**INFORMED CONSENT FORM**

**2020-2021**

**Study Title:** *Treating Nonretentive Encopresis using a Comprehensive Behavioral Intervention*

**Principle Investigator:** *Michael I. Axelrod, Ph.D., LP, NCSP; Director of the Human Development Center; Professor in the Department of Psychology; University of Wisconsin – Eau Claire; 715-836-5020; axelromi@uwec.edu*

**Introduction:** Because your child has been identified as having nonretentive encopresis (i.e., fecal soiling without constipation), he or she has been invited to participate in this research study conducted by Dr. Michael Axelrod from the University of Wisconsin – Eau Claire. Dr. Axelrod will review this Informed Consent Form with you and invite you to ask questions. He will also be available throughout the study for regular consultation. **Your child’s participation in this research study is voluntary and not a requirement for receiving benefits or services from the University of Wisconsin – Eau Claire.** Dr. Axelrod anticipates recruiting between two and four children for this study.

**Purpose of the Research:** Nonrententive encopresis, or fecal accidents without constipation, accounts for less than 10% of encopresis cases and, as a result, has not been studied as extensively as other Elimination Disorders (e.g., fecal accidents with constipation, bedwetting). For example, large studies researching the effects of different interventions have not been conducted with children with nonretentive encopresis. The research that has been conducted indicates that a comprehensive behavioral intervention consisting of regularly scheduled toilet sits, a reward system for successful bowel movements in the toilet, and clean-up procedures for fecal accidents is most promising. However, the existing research is limited to a few studies with few subjects. The purpose of this research study is to extend previous research examining the effects of a comprehensive behavioral intervention across the home and school setting for children with nonretentive encopresis.

**Potential Benefits:** Given that a comprehensive behavioral treatment has had some success decreasing fecal accidents and increasing self-initiated bowel movements in the toilet for children with nonrententive encopresis and encopresis with soiling, there is a possibility that the intervention can lead to improvements in your child’s condition. More broadly, the study hopes to add to the existing research treating nonretentive encopresis.

**Inclusion/Exclusion Criteria:** You and your child have been asked to participate in this study because your child’s primary care physician identified your child as having nonrententive encopresis and referred your family to the Principle Investigator for treatment. There are, however, several criteria that children and families must meet in order to be enrolled in the study.

* In addition to your child being identified by his or her primary care physician as having nonrententive encopresis, the Principle Investigator must confirm this through a brief parent interview.
* Because the study is examining the intervention across the home and school setting, your child’s school must be willing to participate in the intervention.
* Because the intervention is time consuming, both parents must be willing to participate in the intervention. Specific responsibilities are described below. However, at a minimum, both parents must be willing to complete data collection forms.
* Children with encopresis with constipation or incontinence overflow, or encopresis caused by a known medical condition (e.g., Chrone’s Disease) will be excluded from participation.
* Children with developmental or intellectual disabilities will be excluded from participation.
* Children must be between the ages of 8 and 14 years of age.

**Research Procedures:** The study’s procedures involve the implementation and evaluation of a comprehensive behavioral treatment for nonrententive encopresis. The treatment’s procedures are commonly used when treating all forms of encopresis, as well as when toilet training children. Put differently, these procedures are commonly used by parents and not considered experimental. Below is a brief description of the comprehensive behavioral treatment.

* *Brief 2-minute toilet sits scheduled every 15 to 30 minutes across the day*. Parents and school staff will implement these toilet sits by informing your child that it is a good time to use the bathroom, guiding him or her to the bathroom, and providing brief praise statements for compliance. Your child will be instructed to sit on the toilet until either a timer sounds or a parent/school staff indicates the toilet sit is complete, pull up his or her underwear and pants, state if they had a successful bowel movement in the toilet, wash hands, and open the bathroom door. Parents and school staff will be responsible for visually confirming all successful bowel movements in the toilet. At home, a primary bathroom will be selected. At school, we will ask school staff to identify a private bathroom close to your child’s primary classroom.
* *Individualized reward system*. An individualized reward system will be set up through consultation with parents and school staff. Rewards will be delivered following successful bowel movements in the toilet. Families will be responsible for costs related to tangible rewards.
* *Responsibility training*. For fecal accidents and soiling, you child will be required to engage in age appropriate cleaning tasks including placing soiled clothing in a bag, cleaning soiled skin with wipes, and laundering soiled clothing with parental assistance.

The study will include three phases:

1. *Baseline:* Data collection will be introduced. Parents and school staff will conduct pants checks across the day to assess for fecal accidents using visual inspection. You child will not be involved during this phase. This phase will last between 3 and 7 weeks.
2. *Treatment:* Data collection occurs during this phase, which will last between 10 and 20 weeks. The length of this phase depends on how long it takes for your child to achieve success (decreased fecal accidents, increased self-initiated successful bowel movements in the toilet.
3. *Follow-up:* Data collection continues to occur during this phase but treatment will be discontinued. The phase lasts between 3 and 8 weeks. An extended follow-up will occur at approximately 20 weeks following the end of treatment.

Data Collection: You and school staff will be asked to complete several forms daily in order to assess the effects of the treatment. Examples of those forms are attached.

**Possible Risks:** As with any treatment procedure, there is a risk that the condition will either not improve or worsen. Dr. Axelrod has taken the following precautions to limit the possibility of this risk:

1. The treatment procedures being used for this study are commonly used for all forms of encopresis and the toilet training of young children. In addition, the treatment procedures have been shown to be successful at home and in the school setting.
2. You and your child will meet weekly or every other week with Dr. Axelrod to discuss progress, challenges, and next steps. Dr. Axelrod will be available for email and phone consultations in between meetings.
3. Dr. Axelrod will be in weekly phone and/or email communication with your child’s school staff, likely an identified individual (school counselor, school psychologist, classroom teacher), to discuss progress, challenges, and next steps. Dr. Axelrod will be available for consultations at your child’s school.
4. Dr. Axelrod will communicate progress, challenges, and next steps to your child’s primary care provider (the referring healthcare professional).
5. A referral will be made to the appropriate healthcare professional should there be medical complications.

As part of the study, Dr. Axelrod will generate and collect medical records that are considered protected under the Health Insurance Portability Accountability Act (HIPAA). Dr. Axelrod’s program, the Human Development Center, maintains the privacy of all medical records and will only release medical records with your signed permission.

**Confidentiality and Privacy:** The security of your child’s information will be maintained by keeping all paper copies of documents (signed informed consent form, recording forms) in a locked file in the Human Development Center. All electronic information generated as part of this study will be stored on the university’s secure server under Dr. Axelrod’s account. All paper copies of documents will be destroyed after 10 years following the conclusion of the study. All electronic information will be erased after 20 years following the conclusion of the study. You and your child’s privacy will be further maintained by using pseudonyms when reporting the study’s results, referencing “Northwestern Wisconsin” when describing the study’s location, and not referring to your child’s school by name. Your child’s age, grade, sex, and race/ethnicity will be reported, although this information should not allow for others to identify your child by name. In compliance with state and federal law, your child’s information will be kept confidential unless disclosure is required by law or you request disclosure and sign a permission to release information form.

**Contact Information:**

Questions about the research study can be directed to:

Dr. Michael Axelrod

Licensed Psychologist

Director, Human Development Center

Professor, Psychology Department

University of Wisconsin – Eau Claire

Eau Claire, WI 54702-4004

715.836.5020 (office)

715.836.5604 (clinic)

axelromi@uwec.edu

This research study including this informed consent form has been reviewed and approved by the University of Wisconsin – Eau Claire Institutional Review Board for the Protection of Human Subjects (Proposal ID: AXELROMI149942019). This board ensures that research studies involving human participants are ethical and follow appropriate federal and state regulations. Any questions or concerns about your rights and your child’s rights as a participant in this research should be directed to:

Dr. Mary Beth Leibham

Acting Chair, Institutional Review Board for the Protection of Human Subjects

University of Wisconsin – Eau Claire

Hibbard Humanities Hall 259

Eau Claire, WI 54702-4004

715.836.4536

leibhame@uwec.edu

By signing below, you are agreeing to allow your child to participate in this research study as long as he or she meets all inclusion criteria. You acknowledge understanding the research study’s procedures, what will be asked of you and your child as a result of participation, and the potential risks. You understand that participation is voluntary and you may withdraw your child from the research study at any time.

Parent Signature Date

Researcher Signature Date