# **Consent for ROP Remote Digital Fundus Imaging Examination**

This form is intended as a sample. It does not constitute the standard of care nor does it provide legal advice. It contains the information OMIC recommends the surgeon personally discuss with the patient.

**How to use this sample**

* Please modify it to fit your actual practice.
* **Remove this instruction box.**
* Add your letterhead to the first page of the consent form.
* Change font size if necessary.

**After the patient signs the form**

* Give the patient a copy of the signed form.
* Send a copy to the hospital or surgery center as verification that you have obtained informed consent.
* Keep the original in the patient’s medical record.

**Version** 4/11/2022

# **(Informed Consent for Telemedicine Services)**

PATIENT NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DATE OF BIRTH: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LOCATION OF PATIENT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Introduction

**Your baby may have a condition of the retina (the back of the eye) called ROP (retinopathy of prematurity).** After a premature birth, the blood vessels at the back of the eye may stop growing. The baby’s body responds by making a chemical called VEGF (vascular endothelial growth factor) that causes new blood vessels to grow. These blood vessels are not normal: they can bleed and can also pull (detach) the retina away from its normal position. If the retina becomes detached, it can cause blindness.

ROP needs to be treated with 72 hours if it reaches a certain stage. Your baby could go blind without treatment.

The next few months are very important. We need your help to keep your baby from going blind. Your baby’s ophthalmologist will need to examine the baby’s eyes many times. The ophthalmologist is checking for abnormal blood vessels. The exams must continue until the blood vessels heal. Some exams may be needed after you take the baby home.

Infants meeting any of the following criteria need an exam:

* Birth weight of ≤ 1500 g (3 lbs., 4 oz.)
* Gestational age of 30 weeks or less (as defined by the attending neonatologist)
* Selected infants with a birth weight between 1500 g and 2000 g (from 3 lbs., 4 oz. to 4 lbs., 6 oz.) or gestational age of more than 30 weeks who are believed by their attending pediatrician or neonatologist to be at risk for ROP.
* Infants who received oxygen supplementation for more than a few days, or infants who received oxygen without saturation monitoring.

One way to conduct ROP screening is by using telemedicine to obtain *remote* digital fundus imaging (RDFI-TM), instead of a binocular indirect ophthalmoscopic (BIO) examination done in person by the screening ophthalmologist.

The remote technology will include measures to maintain confidentiality of patient identification and imaging data.

Expected Benefits of Remote Screening:

* Improved access to medical care by enabling your baby to remain in his/her location and receive care from a provider at a distant site.
* Ability to obtain consultation from a distant medical specialist without traveling.
* Allow medical evaluation and management of a baby who may be unable to travel.

Possible Risks:

As with any medical procedure, there are risks associated with the use of telemedicine. These risks include, but may not be limited to:

* Information transmitted may be insufficient to allow for appropriate medical decision making by the screening ophthalmologist. In addition, there may be poor resolution of images, requiring an in-person binocular indirect ophthalmoscopic (BIO) examination. This may cause a delay in medical evaluation and treatment.
* Security protocols could fail, causing a breach of privacy of personal medical information.
* A lack of access to complete medical records may result in adverse drug interactions or allergic reactions or other medical errors.

**PATIENT’S ACCEPTANCE OF RISKS**

By signing this form, I understand that:

The laws that protect privacy and the confidentiality of medical information also apply to this form of remote ROP screening with telemedicine, and that no information obtained in the use of telemedicine will be disclosed to researchers or other entities without my consent.

I have the right to withhold or withdraw my consent to the use of telemedicine in the course of my baby’s care at any time, without affecting my baby’s right to future care or treatment.

I have the right to inspect all information obtained and recorded in the course of a telemedicine interaction and may receive copies of this information for a reasonable fee.

Telemedicine may involve electronic communication of my baby’s personal medical information to other medical practitioners located elsewhere, including out of state.

No results from the use of RDFI-TM can be guaranteed.

A binocular indirect ophthalmoscopic (BIO) examination will be done in person by the screening ophthalmologist prior to your baby’s discharge from the hospital.

**Consent**. By signing below, you consent (agree) that:

* You have read this informed consent form, or someone has read it to you.
* You understand the information in this informed consent form and all of your questions have been answered.
* You have been offered a copy of this informed consent form.

I hereby authorize \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of health care provider) to perform remote digital fundus imaging (RDFI-TM) to conduct ROP screening on my baby.

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Parent (or person authorized to sign for parent) Date

Relationship to child if other than parent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_