

Research Consent Form A (Maternal & Child Consent)

Protocol No. 17058	Version No. 1.2	Date: September 19, 2017
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Title of Research Project: Risk factors for low physical activity levels in preschool-aged children in a densely populated urban community in Bangladesh.

Principal Investigators: Mr. Abdullah Al Mahmud (icddr,b) [REDACTED]
Dr. Daniel Roth (Hospital for Sick Children, Canada)
[List of other investigators is available on request]

Sponsorship

The funder of this research is the Hospital for Sick Children and Canadian Institutes of Health Research.

Conflict of Interest

The Principal Investigators, Dr. Roth and Mr. Mahmud, and the other research team members, have no conflicts of interest to declare.

Purpose of the Research

Background


Physical activity is important for the growth and development of children. We think that children in urban Dhaka are not participating in enough physical activity due to inadequate physical environments in the home.




Why invited to participate in the study?

We are doing a study that will measure physical activity in young children in Dhaka who were in the Maternal Vitamin D for Infant Growth (MDIG) trial. We will measure children’s physical activity using very small activity monitor that they wear on their waist. In addition, your child will wear an electronic location-recording device on their waist to provide us information on where your child is the most active. We will also measure and record items in the home that may affect children’s physical activity. In addition, we will check for anemia, which may affect children’s physical activity levels.

Methods and procedures


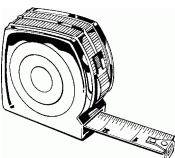


You and your child are being invited to take part in this study because of your involvement in the vitamin D (MDIG trial) study. By consenting to this study, we are asking that your child participate in the following study-related activities:

Activity	Picture	Description
Measure height, weight, waist circumference, and body fat		We will be conducting a home visit to measure your child’s height, weight, waist circumference, and body fat so we can learn about your child’s state of nutrition.

Measure physical activity for 7 days		We ask that your child wear an activity motor, which will record all your child's movements. The device is half the size of a deck of playing cards and will be attached to your child's right hip for 7 days using an activity belt. This will be worn 24 hours each day using an activity belt. It should only be removed during bathing or swimming.
Measure location data for 7 days		In addition to the activity monitor, your child will also wear a location-recording device for up to 7 days. This other device will record where your child goes and will give us an idea of how active your child is. This will be worn next to the activity monitor. This device can be removed from the activity belt during sleeping periods at night, but will need to be re-attached when your child wakes up the next morning.
Anemia check (one-time)		A trained nurse/paramedic will collect a small amount of blood from the tip of your child's finger to check for anemia. This will be done after the activity monitoring is completed.

The activity monitor and location recorder do not send information to the researchers while in use. They will only record information that can be retrieved later, after the recorders are returned to the researchers. These devices cannot get wet, so they must be removed before the child engages in any activities involving water (e.g., bathing, swimming).

In addition, we are asking all mothers to join in the following study-related activities:

Activity	Picture	Description
Measure height, weight, waist circumference, and body fat		During the home visit we would like to measure your height, weight, waist circumference, and body fat so we can learn about your state of nutrition.
Ask questions and take measurements of your home		During the home visit, a research assistant will ask you a variety of questions about the physical environment of your home. They will also use a measuring device to determine the size of rooms in your home, and record information about stairwells and railings, furniture, and toys. This is being done because it gives us information on the home environment and if it facilitates physical activity.
Daily phone calls		Study personnel will call you once every day to ask if the activity belt was removed at any point during the day, and at what time. They will ask you what time your child woke up in the morning and what time they went to bed at night. In addition, they will ask you about whether your child left the house during the day, where they went and how long they were gone.
Measure location data for 7 days		You may be asked to wear a location-recording device for up to 7 days instead of your child. This will depend on whether we have enough devices available. This will be worn or carried on your person from the time that you wake up in the morning until the time that you go to sleep at night.

Potential Harms

Taking part in this study is safe. There are no important risks to you or your child. The devices that your child will wear are very safe, and are safe for children to wear. Blood sample collection may cause slight discomfort, bleeding and/or bruising. We will lower the chance of infection by cleaning the skin and using disposable supplies. Also, only well-trained personnel will take finger prick samples. It is safe for your child to give the small amounts of blood that we will evaluate.

Potential Discomforts or Inconvenience

Wearing the 2 devices on an activity belt for 7 days may be a minor inconvenience. Both devices can be worn comfortably under clothing. None of the other procedures are expected to cause discomfort to you or your child. If

your child feels uncomfortable wearing the location-recording device, you can choose to wear it on your person instead, so long that you are with your child during the day.

Potential Benefits

You and your child will not benefit from being part of this study but the information we get may help inform policy makers in child growth and physical activity levels in Bangladesh.

Privacy and Confidentiality

We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless the existing law requires us to do this. The documents and information from this study will be stored in a secure, locked location. Only members of the research team will be allowed to look at your information. Data related to the study may be sent outside the country for analysis; however, any personal identifiable information will be kept under secured conditions. The research team may also give permission to other people from icddr,b and The Hospital for Sick Children to look at the information. The information will be kept for at least seven years after the study report is published. Published reports will not show your name or any personal information that could identify you.

Future use of information

In case of future use of the information collected from the study, anonymous or abstracted information and data may be supplied to other researchers, which should not conflict with or violate the maintenance of privacy, anonymity and confidentiality of information identifying participants in any way.

Reimbursement

As a token of appreciation you and your child will receive 700 BDT for participating in the activity monitoring, initial home visit and other study visits. The amount will cover any costs for travel or loss of wages because of participation in the study.

Participation

It is your choice whether or not to take part in this study. You can refuse to do some parts of the study without affecting you and your child's participation. The home measurements and blood specimen collection are optional. Even if you join now, you can stop at any time. After this study we may create new tests, new medicines, or other things that may be worth some money. Although the Hospital for Sick Children and icddr,b may make money from these findings, we cannot share this with you or other participants, now or in the future. Signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money to pay for the study, The Hospital for Sick Children and icddr,b are all still responsible for what they do legally and professionally.

If your child does not want to wear the activity monitor, you can take the device off and let the study team know so that you and your child will be removed from the study. Eligibility for receiving reimbursement for study procedures will be decided by study personnel on a case-by-case bases, if your child refuses to wear the activity-recording device.

Consent

By signing this form, I agree that:

1. You have explained this study to me. You have answered all my questions.
2. You have explained the possible harms and benefits (if any) of this study.
3. I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time.
4. I am free now, and in the future, to ask questions about the study.
5. I have been told that study documents and information will be kept private, except as described to me.
6. I understand that no information about who I am will be given to anyone or be published without first asking my permission.

7. I understand that the activity and location monitors are the property of icddr,b and must be returned to the researchers at the end of the participation period. However, I understand that I am not liable for any unintentional damage to or loss of the study equipment.
8. I have read and understood pages 1 to 4 of this consent form. I agree, or consent, to take part in this study.

If you have questions, complaints, or get sick or injured as a result of being in this study, please contact the co-investigator:

Mr. Abdullah Al Mahmud

Telephone: [REDACTED]

If you have any questions about your rights as a study participant, feel that you have not been treated fairly, or have any other concerns, please call or contact the icddr,b Ethical Review Committee:

Address:

Mr. M. A. Salam Khan, Ethical Review Committee Coordination Secretariat, icddr,b 68 Shaheed Tajuddin Ahmed Sharani, Mohakhali, Dhaka 1212

Telephone: [REDACTED]

Fax: [REDACTED]

If you agree to our proposal of enrolling you and your child in our study, please indicate that by putting your signature or your left thumb impression at the specified space below

Thank you for your cooperation

Printed Name of Child Subject

Date

Printed Name of Parent/Guardian/Attendant Subject

Date

Signature or left thumb impression of
Parent/Guardian/Attendant

Date

Signature or left thumb impression of the witness

Date

Signature of the PI or his/her representative

Date

(NOTE: In case of representative of the PI, she/he shall put her/his full name and designation and then sign)

**Research Ethics Board
Photography and Home Measurement Consent Form B**

Title of Research Project: Risk factors for low physical activity levels in preschool-aged children in a densely populated urban community in Bangladesh.

Principal Investigators: Mr. Abdullah Al Mahmud (icddr,b) [REDACTED]
Dr. Daniel Roth (Hospital for Sick Children, Canada)
[List of other investigators is available on request]

Confidentiality:

The measurements and pictures produced from this study will be stored in a secure, locked location. Only members of the research team will have access to them. Following completion of the study, the pictures will be kept as long as required in the SickKids “Records Retention and Destruction” policy. They will then be destroyed according to this same policy. Photographs will contain images of the home environment. There will be no photographs of individuals.

Consent:

By signing this form,

1. I agree that my home will be measured and photographed during this study. These measures and photographs will be used to assess the built physical environment, identify any hazards present and evaluate items that support gross- and fine-motor development of my child. I understand that no people will be included in any photographs.
2. I understand that I have the right to refuse to take part in this study. I also have the right to withdraw from this part of the study at any time (e.g., before or even after the photographs and measures are made).
3. I am free now, and in the future, to ask questions about the picture taking and measurement collection.
4. I have read and understood pages 5 to 6 of this consent form. I agree, or consent, to having pictures and measurements taken of my home as part of the study.

In addition, I agree or consent for this photograph(s) to be used for:

1. Other studies on the same topic
2. Teaching and demonstration at SickKids and the icddr,b.
3. Teaching and demonstration at meetings outside SickKids and the icddr,b.

In agreeing to the use of the photograph(s) for other purposes, I have been offered a chance to view the photograph(s). I also have the right to withdraw my permission for other uses of the photograph(s) at any time.

If you have questions, complaints, or get sick or injured as a result of being in this study, please contact the co-investigator:

Mr. Abdullah Al Mahmud

Telephone: [REDACTED]

If you have any questions about your rights as a study participant, feel that you have not been treated fairly, or have any other concerns, please call or contact the icddr,b Ethical Review Committee:

Address:

Mr. M. A. Salam Khan, Ethical Review Committee Coordination Secretariat, icddr,b 68 Shaheed Tajuddin Ahmed Sharani, Mohakhali, Dhaka 1212

Telephone:

Fax:

If you agree to our proposal of taking photographs inside and outside of your home, please indicate that by putting your signature or your left thumb impression at the specified space below

Thank you for your cooperation

Printed Name of Parent/Guardian/Attendant Subject

Date

Signature or left thumb impression of
Parent/ Guardian/ Attendant

Date

Signature or left thumb impression of the witness

Date

Signature of the PI or his/her representative

Date

(NOTE: In case of representative of the PI, she/he shall put her/his full name and designation and then sign)