Consent for a Parent or Caregiver and Permission for Your Child to Be in a Research Study

1. Parent/Caregiver’s Name________________________________________
2. Child’s Name__________________________________________________

What is the Purpose of this Form?

This form will help you decide if you want to be in the research study. You need to be informed about the study, before you can decide if you want to be in it. You should have all your questions answered before you give your permission or consent to be in the study.

Please read this form carefully. If you want to be in the study, you will need to electronically sign this form. You will get a copy of this signed form e-mailed back to you.

Why is this research being done?

This study is about childhood encopresis. When children suffer from encopresis this means that they can't control their bowel movements and they have bowel accidents in their underwear.

Most children suffering from encopresis have a history of constipation. Children become constipated for a lot of different reasons. Regardless of why this happens constipation frequently leads to large, hard, difficult to pass, and painful bowel movements. When children become constipated and have hard and painful stools, they may begin to hold in their bowel movements to prevent it from hurting again. When a child “holds back,” the child’s colon may slowly fill with stool stretching it out of shape. This is called “megacolon.” Also, if a child holds back, the colon isn’t emptied regularly. Stool builds up in the colon and becomes a large fecal impaction. Soft, liquid stool behind the impaction can then begin to leak around it and out into the child’s underwear, without the child noticing it, or being able to hold it in.

The purpose of this study is:

- To find an effective intervention for encopresis.
- To find out if an Internet intervention is able to help treat encopresis.
- To find out if an Internet intervention is more helpful than a patient education website.
- To find out if offering extra help through e-mail and phone contact adds to the effectiveness of an Internet intervention.
You are being asked to be in this study, because you are the legal guardian of your child, your child has symptoms of encopresis, your child is between 5 and 12 years old, and you and your child have regular access to a computer and the Internet.

Specifically, children in this study:

- Have had symptoms of encopresis (poop accidents) for longer than 3 months.
- Have had more than one poop accident in the past 2 weeks.

Up to 288 parent and child teams will be in this study at the University of Virginia (UVa), although they are not required to come to UVa to participate.

**How long will this study take?**

If you agree to participate, you will read and sign this consent form (electronically) before you begin study participation. Your participation in this study will take one year. During the course of one year, your time commitment will include the following:

- Completion of a brief phone screening to review this consent form and ensure you and your child are appropriate for this study.
- Completion of a 60 minute online questionnaire, 4 different times:
  - On the 1st day you enroll
  - 6 weeks after you’ve begun the program
  - 6 months after you’ve begun the program
  - 1 year after you’ve begun the program
- Completion of 7 days of online diaries*, 4 different times:
  - During the 1st week you enroll
  - During the 7th week after you’ve begun the program
  - During the 27th week (6 months) after you’ve begun the program
  - During the 53rd week (1 year) after you’ve begun the program
  *The diary is an online form that takes 1-2 minutes to complete.
- Use of an Internet Intervention for at least 4 weeks:
  - During the 1st week, the Internet Intervention will take approximately 1-2 hours of your time.
  - During the 2nd through 4th weeks, the Internet intervention will take between 15 minutes to 45 minutes of your time each week.
  - After the 4th week, there are no time requirements for use of the Internet Intervention.

**What will happen if you are in the study?**

**PRE-ASSESSMENT:**
• Prior to completing this consent form, you will submit an online Interest Form and participate in a phone screen to review the criteria for enrollment in this study.
• If you agree to participate, you will electronically sign this consent form before any further study related procedures take place.
  o You will be e-mailed a unique password to access our secure website.
  o Once you’ve logged in to our website, you will review this consent form with the study coordinator.
  o When you feel comfortable to sign, you will use your mouse to draw your signature at the bottom of the electronic version of this form.
  o Once we receive your consent form with your electronic signature, we will e-mail a copy back to you.
• After you have successfully consented to participate in the study, we will continue with the phone screen. We will ask you some additional questions about your child’s health and history.
• After the phone screen is complete, you will begin using the study website with your child.
• You will first learn about how to use the program.
• You will then be instructed to complete an online Questionnaire. These questions will take about one hour to complete. They are questions about your family history, child’s health history, well-being, and activities.
• You will receive daily reminder e-mails until the Questionnaire is complete.
• Once you complete the Questionnaire, you will begin keeping online Daily Diaries – behavior and symptom reports for your child. This is a short form that takes 1-2 minutes to enter.
• You will receive daily reminder e-mails until 7 Daily Diaries are complete.
• After you have completed the Questionnaire and entered 7 Daily Diaries, you can log in to the study website and begin using your assigned Internet program.

RANDOMIZATION and STUDY TREATMENT (4-6 weeks):

• You will be randomly assigned (like the flip of a coin) to 1 of 3 study groups. You have an equal chance of being assigned to any one of the groups. Neither you nor the researchers can choose your group.

GROUP 1: Patient Education Website Group: You and your child will use a website with information about encopresis.

GROUP 2: Internet Intervention Group: You and your child will use the Internet intervention, an interactive program designed to teach parents and children about encopresis. You will also complete weekly questionnaires, which will help the program figure out what information might be most helpful to you.
GROUP 3: Internet Intervention plus Support Group: You and your child will use the Internet intervention and complete weekly questionnaires, which will help the program figure out what information might be most helpful to you. If you have trouble finishing each part of the program, we will contact you to provide additional help through e-mail or phone calls.

FOLLOW UP:

- After six weeks from completing the Pre-Assessment, you will be instructed (e-mailed) to complete an online Post-Assessment Questionnaire. These questions will take about two hours to complete. The questions will ask you about your child’s encopresis.
- You will receive daily reminder e-mails to complete the Post-Assessment Questionnaire until it is complete.
- Once you complete the Post-Assessment Questionnaire, you will begin collecting and entering online Daily Diaries.
- You will receive daily reminder e-mails until 7 Daily Diaries are complete.
- Once you have completed the 7 Daily Diaries, you can freely use your assigned Internet program (visit the website, or use the Intervention)
- The Post-Assessment (Questionnaire and Daily Diaries) will occur again after six months from completing your Pre-Assessment and again after one year from completing your Pre-Assessment.
- You will receive two reminder e-mails for each approaching Post-Assessment. Each e-mail will tell you how much time is left until you will need to complete the next Post-Assessment Questionnaire and Daily Diaries.
- By signing this consent form, you also agree to be contacted after this study is done for follow up information or to be asked to be in other studies.

Study Schedule

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<thead>
<tr>
<th>Study Week</th>
<th>Screening</th>
<th>Pre-Assessment</th>
<th>Study Treatment</th>
<th>Post-Assessment 6 weeks</th>
<th>Post-Assessment 6 months</th>
<th>Post-Assessment 1 year</th>
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<tbody>
<tr>
<td>Informed Consent</td>
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<td>1</td>
<td>2-7</td>
<td>8</td>
<td>28</td>
<td>54</td>
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<td>Review study eligibility</td>
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<td>Pre-Assessment</td>
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If you want to know about the results before the study is done:
The study leader will contact you if we learn of information related to the study that is important for you to know, because it may affect whether you want to continue being in this study. We cannot tell you any other information until the results have been studied. After the study is complete, you can ask for more information.

What are the risks of being in this study?

There are minimal risks of being in this study. However the risks, though unlikely, are:

- During this study, you will be asked questions of a sensitive or personal nature. Answering these types of questions could potentially cause some discomfort or embarrassment.

- There is a small risk that exchanging your personal health information over the Internet may result in a violation of your privacy.

- You will be given instructions about the use of over-the-counter laxatives and enemas. As with all medications, there will be some risk of side effects. Possible side effects from laxative and enema use are diarrhea, nausea, vomiting, rectal irritation, stomach cramps, or bloating. We strongly recommend that you talk to your Primary Care Physician if you have any concerns or questions about laxative or enema use.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

We cannot promise that you will be helped by being in this study, but you may benefit from being in this study. Possible benefits include: If you are in this study, you may help improve your child’s behaviors and symptoms related to encopresis. In addition, information researchers get from this study may help others in the future.
What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment for your child even if you choose not to be in this study. The usual treatment would include a visit with your doctor.

Will you be paid for being in this study?

You will be paid up to $200 for completing the assessments in this study. After completion of the Post-Assessment at 6 weeks, you will be sent a $50 gift card. After completion of the Post-Assessment at 6 months, you will be sent another $50 gift card. After completion of the Post-Assessment at 1 year, you will be sent a $100 gift card.

You will not be paid if you decide not to finish this study. However, if the study leader decides you should not continue, but you met full criteria and completed the necessary steps in the timeline presented, you will be paid the full amount for the study.

Will being in this study cost you any money?

In this study, we recommend the use of over-the-counter medication and we also require that you have computer and Internet access. The costs associated with the purchase of over-the-counter medicines, and the costs associated with use of a computer and the Internet will not be paid for by the study.

What if you are hurt in this study?

If you are hurt as a result of being in this study, we have no plans to pay you for lost wages, disability, or discomfort. If you are hurt in the study in a way that is unexpected, your insurance company may pay for your treatment. If they do not pay, University of Virginia will treat you free of charge. If you have questions about what will be covered if you are hurt in the study, talk to the study leader. You do not give up any legal rights by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study at any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.
Even if you do not change your mind, the study leader may decide to take you out of the study. This might happen if the study leader is concerned about your health. Or it might happen if you do not follow instructions given to you.

If you decide to stop being in the study, we will ask you to notify us by calling 434-924-8020, or by emailing Dr. Lee Ritterband, the principal investigator of this study at lr5b@virginia.edu, or Aly Curmaci, the study coordinator at aac2c@virginia.edu. Please note that any information already obtained will continue to be used. As you may recall, we also obtained some information from you over the Internet before you read this consent form. If you agree to participate in this study, you are also agreeing to let us use that data.

**How will your personal information be shared?**

The UVa researchers are asking for your permission to gather, use, and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

**If you sign this form, we may collect any or all of the following information about you:**

- Personal information such as name, address, e-mail address, phone number, date of birth, social security number
- Records and test results that relate only to this study

We will not access any of your medical records or test results existing outside of this study.

**Who will see your private information?**

- The researchers in the study to make sure they observe the effects of the study and understand its results
- People or committees that oversee the study to make sure it is conducted correctly
- People who pay for the study, the National Institutes of Health
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

**What if you sign the form but then decide you don't want your private information shared?** You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation. UVa researchers will do everything possible to protect your privacy.
We have asked the federal government to issue a Certificate of Confidentiality, to help protect the privacy of your study records. If we receive a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, we will not use it in the following cases. We may report to authorities and provide study information about you where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect. In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy. This Certificate will not protect your information if you give permission for your insurance company, employer or another person to see your records. It also may not protect your information if you tell other people that you are in this study. To protect your privacy a copy of this consent form will not be put in your medical record. (This is not the same as the record of this research study.)

Please contact the researchers listed below to:

- Obtain more information about the study.
- Ask a question about the study procedures or treatments.
- Report an illness, injury, or other problem (you may also need to tell your regular doctors).
- Leave the study before it is finished.
- Express a concern about the study.

Principal Investigator: Lee Ritterband, PhD
Psychiatry and Neurobehavioral Sciences, School of Medicine
Telephone: (434) 924-5988
E-mail: lr5b@virginia.edu

Study Coordinator: Aly Curmaci, MS
Psychiatry and Neurobehavioral Sciences, School of Medicine
Telephone: (434) 924-8020
E-mail: aac2c@virginia.edu

The Department of Psychiatry and Neurobehavioral Sciences
Behavioral Health and Technology
310 Old Ivy Way, Suite 102
Charlottesville, Virginia 22903

What if you have a concern about a study?

You may also report a concern about a study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.
When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Conclusion

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you understand the information given to you about the study and in this form. If you sign the form it means that you agree to join the study. By signing below you also confirm you have the legal authority to sign for your child.

☐ Please check this box to indicate that you understand the consent process and what this study will involve.

☐ Please check this box to indicate that you have discussed this study with your child, and he or she has given his or her assent to participate.

Use your mouse to sign below. With your cursor in the box, hold your mouse button down and move your mouse to sign your name. When ready, click SUBMIT.

________________________
PARENT/GUARDIAN
(SIGNATURE)

________________________
PARENT/GUARDIAN
(PRINT)

________
DATE

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_______________________________
PERSON OBTAINING CONSENT
(SIGNATURE)

_______________________________
PERSON OBTAINING CONSENT
(PRINT)

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DATE