

## PARENT PERMISSION FORM

**Title:** Feasibility and acceptability of a low-cost, mobile telemedicine platform for remote assessment of children transported by ambulance

**IRB Number:** H-38282

**NCT05967624**

**Funder:** National Heart, Lung, and Blood Institute

### Principal Investigator:

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**Study Phone Number:** 617-414-3682

### Purpose

We are asking you to allow your child to be in a research study. Boston Children's Hospital is working with Boston Medical Center to learn how to better care for sick children in ambulances. Usually, we talk to a pediatric expert by telephone when we need to give extra care to your child. We think a video-call will be a better way for the expert to see how your child is doing before we arrive at the hospital and could improve the care your child gets, but we don't know the best way to use this video yet. If you agree, we will use Zoom on an iPad to see if a pediatric expert in the hospital can **assess your child** in the ambulance using a video camera **as well as someone can in-person**.

Being in this research study will not change how we treat your child. There will be no additional charge or test. The video of your child will not be saved or recorded in any way. A nursing supervisor will access your child's medical records to pair medical information with the results of the video-call in the ambulance.

We would like to include your child in this study with your permission. If at any point you decide you do not want to your child to be videoed, please let us know.

### Confidentiality

We must use information that shows your child's identity to do this research. Information already collected about your child will remain in the study record even if your child later withdraws.

We will store your child's information in electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC. The CoC provides how we can share research information. Because we have a CoC, we cannot give

out research information that may identify you or your child to anyone that is not involved in the research except as we describe below. Even if someone tries to get your child's information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you or your child from sharing your child's own research information.

If you agree for your child to be in the study, we will share information that may show your child's identity with:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your child's information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial is available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

### **Use and Sharing of Your Child's Health Information**

The research team has to use your child's health information to do this study, including information that may identify you or your child. By agreeing to allow your child to be in this study, you are giving us your permission where needed to use and share your child's health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your child's hospital health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.

The reasons that your child's health information might be used or shared with others are to:

- Do the research described here.
- Make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information.

The people and groups that may use or share your child's health information are:

- Researchers involved in this research study from Boston Medical Center/Boston University and Boston Children's Hospital
- Other people within Boston Medical Center and Boston University who may need to access your

health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations

- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research

We ask anyone who gets your child's health information from us to protect the privacy of your child's information. However, we cannot control how they may use or share your child's health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your child's health information is not known. Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your child's health information for research. If you do not sign this form, your child cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits for you or your child.
- You have the right to withdraw your permission to use or share your child's health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, your child cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your child's treatment or payment decisions. If you ask for research information that is not in your child's medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your child's health information. You may also contact the Boston Medical Center HIPAA Privacy Officer at [DG-privacyofficer@bmc.org](mailto:DG-privacyofficer@bmc.org) or the Boston Children's Hospital Privacy Officer at [\(857\)-218-4680](tel:857-218-4680).

### **Questions**

The investigator or a member of the research team will try to answer all your questions. If you have questions or concerns, contact **Dr. Tehnaz Boyle** at **617-414-3682** or email [tehnaz.boyle@bmc.org](mailto:tehnaz.boyle@bmc.org); OR **Dr. Monica Kleinman** at 617-355-7327 or email [monica.kleinman@childrens.harvard.edu](mailto:monica.kleinman@childrens.harvard.edu) .

You may also call **617-358-5372** or email [medirb@bu.edu](mailto:medirb@bu.edu). You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your child's rights as a research subject. You



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should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

You may also contact the Boston Children's Hospital IRB: email [IRB@childrens.harvard.edu](mailto:IRB@childrens.harvard.edu) or call (617) 355-7052 between the hours of 8:30 am and 5:00 pm, Monday through Friday.