The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number:_____ Name of Subject: _____
Medical Record Number: _____

STUDY TITLE: **Let's E.A.T.! (Eating with Assistive Technology): An intervention to support children with feeding tubes and tracheostomies**

Doctors Directing Research: **Sarah Sobotka MD MSCP**
Address: **950 E. 61st Street, SSC Suite 207 Chicago, IL 60637**
Telephone Number: **773-702-1187**

KEY INFORMATION

We are asking you to choose whether or not to volunteer for a research study of a new feeding therapy intervention. This section is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is above.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn if a new model for feeding therapy is useful for children with tracheostomies and feeding tubes. In total your child's participation in this research study will last about one year. We will complete our enrollment assessment in your home. If our team determines your child can be safely enrolled in therapies to promote eating by mouth, you will then be randomly assigned to the Green or Yellow Group. If you are assigned to the Green group, you will participate in bi-weekly individual virtual feeding therapies with your child and weekly mealtime group therapy sessions with your child and other families in the Green group. If you are in the Yellow group, you will participate in a weekly group mealtime therapy session with your child and other families in the Yellow group. Both groups will complete assessments with our team at 5 different time points (enrollment, 3-month, 6-month, 9-month, and 12-months). The first and final assessments will be in person in your family home. You will complete virtual assessments with the study team at 3-months, 6-months, and 9-months after enrolling in our study.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The program may improve oral feeding outcomes of children with tracheostomies. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is a potential risk of weight loss from feeding tube reduction and risk of aspiration. As well as a minimal risk of potential loss of confidentiality because data will be collected about your child and their care. For a complete description of risks, refer to the Detailed Consent

DO YOU HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

You may choose for your child to not to participate at any time during the study. You will not lose any services, benefits or rights you would normally have if you choose to leave the study. The University of Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating you on whether you sign this Authorization or revoke your authorization at a later time. If you do not sign this form, you will not receive the research-related intervention(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Dr. Sobotka of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: Dr. Sarah Sobotka at 773-702-1187.

For questions about your rights as a research subject, please contact the University of Chicago BSD IRB at 773-702-6505.

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DETAILED CONSENT

WHAT IS INVOLVED IN THE STUDY?

About 40 families will take part in this study at the University of Chicago**.**

The study will involve 4 main sections.

1. A screening and consent session will take place over Zoom video conferencing with a study coordinator and Developmental and Behavioral Pediatrician to explain the study and determine the appropriateness of enrollment in this program based on your child's diagnoses and prior experiences with feeding and therapies. The Developmental and Behavioral Pediatrician will also ask you questions about your child's feeding and medical history. After the visit, you will be invited to complete a demographic survey via REDCap which is a secure online research survey database which may save you time during our in-person enrollment visit. This survey will contain items related to characteristics about yourself and your family and your experiences and attitudes with feeding and advocating for your child.

2. An enrollment visit will take place with the interdisciplinary study intervention team (Developmental and Behavioral Pediatrician, Speech Therapist, Occupational Therapist, Registered Dietitian, and Study Coordinator) in your home to determine achievable feeding goals. The Speech Therapist and Occupational Therapist will complete a comprehensive feeding assessment, which will include a combination of validated surveys, structured interviews, and physical exams. These surveys include the Feeding and Swallowing Impact Survey (FS-IS) which measures caregiver issues related to feeding (e.g. "I worry that my child will never eat or drink like other children."), and the PediEAT survey (which includes questions about problems with feeding) The Occupational Therapist and Speech Therapist assessments will include an oral feeding session if your child is already feeding by mouth. If your child is not medically ready to be eating by mouth at the time of enrollment we will defer their enrollment in our study until a potential later date and plan to re-assess after a period of time. The registered dietitian will take a detailed dietary history to obtain a total daily calorie count and determine what percent is currently oral versus tube-fed. The Speech Therapist or Occupational Therapist will complete the Children's Eating and Drinking Activity Scale (CEDAS), which describes children's dependence on tube feeding and ability to take food orally on a scale of 1-6. In addition to feeding skills, the Developmental and Behavioral Pediatrician will observe your child's overall development and may conduct standardized developmental testing when appropriate to clarify overall developmental levels (these may include tests such as the Capute scales which is an assessment that involves interacting directly with your child and may include some questions to you about your child's skills and abilities). We will also measure your child's height and weight, head and mid-arm circumference. Internet connectivity and access to a device (computer/iPad/smart phone) for future virtual visits will be checked and as needed, technology support provided.

With your consent we will review your child's prior feeding evaluations including clinical and fluoroscopic swallow studies, and contact your child's primary physician or subspecialty physicians for clarification of medical issues, and to collaborate with existing therapists as needed. It is important that we are entering as a care team as informed as possible about your child's medical issues which may impact what we do when we work with your child. If you do not wish to share these prior records, you will not be enrolled in the study. In addition, if you have early intervention evaluations we will ask to review these as well.

3. Your child will then be randomly placed into either the Yellow or Green study groups. The Yellow Group will participate in a virtual weekly group mealtime therapy sessions with either the speech or occupational therapists and other families in the Yellow group. The Green group will participate in bi-weekly individual virtual feeding therapies in addition to a weekly mealtime therapy session with other families in the Green group. Your assignment to yellow or green groups will be completely random, much like the flip of a coin. After each mealtime and therapy session we will ask you to complete a survey about what you learned and what you would like to cover in the next session.

4. At 3, 6, and 9 months after enrollment, the team will complete an assessment where the standardized measures will be completed over video conferencing, and we will take an updated dietary history and height and weight of your child. We will also repeat the CEDAS, PediEAT, and FS-IS. A year after you are enrolled in the study, we will complete a final in-home assessment which will include an exit survey which will include some elements from the enrollment survey as well as the CEDAS, PediEAT, FS-IS and the OT Assessment, Registered Dietitian Assessment and Speech Therapy Assessment. In addition, you will complete a brief structured interview with the Developmental and Behavioral Pediatrician about your experience with the program and what you have learned. Our team will refer your child for ongoing therapies or subspecialists as needed after you have completed the study.

Study enrollment and all touch points will take place in the family home in person or over video conferencing. Scheduling may include phone call, or text message or email exchange.

Any clinical assessments and diagnoses will be communicated to the patient/family as it would during typical practice procedures throughout the intervention. You will meet with Dr. Sobotka at the end of the program to discuss your child's progress and any concerns that you have as is standard of care practice.

Dr. Sobotka may decide to take your child off of the study without your consent if:

- You are unable to meet the requirements of the study or your medical condition changes.
- You decline to allow access to your child's prior feeding evaluations or swallow studies
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

Children in this study will be participating in behaviors designed to increase eating by mouth and reduce tube feeding. As such there is a potential risk of weight loss from feeding tube reduction and aspiration which is when food, liquid or other material enters a person's airway and eventually lungs by accident. Safe feeding practices will be the focus of the treating therapists. Your team (the speech/feeding, occupational therapy, registered dietitian, and pediatrician collaborators) are experienced with feeding for children with tracheostomies and feeding tubes and will be using their expertise to guide the program. We will be monitoring your child's weight. If he/she loses more than 10% of your child's total body weight, we will increase his/her tube-fed calories. We will coordinate and consult with other sub-specialists when needed.

The screening tests involved include surveys that the Occupational Therapist and Speech Therapist will ask you about your child's eating. In addition, they will observe your child eating and interacting with items in their mouth.

The only other potential risk involved is the potential for loss of confidentiality.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?
We cannot promise that your child will benefit from participating in this study. However, the potential benefits from participating in this intervention include improved oral feeding and reduction of tube feeding. We hope that the information learned from the study will benefit children and families with tracheostomies and feeding tubes.

Benefits to society may include a potential new virtual intervention designed to support children with feeding tubes which has potential for greater dissemination.

WHAT OTHER OPTIONS ARE THERE?
Instead of being in this study, you may choose not to participate. Only participants in the research study will be able to participate in this program. Patients who are invited to participate who decline will receive usual care. Participants who are receiving usual care therapies will not have their therapies stopped if participating in this program.

The decision whether or not you wish to participate in this study will not affect your care with UChicago Medicine.

WHAT ARE THE COSTS?
Clinical services provided during a clinical trial are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as 'usual medical care'. 'Research-related' is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. This often includes regular visits with your doctor, lab tests and imaging used to measure your response to treatment, and other tests and procedures deemed medically necessary by your care team. Financial responsibilities for routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study and would not be performed if you were not participating in this clinical trial. This includes the cost of the therapies you are receiving as part of this clinical trial or additional tests performed to answer a research question but not required for your routine clinical care. If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT HAPPENS IF I HAVE AN INJURY?

In the event of an emergency, you should seek care at the nearest emergency room or call 911. If your child suffers an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. Costs of related non-emergency care for an unanticipated research injury will be covered if that care is provided at the University of Chicago Medical Center. You must notify Dr. Sobotka as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure. If you think that you have suffered a research related injury, you must let Dr. Sobotka know right away.

WILL I BE PAID FOR MY PARTICIPATION?

After each assessment you will receive $50. Children who are able to be enrolled in the intervention will continue on for additional 4 assessments over the year, for a total of 5 assessments or $250 given for each family enrolled in the family study. Your child will receive a developmentally appropriate toy/tool for assistance with eating.

WHAT ABOUT CONFIDENTIALITY?

There is a risk of potential loss of confidentiality. To minimize this risk, study records that identify you will be kept confidential.

Upon entering the study, your child will be assigned a study identification number which will be used in record keeping and analysis. All personally identifying information will be stored separate from study records. All subject materials will be kept in a locked office and on encrypted, password-protected University-owned computers. Survey data and videos will be stored on password-protected computers accessed only by research staff and behavior therapists. The coded document linking the study code to participants' names will be stored in an encrypted file on encrypted computers.

During this study, Dr. Sarah Sobotka and her research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. PHI consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The information to be used on this study includes name, medical record number, gender, medical diagnoses, contact information (email address, telephone number, mailing address), and dates including date of birth, dates of medical procedures and tests, and dates of clinic visits. Some of this information will be used to access your child's prior swallow studies. In order to maintain contact with you we will need contact information including names, addresses, email addresses, and telephone numbers. In addition we may need medical record numbers to document study procedures in our medical record system. Medical diagnoses will be collected in order to ensure eligibility and safety of your participation in the study as well as to understand the impact of the program. Study records will be maintained by the PI and study team members. Data will be reviewed on a regular basis by the study team to ensure validity and compliance. All subject materials will be kept in a locked office and on password-protected computers.

A description of this clinical trial will be 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 Website at any time.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Sobotka is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team until completion of this study.

At the time of study completion, either the research information not already in your child's medical record will be destroyed or information identifying you will be removed from study results.

Data from this study may be used in medical publications or presentations. Your child's name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time. We may also share de-identified data with collaborators or others for research purposes.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Sobotka in writing at the address on the first page. Dr. Sobotka may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date.

CONSENT

PARENT/GUARDIAN/ OR LEGALLY AUTHORIZED REPRESENTATIVE:

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will

receive a signed copy of this consent form for my records.

I give my permission for my child/relative/the person I represent to participate in the above-described research project.

Signature of Parent/Guardian/ or Legally Authorized Representative: _____
Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT
I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject and family.

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ AM/PM (Circle)