Participant Information Sheet – For
Parent/Guardian/Caregiver of Child (Phase-II)
Date: 03 November 2021, Version: 1.0

Developing a video expert panel as a reference standard to evaluate respiratory rate counters in paediatric pneumonia diagnosis

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Pneumonia is a leading cause of mortality in children age below five years worldwide. In Bangladesh, there is about 2.7 million of pneumonia episodes in children which result in more than 20,000 deaths every year. Fast breathing is the most common sign of pneumonia in children. The health workers identify fast breathing by observing the child's chest and counting breathing rate using a timer or a watch. Sometimes, manual counting of breathing rate can be difficult for them and they misdiagnose pneumonia and provide inappropriate treatment.

In the recent times, there have been some devices available in the market to support health workers which can count breathing rate automatically. Philips, a renowned manufacturer, has developed a device named 'ChARM' which can count child's breathing rate and identify fast breathing automatically. There are some other devices having similar function developed by other manufacturers. To evaluate the performance of these new devices, a comparable method is needed which is called 'reference standard'. Usually an expert's manual breathing rate count is considered

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as the reference standard. However, there might be a possibility of bias using currently practised reference standards. The absence of an appropriate reference standard is a challenge.

In this study, we will evaluate the performance of ChARM device by a video expert panel, consisting of a panel of physicians. We will videotape the child's chest movements and then the video expert panel will interpret breathing rate watching the video. We think that the video expert panel could be an ideal and non-biased reference standard for evaluating new breathing rate counting devices. The video expert panel will also evaluate few other severe signs related to pneumonia. For this study we will enrol a total of 434 children in six months from the community clinics and hospitals.

The study will be conducted in two phases. In Phase I, we will enrol 180 children from Institute of Child and Mother Health and Centre for Woman and Child Health. In Phase II, we will enrol 254 children from three community clinics in Zakiganj subdistrict, Zakiganj Subdistrict Hospital and Sylhet Osmani Medical College Hospital.

Why have I been invited to take part?

You have been asked to take part in Phase II of this study because your child is below 5 years of age and your child is presented at this hospital or community clinic with cough and/or difficult breathing or other symptom which might be possible signs of pneumonia.

Do I have to take part?

No, it is up to you to decide whether or not you wish for your child to take part in this study. If you do decide to consent for your child to take part, you will be given this information sheet to keep and be asked to sign or put thumbprint a consent form. You may take as much time you wish by today's working hours of the clinic/hospital to think about whether you would like your child to be part of this study or not.

If you decide to take part, you are still free to withdraw your child at any time and without giving a reason. Deciding not to take part or withdrawing your child from the study at any time will not affect the healthcare that you and your child receive, or your legal rights.

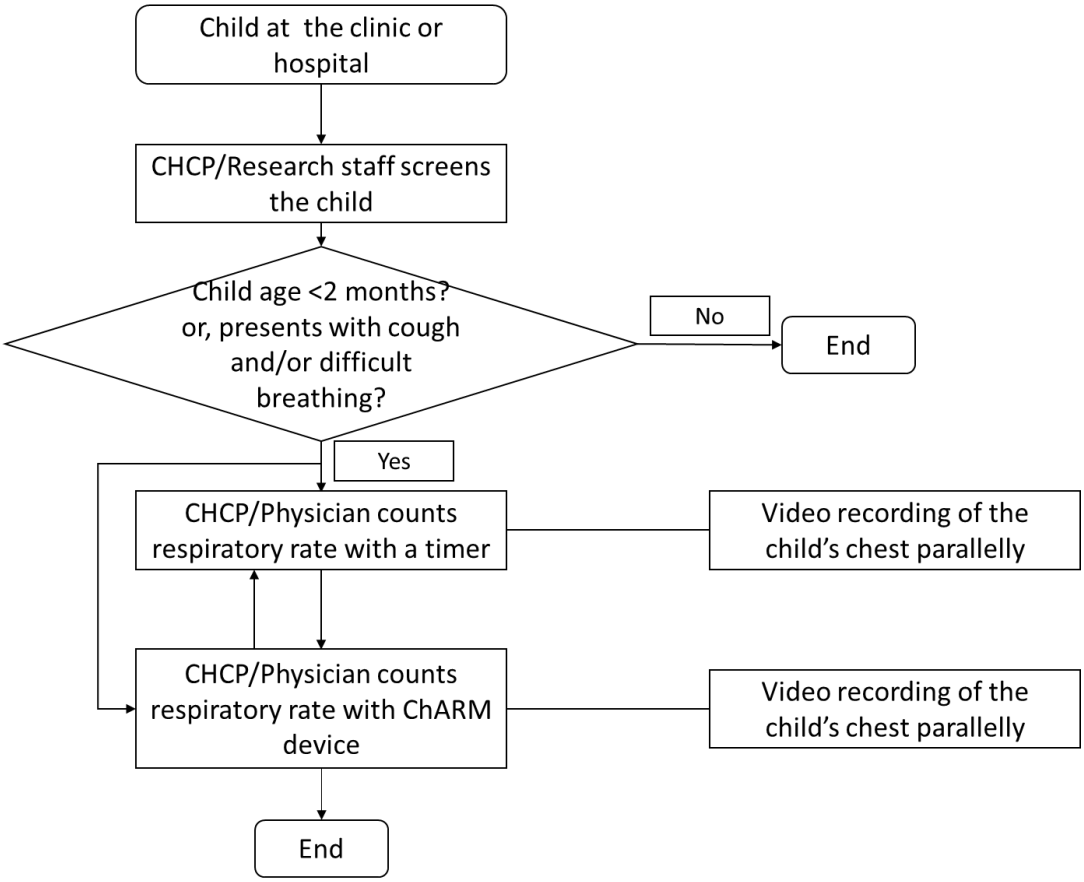
What will happen if I take part?

A project staff or health worker will read out the consent form to you and explain the study procedures. If there are any questions, they will answer and ensure that you understand the research project. If you decide to consent for your child to take part, you will sign or put thumbprint as a proof of consent. In case of an illiterate caregiver, a person not involved in the study and present during the consent taking procedure will be requested to sign the consent document as a witness.

If you give consent for your child's participation in this study, the project staff or health worker will ask some questions on demographic information and medical history and will examine your child. Your child's shirt or top will be removed so that the chest and upper part of belly are exposed. The health worker or physician will count breathing rate by manual method with a timer as well as using ChARM device. The ChARM device is strapped around the belly of the child with an elastic belt, and it automatically counts breathing rate and identify fast breathing. It may take 1 to 5 minutes to measure breathing rate. The procedure is safe and do not cause any harm or pain. The project staff will videotape your child's chest movements during counting breathing rate. They will not record your child's face or any other identifiable part. The whole procedure will take approximately 30

minutes and it will take place in this health facility. You can stay in the same room as your child while this procedure is being conducted.

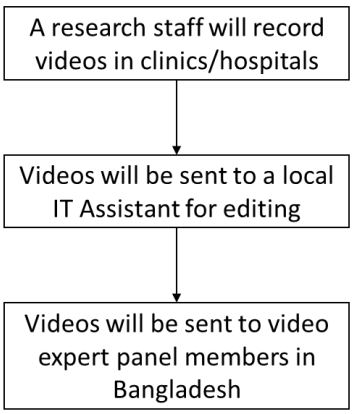
The following flowchart will help you understand what will happen to you child in this study:



We will enrol a further 254 children in this phase. We will do everything we can to ensure the video recording position and angles do not cause distress to your child. If you would like us to pause the procedures at any time, please let us know and we will do so immediately.

This video recording of your child's breathing will be edited and de-identified to remove all identifying features, then sent to the MBBS physicians who work in other hospitals in Bangladesh. These physicians will watch the video and interpret your child's breathing rate and few other signs related to pneumonia.

The following flowchart will help you understand the movement of your child's video data in this study:



No payment will be offered for your participation in the study. There is no cost to you other than the time you will spend by joining this study.

The healthcare provided to the child will remain same whether you chose to enrol your child to this study or not. Assessment of breathing rate using ChARM device will be carried out for research purpose only and this information will not be used for treatment decision making for the child. If it is found that your child's breathing rate is above the normal level, we will refer your child to a higher-level hospital or inform the duty doctor for further assessment. During the study, you will be informed any new information on risks or benefits from participation in the study.

In this current COVID-19 pandemic situation, adequate precautions will be taken during data collection, instructed by the Government of Bangladesh. The project staff will maintain adequate distance and use face mask and other protective measures during video recording and data collection. The patient contact surface and the belt of the device will be sterilized every time before using on each child.

Is there anything I need to do or avoid?

No, there is no special precautions or requirements for you or your child to participate in this study.

What are the possible benefits of taking part?

There are no direct benefits to you or your child taking part in this study, but the results from this study might help improve the diagnosis of pneumonia in children by the health workers at the community level in future.

What are the possible disadvantages of taking part?

Participation in this study will take approximately half an hour. There is no cost to you other than the time you and your child will spend by taking part this study. The procedures are safe and do not cause any harm or pain. If your child experiences any distress during any of the procedures, we will pause the procedures and do everything we can to ensure the child is not exposed to further discomfort. We do not anticipate any risks from your child's participation in this study. However, if there are any incidental findings such as your child develops any complications, we will arrange referral to a higher-level hospital or inform the duty doctor.

What if there are any problems?

If you have a concern about any aspect of this study, please contact Dr Ahad Mahmud Khan; the Principal Investigator of this study on +88-01670835330 or email on: A.M.Khan@sms.ed.ac.uk

You can also contact the National Research Ethics Committee of Bangladesh Medical Research Council (BMRC), BMRC Bhaban, Mohakhali, Dhaka-1212, Bangladesh, Telephone: +880-2-9848396, Fax: +880-2-9848820; Email: info@bmrc.org.

What will happen if I don't want to carry on with the study

Your child's participation in this study is completely voluntary.

If you decide to enrol your child to this study, you are still able to withdraw your child's participation at any time during the study without giving reason. Declining to take part or withdrawing your child from the study will not affect your child's healthcare in any way and your child will continue to receive same health care from this health facility.

If withdrawal occurs, you will have the option of withdrawal from either:

(i) all aspects of the study but continued use of your child's data collected up to that point

(ii) all aspects of the study with removal of all of your child's previously collected data.

What happens when the study is finished?

All the reports and results derived from the participants will be analysed. Your child's personal data (including the video/audio recordings of chest movements) will be de-identified and only the de-identified results of the study will be published for knowledge dissemination. The de-identified information collected from your child may be used in future in designing intervention to identify pneumonia cases.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your and your child's privacy at every stage.

In order to conduct this study, we will need to collect from you the following personal identifiable data:

- Your name as mother/father/caregiver of the child
- Your child's name
- Your child's date of birth or age (if date of birth not known)
- Your child's sex
- Video/audio recording of your child's breathing

All of your child's personal identifiable data will be removed when the data is analysed and all personal identifiable data will be kept confidential. Hard copies of the study-related forms will be stored in a locked cabinet in a locked room in Projahnmo Research Foundation office at Dhaka, Bangladesh under the supervision of the Principal Investigator and access will be restricted to the

Principal Investigator and approved study personnel only. All study documentation will be kept for a minimum of 3 years and maximum 5 years after completion of the study.

Data in digital format will be stored in the server at Projahnmo Research Foundation with restricted access. Only de-identified data may be shared and deposited to the University of Edinburgh's DataShare facility - a repository for knowledge sharing and future learning, but none of your or your child's personal identifiable information will be transferred to the University of Edinburgh. Yours and your child's identify will remain confidential.

Videos, in de-identified format, are to be retained for future learning in the PRF secured server at Dhaka in Bangladesh and University of Edinburgh data repository (DataShare) after the study is finished.

What will happen to the results of the study?

This study will be written up as conference presentations and publications. However, you and your child will not be identifiable in any published results or future presentations.

Who is organising and funding the research?

This study has been organised by Projahnmo Research Foundation and sponsored by The NIHR Global Health Research Unit on Respiratory Health (RESPIRE) at the University of Edinburgh and the research is sponsored by the University of Edinburgh in the United Kingdom.

Who has reviewed the study?

The study proposal has been reviewed by National Research Ethics Committee of Bangladesh Medical Research Council, Bangladesh and by EMREC, the research ethics committee at the University of Edinburgh, United Kingdom. –

Researcher Contact Details

If you have any further questions about the study, please contact Dr Ahad Mahmud Khan on +88-01670835330. Or email on: A.M.Khan@sms.ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact Dr Iqbal Kabir, President, Projahnmo Research Foundation, Flat: 5B, House: 37, Road; 27, Block: A, Banani, Dhaka-1213, Bangladesh; Phone: +88-01730-095515; email: drkabir51@gmail.com

Complaints

If you wish to make a complaint about the study, please contact:

National Research Ethics Committee of Bangladesh Medical Research Council (BMRC), BMRC Bhaban, Mohakhali, Dhaka-1212, Bangladesh, Telephone: +880-2-9848396, Fax: +880-2-9848820; Email: info@bmrc.org

Privacy Notice

The University of Edinburgh is the sponsor for this study based in United Kingdom and the study is being conducted by Projahnmo Research Foundation in Dhaka, Bangladesh. The Sponsor has overall responsibility for the running of the study. To follow the United Kingdom's data protection regulations, we must inform you of how we will use and store your personal data.

As a university, we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your and your child data in the ways needed to conduct and analyse the research study.

We will use information from you and your child in order to undertake this study. The sponsor will keep identifiable information about you for 5 years after the study has finished.

The University of Edinburgh will act as the data controller for this study. This means that they are responsible for looking after your and your child information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you and your child that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Participant ID:		Centre ID:	

CONSENT FORM

Developing a video expert panel as a reference standard to evaluate respiratory rate counters in paediatric pneumonia diagnosis

Please **initial/thumb impression** box

1. I confirm that I have read and understand the information sheet (03 Nov 2021 and Version Number 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐

2. I understand that my or my child participation is voluntary and that I am free to withdraw at any time without giving any reason and without my/my child medical care and/or legal rights being affected. ☐

3. I agree to my child's shirt being removed at the time for breathing rate measurement. ☐

4. I agree to my child's chest movements being audio/video recorded for the purpose of this research. ☐

5. I agree to my child's de-identified video recordings being transferred to expert paediatricians who are based on outside Bangladesh in the UK and in the US. ☐

6. I agree to my child's de-identified data being used in future studies. ☐

7. I agree to my child's de-identified video recordings being retained for future learning. ☐

Participant ID:		**Centre ID:**	

8. I agree to my child taking part in the above study. ☐

Name of Person Giving Consent	Date	Signature/ Left Thumb Impression
Name of Witness if provide thumb impression	Date	Signature
Name of Person Receiving Consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record

This research was commissioned by the UK National Institute for Health Research (NIHR) Global Health Research Unit on Respiratory Health (RESPIRE), using UK Aid from the UK Government. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.