Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Parent Permission for a Child to Take Part in a Research Study

Study Name: Brief Cognitive Behavioral Therapy to Treat Itch Rumination "Itch CBT" in Eczema
Sponsored by: National Eczema Association
Name of Researcher: Amy S. Paller, MD

This consent form describes a research study for which your child might qualify being conducted by a researcher at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's") and NU. Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to allow your child to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family or healthcare providers before you decide to allow your child to take part in this study. The study staff will also explain the study to you and answer any questions that you may have. Your decision will not affect your child's regular care at Lurie Children's in the future.

What are the purpose and goals of this study?

The main purpose and goal of this study is to adapt cognitive behavior therapy (CBT) to improve itch in children with eczema. Cognitive behavior therapy, or CBT, is a common type of mental health "talk therapy" that is an effective treatment to help improve mental health. This study will enroll children with moderate-to-severe atopic dermatitis. About 24 child/parent pairs will be enrolled. Each pair will be randomly assigned to one of two treatment options: CBT, or routine atopic dermatitis education (usual care) that is normally provided as part of standard of care treatment. You and your child will know which group your child is placed into.

If I agree to have my child take part in this study, what would my child need to do?

<u>If you/your child are randomized to the CBT group, you will be asked to</u>:

- Participate in four telehealth visits (using an encrypted version of the video communication app, Zoom) with a therapist on the research team. At the first visit, the therapist will ask you and your child questions to assess common concerns related to atopic dermatitis, including medication adherence, coping strategies, depression, anxiety, social stigma, and sleep disturbance. The assessment will last about 60-90 minutes. Then you and your child will complete three follow-up telehealth therapy appointments to help address your child's concerns related to atopic dermatitis. These will last about 60 minutes.
- Complete study questionnaires before the assessment appointment and after each therapy appointment. The questionnaires will ask you and your child about itch symptoms and severity as well as other health topics, such as sleep, anxiety and depression. You and your child will complete separate questionnaires electronically. The questionnaires before the assessment appointment will take about 20-25 minutes to complete. The questionnaires after each therapy appointment will take about 10-20 minutes to complete.

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- Complete one set of study questionnaires 4 weeks after the end of the study. The questionnaires will ask you and your child about itch symptoms and severity as well as other health topics, such as sleep, anxiety and depression You and your child will complete separate questionnaires electronically. The questionnaires will take about 20 minutes to complete.

<u>If you/your child are randomized to the Usual Care or routine atopic dermatitis education group, you will be asked to</u>:

- Complete study questionnaires every week for 4 weeks. The questionnaires will ask you and your child about itch symptoms and severity as well as other health topics, such as sleep, anxiety and depression. You and your child will complete separate questionnaires electronically. The questionnaires will take about 10-20 minutes to complete.
- Complete one set of study questionnaires 4 weeks after the end of the study. The questionnaires will ask you and your child about itch symptoms and severity as well as other health topics, such as sleep, anxiety and depression. You and your child will complete separate questionnaires electronically. The questionnaires will take about 20-25 minutes to complete.

What are the risks, side effects, or discomforts related to the study?
For the questionnaires, your child can choose to not answer a question, skip a question, request a break, or to stop/leave the interview at any time. Because part of this study uses CBT, we may talk about some topics that can make your child feel upset. Your child can talk to their therapist if something makes them upset or stop/leave the visit at any time.

Every research study involves some risk to private information. It is possible that other people could find out your child was in the study or see their study information. We will take every step to keep this from happening.

What are the benefits from this study?
We cannot promise that your child will benefit from taking part in this study. Cognitive behavior therapy (CBT) can be effective for helping with some forms of emotional distress. If your child is randomized to the CBT arm of the study, the CBT treatment provided may be beneficial in helping to manage itch and distress related to atopic dermatitis. The information learned from this study may help other children in the future because it will help us understand which treatments work or do not work.

What other options does my child have?
Your child does not need to participate in this study. The decision whether to participate in this study or not will not affect your care at Lurie Children's.

What if the researcher or I do not think my child should stay in the study?
Your child can stop taking part in this study at any time. Your decision will not affect your child's regular care.

Returning Study Results:
The study team will not return study results to you and your child from the therapy visits. You can ask the study team any questions you have about study results.

Important New Information:
We will tell you if we learn new information that may make you change your mind about your child being in this study.

Will my child's information be used in future research studies?
The study team may use or share your child's data from the questionnaires for future research. They will remove identifiers such as your child's name and other information that can be linked to your child before this is done. The study team and other researchers may use this for other studies without getting consent from you or your child.

Costs Related to this Study:
There are no study related costs to you.

Payment for Taking Part in this Study:
Surveys:
You and your child will be asked to complete separate study surveys and will be paid individually for your time and effort. At Visit 1, Visit 4, and follow-up, you and your child will be paid $20 each for completing study surveys. At Visit 2 and Visit 3, you and your child will be paid $10 each for completing study surveys. If you and your child complete all the surveys in the study, we will pay you and your child an extra $10 each for your effort. You can earn up to a maximum of $90 total if you complete all of the study surveys. Your child can also earn a maximum of $90 total.

We will email you and your child an e-gift card for all completed surveys/visits at the end of the study or when you/your child tells us you no longer want to be in the study. You will receive your e-gift card about 2-4 weeks after you finish the study.

CBT Visits:
If your child is randomized to the CBT group, your child will be paid an additional $10 for completing each 1-hour visit. You will also be paid $10 for each 1-hour visit. You and your child can earn a maximum of $40 each ($80 total) if you complete all of the visits.

You and your child will be paid for each part of the study you complete. If your child is randomized to the usual care group, you can earn a maximum of $90 total for completing the study surveys. Your child can also earn a maximum of $90 total.

If your child is randomized to the CBT group, you can earn up to a maximum of $130 for completing the study surveys and telehealth visits. Your child can also earn up to a maximum of $130.

We will email you and your child an e-gift card for all completed surveys/visits at the end of the study or when you/your child tells us you no longer want to be in the study. You will receive your e-gift card about 2-4 weeks after you finish the study.

Your and Your Child's Rights When Taking Part in this Study:

If you agree to have your child take part in this study, you are not giving up any of your or your child's legal rights. Your child can stop participating in this study at any time. Your choice will not affect your child's regular care at Lurie Children's and NU in the future.

Who can answer my questions about this study?

If you or your child have any questions, contact the researcher, Dr. Amy Paller at 312-695-3721, or a member of the research team at 312-503-5944 during a workday or 312-695-4000 at night or on weekends.

If you have questions about your child's rights or if you have a complaint, you can call the IRB Office at (312) 503-7110; or via email at IRB@luriechildrens.org.

You will be given a copy of this consent form.

Planned Sharing of your Child's Information:

If you agree to let your child take part in this study, you also give permission to the use and sharing of your child's information. This permission lasts until the study is completed.

This information that may be collected and shared will include your child's:

- Personal and health information
- Past and present medical records
- Records from study visits and phone calls

The study staff, including Lurie Children's employees and Medical Staff and Northwestern University (NU) may use your child's information and share it with:

- The study sponsor, (National Eczema Association) and those working with the sponsor.
- Northwestern University
- The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
- Your child's other providers and their staff directly involved in your child's care, if your child's provider is a part of the Lurie Children's electronic health information exchange.
- The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.

These are the only people to which we will give your child's information. We cannot guarantee that those listed above will not share it with others without your permission.

Your child's name will not be included in any written or verbal reports of study results.

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What if I decide not to give permission to use and give out my child's information?
If you decide not to allow the release your child's information, your child will not be able to take part in this study. If you give permission to the use of your child's information, you can withdraw it at any time. Your request should be in writing and sent to the researcher. The study team can still use any information collected before you tell them to stop.

Can I review or copy my child's information?
You cannot see your child's study records. You still have a right to request a copy of your child's medical record.

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Printed Name of Child:

Parent/LAR Signature:

By signing this form, I affirm: 1) I have read this form. 2) The research has been explained to me. 3) All of my questions have been answered. I give my consent for my child to take part in this research study.	
Signature of Parent or Legally Authorized Representative (LAR):	Date:
Printed Name:	
Relationship to Child:	

Signature of Authorized Person Obtaining Consent:

I certify that I have explained the above to the parent(s)/LAR and the signature(s) was obtained voluntarily.	
Signature:	Date:
Printed Name:	

Note to Investigators: When obtaining consent from a non-English speaking parent/LAR

When a study-specific translated consent document is not available, a translated "short form" (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

a. *The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*

b. *The parent/LAR should sign the short form (in the language they understand).*

c. *The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*

d. *A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the parent/LAR.*

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PARENT/GUARDIAN PARTICIPATION ADDENDUM

Taking part in this research study is voluntary. It is your choice to take part in this research study. Please read this consent form and ask questions about anything you do not understand. Your decision will not affect your child's regular care.

Why are parents being asked to take part in this study?

As a part of this research study, we would like to have a one-on-one interview with you to discuss your child's itch and eczema. We plan to use this information to adapt cognitive-behavioral therapy to improve itch in children with eczema. Your part in the study should take about 60 minutes. The interview will be audio-recorded.

What are the possible risks?

Because the study procedures take the form of an interview, participation in this study does not involve any physical or emotional risk to participants beyond that of everyday life. You can choose to not answer a question, skip a question, request a break, or to stop/leave the interview at any time. Breaks will be offered to you throughout the interview. There is a very small risk of loss of confidentiality. Every measure to safeguard the information will be taken by the research team, including keeping all identifying material in a locked cabinet and/or password-protected research server and keeping all questionnaire data de-identified using a study ID number.

What are the possible benefits?

There may be no direct benefit to from taking part in this study. This information learned from this study may help other children in the future.

How will you protect my information and what are my rights?

The same procedures that are in place to protect your child's information are also in place to protect your information given during this study. You can find these in the form under the section "**Planned Sharing of Your Child's Information.**" This section also describes with whom your study information will be shared.

You may cancel your consent and take yourself out of this study at any time. It will not affect your child's regular care. Your child may still be able to continue in this study. If you want to stop the study, tell the researcher. Your request should be in writing and sent to the researcher. The study team can still use any information collected before you tell them to stop.

If you wish, you may ask for a copy of your study information when the study is over or when you are no longer taking part in the study. If you have questions about the study, your rights, or feel you have been harmed by the study, please contact the study team members listed above in this form.

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Parent/LAR Signature:

By signing this form, I affirm: 1) I have read this form. 2) The research has been explained to me. 3) All of my questions have been answered. 4) I consent to take part in this research study.	
Signature of Parent or Legally Authorized Representative (LAR):	Date:
Printed Name:	