Nepal Netra Jyoti Sangh

Tripureshwor, Kathmandu

" Evaluating a deep learning algorithm in the diagnosis of retinopathy of prematurity in Nepal and a prediction model for development of ROP"

Patient Information Sheet

[In case the parent(s)/legal representative(s) cannot read, a witness should be present to ensure that the parent information is explained correctly. Read out loud:]

We are asking you to take part with your baby in this study because your baby is at risk of retinopathy of prematurity (ROP). As part of routine medical care, your baby should be screened and regularly monitored for the development of ROP in a timely manner.

Before you decide whether you want to take part in this study, you will be given an explanation about what the study involves. Participation is voluntary. In order to participate your written consent is required. It is important that you read and understand the study procedures, benefits, risks, your right to withdraw and participant's confidentiality. Please take your time to read this information and ask the investigator or attending physician if you have any questions. You can also discuss it with your partner, friends or family.

1.Background of the study

Retinopathy of Prematurity (ROP) is an eye condition that can affect premature babies, where abnormal blood vessels grow in the retina, the part of the eye responsible for seeing. It is estimated that nearly one in four premature babies develop this eye condition. In some cases, it can lead to vision problems or blindness if not treated. However, with early detection and treatment, the risk of severe vision loss can be reduced. Babies are usually screened starting around 4-6 weeks after birth, or at 31-33 weeks of gestational age, and follow-up exams continue every 1-2 weeks until the retina is fully developed or treatment is no longer needed. For babies with more severe cases, the follow-up may be more frequent and continue for a longer period

2.Aim of the study

The study aims to assess the effectiveness of an artificial intelligence (AI) system on detection of ROP. Additionally, there is a plan to evaluate the performance of a new, simple and cost-effective smartphone-based diagnostic tool for ROP in a later phase.

3. General information

This study is carried out by Nepal Netra Jyoti Sangh (NNJS) in collaboration with Tilganga Institute of Ophthalmology (TIO), Kathmandu Medical College (KMC), Tribhuvan University Teaching Hospital (TUTH) and other partner hospitals. Three hospitals from Kathmandu valley namely TIO, KMC and TUTH are participating in this study. Nearly 700 premature infants will be participating in this study. All eligible patients, whether admitted to the participating hospitals or visiting the outpatient departments (OPD) will be invited to participate. Ethical approval has been granted by the Ethics Review Board (ERB) of NHRC, along with additional approvals from the hospitals involved. The study is being carried out by trained ophthalmologists, ophthalmic assistants, and data enumerators to ensure accuracy and reliability of the results.

4.What does participation in this study involve?

Participation in this study is entirely voluntary. The process of obtaining retinal images of your baby and interacting with you will take no more than 20 minutes. Additionally, you are requested to provide deliberate and honest answers to all questions posed during the study. Your participation and accurate responses are crucial for the success of this research.

Please note that the retinal images of your baby will be shared with the international study team for research purposes. Furthermore, the medical information of your baby will be recorded, and we kindly request you to provide your consent for this process to ensure a comprehensive understanding of your baby's condition.

As the risk of ROP continues for several weeks after birth, you need to bring your baby for the follow up retinal examination and we will collect retinal image of your baby during follow up visit as well. You will get reminder phone call from the research team to come for OPD visits.

5 What are the risks and benefits of the study?

Your cooperation and support in this study are essential for enhancing ROP services across eye hospitals in Nepal and beyond. Your participation will contribute to enhancing ROP care by aiding in the development of a simple diagnostic tool, develop timely strategies for eye care, and expand services to address this critical issue. We would like to assure you that there are no risks associated with participating in this study, nor will you receive any direct benefits such as cash or gifts. However, if your baby develop ROP and need any medical treatment, such as AntiVEGF injections or laser therapy, the treatment expenses will be covered from the study.

6.How will my information be kept private?

Data collected through your child's retinal images and your responses will be kept confidential and used solely for a study of national importance. Your name, your child's name, address, and personal or clinical details will not be published in any reports or communications; only an introductory code will be used. Your support and cooperation are crucial for the formulation and development of eye-related policies. Therefore, you are requested to answer all questions deliberately and truthfully.

7. Can I leave the study if I change my mind?

You can change your mind any time you want, also after your decision to participate. If you want your information removed from the study, you can contact us. You do not have to provide a reason for stopping. The data that have been collected until the time you withdraw your consent will still be used in the study. Your decision to be in this study or not will not affect the health care your baby. If there is any new information about the study that is important for you, the research team will inform you of this. You will then be asked if you wish to continue your baby's participation.

8. End of the study

Your baby's participation in the study ends when his/her retinal matures which typically ranges from several weeks to a few months, depending on the severity of the condition. The entire study ends when the last participant has finished with the study.

9.Who can I call if I have questions about the study?

If you have any questions or concerns regarding the study, please feel free to contact the study team at any time. For more details, you can reach the Central Office of Nepal Netra Jyoti Sangh in Tripureshowr, Kathmandu at Tel: 01-5361066.

If you would like independent advice about participation in this study, please get in touch with the independent doctor. He knows a lot about the study but has nothing to do with this study.

If you have any complaints about the study, you can discuss this with the investigator or your regular doctor. Or you can directly reach out to the ERB of NHRC at 01-5354220; Email: approval@nhrc.gov.np for the any inquiries or appeals related to ethical violations or human rights you can contact.

10.Signing of informed consent form

When you have had a sufficient reflection period, you will be asked to decide about participation in this study. If you consent, you will be asked to confirm this on the corresponding consent form, in writing. With your written consent, you indicate that you have understood the information and agree to participate in the study.

Thank you for your attention.

Yours sincerely,

Dr. Eli Pradhan

Dr. Srijana Basnet

Dr Pratap Karki

Study Team

Consent Form for parents or legal representative

Participant ID

I understand the objectives and background of this study, including the interview process, my roles and responsibilities, potential risks and benefits, and confidentiality measures. I am aware that retinal images of my baby will be taken and will be shared with an international research team, and I will also participate in an interview because my baby was born prematurely and may be at risk for Retinopathy of Prematurity (ROP). I acknowledge that my and my baby's personal and medical/clinical details will also be collected keeping confidential and used solely for research of national importance. I have been informed that I can choose to skip any question or withdraw from the study at any time. I have received this information through either reading the consent form myself (…….) or having it read to me by the interviewer (…….).

Name of parent/ legal representative:……	Name of investigator or his/her representative……..
Signature:……	Signature:……
Date: ___(day)/ ___(month) / _____(year)	Date: ___(day)/ ___(month) / _____(year)

In case parent(s)/legal representative(s) cannot read, a witness should be present to ensure that the parent information is explained correctly:

Name of witness……..
Signature:……
Date: ___(day)/ ___(month) / _____(year)

I hereby certify that I have informed the above person/persons fully about the said study. If information becomes known during the study that could influence the consent of the parent or legal representative, I will inform him/her of this on time.

Name of investigator or his/her representative……..
Signature:……
Date: ___(day)/ ___(month) / _____(year)