, keeping and storage of all primary documents obtained from the polyclinic pediatricians taking part in the PROBIT project;

ensure the completeness and quality of the database; and periodically send the data to Harvard Pilgrim Health Care Institute for analysis.

Polyclinic patient representative: Each polyclinic will identify a polyclinic patient representative to address any ethical or other concerns raised by the study participants or their mothers.

B. ORGANIZATION OF THE STUDY

B1. Materials

The pediatricians shall have following:

- o Contact information for PROBIT mothers and participants, either on paper or an electronic list;
- o Mother and participant packs to mail (***Mother's Letter & Information Form, Polyclinic address and telephone number; Participant's Letter & Information Form, Polyclinic address and telephone number***)
- o Mother and participant questionnaires for pediatricians to complete (***Pediatrician's Copy of Mother's Form; Pediatrician's Copy of Participant's Form***)
- o A ***Maternal Delivery Record Data Abstraction Form***
- o ALL SHEETS MUST BE STAMPED WITH HOSPITAL AND SUBJECT NUMBER for the study participant
- o Each form must have the section below (questions 1.01, 1.02, and 1.03) completed by the pediatrician with the participant's details, including the form for the mother's consent and data abstraction:

1.01	PROBIT hospital ID	__ __	1.02	PROBIT subject ID:	__ __ __
1.03	PROBIT participant's date of birth (DD/MM/YYYY):	__ __ / __ __ / <u>1</u> <u>9</u> <u>9</u> __			

B2. Main study actions

Within 1 month after receiving PROBIT V materials, participating polyclinic pediatricians will begin to establish contact with each PROBIT mother and participant. The oldest participants (i.e., those around 21 years) should be located and contacted first.

The actions described below are to be undertaken by the study pediatricians for each PROBIT mother and participant. Please also refer to Flowchart 1 and 2.

CONTACTING THE PROBIT MOTHER:

1. Using address information from the paper-based or electronic list, the pediatrician mails the PROBIT pack to the mother (***Letter to Mothers, Information Form, Polyclinic address and telephone number***)
2. The mother can opt out by telephoning to inform the pediatrician of her wishes.
3. Within two weeks, the pediatrician phones the mother and asks if she received the PROBIT pack:
 - o If the mother **has not received the pack**, the pediatrician confirms her address and sends her another pack.
 - If the pediatrician does not hear from the mother within two weeks, the pediatrician phones the mother and asks if she received the PROBIT pack.
 - o If the mother **has received** the pack, the pediatrician asks if the information has been read.
 - o If the mother **has not read the pack**, the pediatrician asks if she is willing to read the documents. The pediatrician arranges to phone again to answer any questions and request verbal consent.
 - o If the mother **has read the pack**, the pediatrician asks if she wants to take part:

- If the answer is No, the pediatrician records this outcome on the pediatrician copy of the PROBIT pack (***Pediatrician's Copy of Mother's Form***) and thanks the mother for her time. No further action is required.
- If the answer is Yes, the pediatrician asks if she is willing to complete the forms over the phone. The pediatrician should check that she has understood the information sheet and only then proceed to collect consent and all other details that she is willing to provide. This includes updated contact information for the PROBIT participant. The pediatrician signs the consent form at the mother's direction, prints the pediatrician's name, and records the date and time on the consent form.

Verbal consent should be sought only if the pack has been received and the mother has read them.

If the mother **gives her consent by phone** to data abstraction from her maternity records, the pediatrician finds her maternity records and abstracts the required data onto the ***Maternity Delivery Record Data Abstraction Form***. If the mother **does not consent** to data abstraction, data abstraction is not performed for that mother. (See section C for more information on Data Abstraction.)

CONTACTING THE PROBIT PARTICIPANT:

1. If the PROBIT mother provided updated contact information for her son/daughter who participated in PROBIT, the pediatrician uses that information and mails the PROBIT pack to the participant (***Letter to Participant, Information Form, Polyclinic address and telephone number***). If the PROBIT mother declined to provide this information or could not be contacted, the pediatrician uses the address on file and mails the PROBIT pack to the participant.
2. The participant can opt out by telephoning to inform the paediatrician of his or her wishes.
3. Within two weeks, the pediatrician phones the participant and asks if he/she received the PROBIT pack:
 - o If the participant **has not received the pack**, the pediatrician confirms his/her address and sends another pack.
 - If the pediatrician does not hear from the participant within two weeks, the pediatrician phones the participant and asks if he/she received the PROBIT pack.
 - o If the participant **has received** the pack, the pediatrician asks if the information has been read.
 - o If the participant **has not read the pack**, the pediatrician asks if he/she is willing to read the documents. The pediatrician arranges to phone again to answer any questions and request verbal consent.
 - o If the participant **has read the pack**, the pediatrician asks if he/she wants to take part:
 - If the answer is No, the pediatrician records this outcome on the pediatrician copy of the PROBIT pack (***Pediatrician's Copy of Participant's Form***) and thanks the participant for his/her time. No further action is required.
 - If the answer is Yes, the pediatrician asks if the participant is willing to complete the forms over the phone. The pediatrician should check that the participant has understood the information sheet and only then proceed to collect consent and all other details that he/she is willing to provide. The pediatrician signs the consent form at the participant's direction, prints the pediatrician's name, and records the date and time on the consent form.

The pediatrician's forms have been printed with pressure paper to create a duplicate copy of each form. Please use a dark pen and press firmly as you write to create a legible copy.

For **all forms completed by the pediatrician**: one copy is kept at the polyclinic, and one is sent by driver to the “Republican Scientific and Practical Centre Mother and Child” to be entered into the database.

B3. Phone call script

IMPORTANT: No conversations with the mother or participant should be coercive. The pediatrician will attempt to determine what the mother or participant wishes to do and abide by that.

Normal introduction, ask to speak to the mother/participant.

When talking to the mother/participant

Explain you appreciate his/her past involvement in PROBIT, and how important and valuable the participation in this unique study has been.

Make sure the mother/participant has read the information sheet and forms. Answer any questions he/she may have.

Explain that participation is voluntary. If the mother/participant does not wish to take part, he/she does not have to give a reason, and no pressure to participate should be applied. Explain to the mother/participant that his/her decision will not affect the medical care he/she receives now or in the future.

Let the mother/participant know that he/she can change his/her mind at any time.

Explain what will happen. If the mother/participant agrees to participate, ask **if he/she is willing for you [the pediatrician] to fill in the forms over the phone for them**. Tell the mother/participant that if he/she feels uncomfortable answering any of the questions, those questions can be skipped and remain unanswered.

Please say the following:

[To the mother] “If you agree to take part, we will try to find your maternity record from the birth of your child who took part in PROBIT and copy some details from it onto a specific questionnaire. We will combine the responses about your health before and during pregnancy with the information we obtained at earlier PROBIT study visits. We will keep your information and details of your other close contact(s) on record so that we can contact you in the future about research projects in which you may be interested in taking part.”

[To the participant] “If you agree to take part, we will ask you to provide us with your school-leaving examination scores. We will keep your information and details of your other close contact(s) on record so that we can contact you in the future about research projects in which you may be interested in taking part.”

Skip any questions the mother or participant does not feel comfortable answering. Please sign on his/her behalf and complete your requested details.

Once he/she has completed providing as much of the information as he/she is willing to, thank the mother/participant for his/her time.

B4. Frequently asked questions for Mothers/Participants

Do I have to take part?

No, taking part is voluntary. If you decide not to take part, it will not affect or diminish the quality of care that you receive now or in the future. You can leave the study at any time.

Can I have time to think about taking part?

You can have as much time as you like to think about taking part. If you want me to phone you back, we'll arrange another time after you have decided.

What will you do with my contact details?

We are collecting contact details so we can stay in touch, and perhaps ask you to join research projects in the future.

Will my contact details be stored safely?

Your contact details will be stored safely. Your personal information (your name, address and date of birth) will be securely stored and not shared with anyone outside of the study.

What if I change my mind about taking part?

If you change your mind about taking part in the study or would like to stop participating in the research, you can let me know at any time.

[Mothers] Which medical records will you look at?

We will look ONLY at the maternal delivery records from the birth of the child who participated in PROBIT. We will NOT abstract data from maternal delivery records for any other children born to you or examine any of your other medical records.

B5. Frequently Asked Questions for Pediatricians

Should pediatricians contact PROBIT mothers whose participant children have died?

If you know that a PROBIT child has died, do not attempt to contact that child's mother. If you contact a PROBIT mother and learn that her PROBIT child has died, please note the child's PROBIT ID number, and do not ask that mother to participate in PROBIT V.

Should pediatricians contact PROBIT mothers or participants if they did not take part in earlier phases of PROBIT?

Yes, pediatricians should try to contact mothers and participants who did not take part in one or more of the earlier phases of PROBIT. Several hundred children participated in PROBIT IV without having participated in PROBIT III and/or PROBIT II; they and other children may still be willing to participate in PROBIT V.

Should pediatricians contact PROBIT mothers who have been deprived of their maternal rights?

Pediatricians should attempt to contact those mothers and participants to obtain their consent. The mother may be unable or unwilling to provide updated contact information for the PROBIT participant.

What should pediatricians do if the PROBIT mother has died?

Our understanding is that if the PROBIT mother has died, the records from her delivery of the PROBIT child in 1996-1997 belong to the hospital. In cases where the PROBIT mother has died, it is not necessary to obtain anyone's consent to review and abstract data from her delivery records.

C. DETAILED DATA ABSTRACTION PROTOCOL

C1. Contacting mothers whose children participated in PROBIT I and obtaining their consent

ONLY the mother of the PROBIT child can give consent for data to be abstracted from her delivery record.

Do NOT request, review or abstract data from the maternal delivery records of mothers who could not be contacted or who did not give consent for data abstraction.

C2. Reviewing and abstracting data from the maternal delivery records

Once consent has been obtained from the mothers as part of PROBIT V, the pediatrician will arrange to view the maternal delivery records from the PROBIT I enrolment period (June 1996-December 1997) at the local maternity hospital.

We are interested ONLY in the maternal delivery records from the birth of the child who participated in PROBIT I. Do NOT request, review, or abstract data from maternal delivery records for any other children born to the PROBIT I mother.

The pediatrician will use the standardized PROBIT V data abstraction form to record specific data from each mother's maternal delivery record. The PROBIT V data abstraction form is modeled after the maternal delivery form used by Belarusian maternal delivery hospitals in 1996-1997. The pediatrician will record the following information from each form, if available:

- General information:
 - o Record date
 - o Health institution (maternal delivery hospital)
 - o Maternal delivery record number
 - o Family status at the time of birth (registered marriage, unregistered marriage, or single)
 - o Place of work
- Information on the mother's health, including:
 - o Maternal age at time of delivery
 - o Maternal blood results (hemoglobin and any blood glucose test results, including dates if multiple analyses conducted)
 - o Any chronic diseases (diabetes mellitus, high blood pressure, urinary tract infection, etc.)
 - o Age at which the mother began menstruating
 - o Her health upon being admitted to the hospital for delivery
 - o Her heart rate upon being admitted to the hospital for delivery
 - o Blood pressure (including dates, if multiple measurements taken)
 - o Weight and height (including dates, if multiple measurements taken)
 - o Glucose and urinalysis protein results (including dates, if multiple analyses conducted)
- Information on the pregnancy, including:
 - o Whether the mother attended antenatal clinic (ANC) visits during pregnancy, how many ANC visits she attended and the type of consultation she received
 - o The date (first day) of the mother's last menstrual period (LMP) and whether the mother experienced regular menses prior to this pregnancy
 - o Date of first fetal movement

- o Ultrasound measurements, including dates, estimated gestational age, estimated fetal weight, head circumference, presence of fetal heartbeat, and chest circumference (with dates if multiple ultrasounds conducted)
- o General course and complications of the pregnancy
- *Information on the labour and delivery, including:*
 - o The mother's admission, clinical and final diagnoses
 - o Abdominal circumference and height of uterine fundus at delivery
 - o Fetal heart rates during labour and delivery
 - o The date and time of the start of labour, ruptured membranes, and active labour
 - o The position of the fetus during labour, its presentation at delivery (e.g., cephalic, breech, etc.) and the fetal heart rate.
 - o The infant's weight, length, head circumference, chest circumference, and APGAR scores at delivery
 - o Complications during or after labour
 - o Any surgeries or assistance provided during labour (e.g., vacuum extraction or forceps)

If any of the requested information is not included in the maternal delivery record, the pediatrician should tick the box indicating that the data were “not available” for that question. If a “not available” option is not provided, the pediatrician can leave that section of the PROBIT V data abstraction form blank and note the missing data in the “Notes” section on the final page.

The final page of the data abstraction form includes spaces for additional weight and blood pressure measurements (if available).

C3. Frequently Asked Questions About Data Abstraction:

What should the pediatrician do if the mother's delivery record cannot be located?

If the mother's delivery record cannot be located, the pediatrician should note her name and PROBIT ID number, and record the reason that it cannot be found, if known (i.e., fire, flood, disposal of records by hospital).

What should the pediatrician do if the mother's delivery record does not contain some of the information requested on the abstraction form?

Most questions on the abstraction form include a tick box for “Not available” or “Not indicated”; use this box to indicate that specific information is not included in the record.

What should the pediatrician do if the mother's delivery record contains information in a different format or scale than specified on the abstraction form? For example, the infant's weight is listed in kilograms, not grams.

If possible, convert the data into the specified format (e.g., calculate and record the infant's weight in grams). If this is not possible, cross out the incorrect format or scale, write in the correct format or scale, and make a note of this change in the “Notes” section on page 5 of the form.

What should the pediatrician do if the mother's delivery record does not contain *any* of the information requested on the abstraction form, or if the information cannot be read (i.e., the form has been damaged or pages are missing or faded.)

You can indicate that a maternal record cannot be abstracted by ticking the “Yes” box to question 1.06, or by noting its condition in the “Notes” section on page 5.

C3. Completing data abstraction and sending forms to The Republican Scientific and Practical Centre Mother and Child

Once the pediatrician has abstracted the maternal delivery records for each of the women who gave their consent, the pediatrician will keep one copy of all data abstraction forms at the polyclinic and send the other copy by driver to the Data Centre in Minsk.

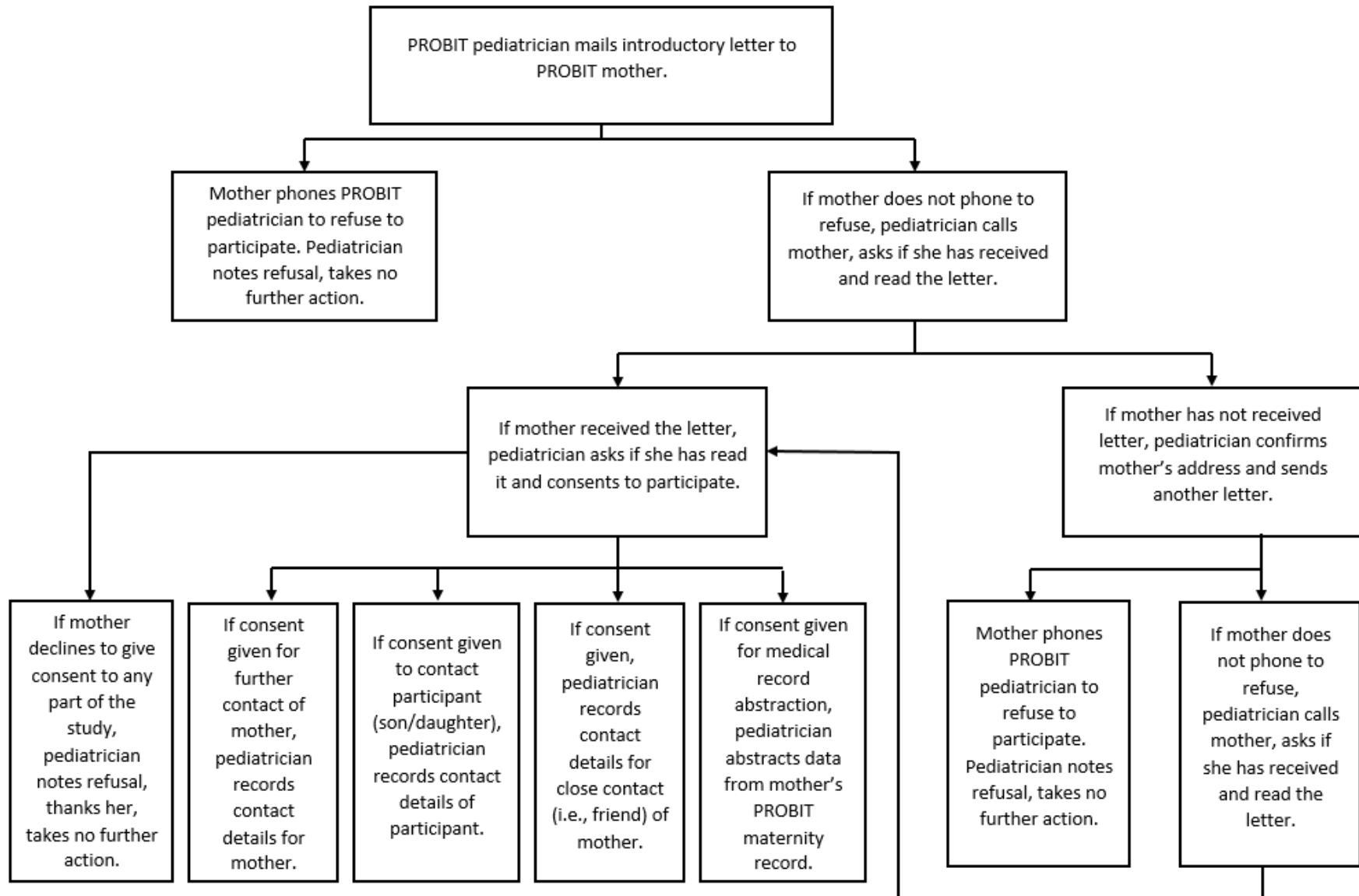
C4. Role of the Data Centre

Data technicians in the Republican Scientific and Practical Centre Mother and Child will input the data from the PROBIT V maternal delivery record data abstraction forms into a database.

<i>D. RULES FOR COMPLETING THE DATA FORMS</i>
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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, with zeroes entered in the empty cells on the left.
5. All corrections made to data in the questionnaires should be initialed by the pediatrician.
6. Please complete the questions in the order they are printed.
7. ALL SHEETS MUST INCLUDE THE HOSPITAL AND SUBJECT NUMBER.
8. Each form must have the SUBJECT DETAILS section completed by the pediatrician.

Flow chart 1



Flow chart 2

