UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

FACT SHEET (Version 1)

Title: Implementation of Effective Home Oxygen Weaning Strategies in Premature Infants

IRB Docket Number: H00022159

Investigator: Dr. Lawrence Rhein, MD, MPH

Sponsor: Patient Centered Outcomes Research Institute (PCORI)

A. We are inviting you to participate in a research study.

B. Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

C. The purpose of this study is to test your medical center's use of the Recorded Home Oximetry (RHO) Program. We will be comparing your centers outcomes using the RHO Program to other centers across the U.S. that are implementing the same program.

D. If you agree to have your infant's data shared, we will collect data on their neonatal intensive care unit (NICU) stay, home oxygen duration, and any hospitalizations or emergency department visits they may encounter during weaning from oxygen outpatient.

E. There is a risk that you child's data may be shared with outside parties, such as the UMass Institutional Review Board or the Committee that oversees the safety of this research. We are taking every step to ensure that your child's data is protected and does not breach confidentiality.

   There is a risk that someone could get access to the information about you and misuse it. To help protect your personal information, we will store your name separately from your research data and code your research data with a subject ID. The patient health information to be collected includes last name, date of birth, NICU discharge date, and date home oxygen is discontinued. We will keep paper documents under lock and key. We will keep electronic information on secure computer networks. These computer networks will have many levels of protection.

   Your child will need to wear a clinically provided oximeter as standard of care due to their requirement for home oxygen. The oximeter being worn by your child has been approved by the Food Drug Administration (FDA) for continuous use in infants. Your child's clinical team will advise you to rotate the probe "sticker" every 12 hours to limit the risk of skin irritation or burn. If rotated every 12 hours this risk will be reduced.

F. There is no limit on the length of time we will store your child's data. We will destroy the list that links your identity to your data at the completion of the study.

G. It is possible that we might use the research data in other future research. We may also share data with researchers and companies that are not part of UMMS. In these cases, we will not share your name or other information that identifies you directly, and we will not

come back to you to ask you for your consent.

H. You may ask us to destroy your child's data at any time. However, we will not be able to destroy any research data that has already been created.

I. The research data (linked to your child with identifiers removed) may be used to make new health care programs or findings related to home oxygen weaning. These may have value and may be developed and owned by the study staff, University of Massachusetts. If this happens, there are no plans to share any financial gain with you.

J. Your participation may help us to gain knowledge about how best to wean premature infants off home oxygen therapy. However, there is no direct benefit to you.

K. It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

L. We will try to limit access to your personal information to people who have a need to review this information. We cannot promise complete privacy. The University of Massachusetts Medical School, including the Institutional Review Board (IRB) and research, billing, compliance offices, or the sponsor (PCORI) may see your information.

M. The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. Your child is receiving standard of care treatment for their oxygen weaning. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by participating in this research.

N. If you have any questions, concerns, or complaints, or think that the research has hurt you, you can talk to the Program Director, Heather White at 508-334-8063. This research has been reviewed and approved by an Institutional Review Board. You can reach them at (508) 856-4261 or irb@umassmed.edu if you would prefer to speak with someone not associated with the study or have questions about your rights as a research subject.

I understand that The University of Massachusetts Medical School will be conducting the above study. I do not wish my son/daughter to be included in this study.

☐ I choose to opt-out of my child's data being included in the above study.

Please return this form to child's physician responsible for weaning their home oxygen. If you have further questions or want to speak with a study staff member you can call, Heather White, the Project Director, conducting this study at UMass Medical School at 508-334-8063 or by email at Heather.White@umassmed.edu.