Understanding the knowledge, behavior change, engagement and retention of the key stakeholders of Bladder Basics

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**Please check all that are applicable:**

[] I am an adult participant in this study.

Print your name here:

_____

[] I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

Are you participating in any other research studies? _____ Yes _____No

**FOR QUESTIONS ABOUT THE STUDY, CONTACT:**
Kathleen M. Kan,
300 Pasteur Dr
S-287
Stanford, California 94305-2200
(650) 497-8000

**DESCRIPTION:** You are invited to participate in a research study that aims to understand the retention, engagement, knowledge, behavior change, and user experience among potential Bladder Basics stakeholders. We want to understand if Bladder health education tools such as Bladder Basics are effective in increasing knowledge and improving bladder health habits among children with bladder health issues. The total number of people expected to be enrolled in the study is 1050.

You were selected as a possible participant in this study because you are a parent or guardian of children under age 18 with bladder health issues. You will be sent a survey in the email and/or you will be asked to participate in video reaction interview. If you are participating in the video reaction interview, video recording will be done to read your facial reactions, study retention and engagement as well as improve transcription.

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A 30-minute virtual meeting will be conducted with the study team to obtain your consent. The consent meeting will be recorded for enrollment purposes.

All recordings will be stored in a password protected/encrypted University computer. They will not be shown to anyone outside the research team and will be deleted after the completion of the study.

Future use of Private Information

Research using private information is an important way to try to understand human disease. You are being given this information because the investigators want to save private information for future research.

Identifiers might be removed from identifiable private information, and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical or sexual abuse, etc.) about your health and/or safety; in such a case, the researchers may contact you and provide a referral for your care.

It is possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

**RISKS AND BENEFITS:** The risks associated with this study are a minimal risk of emotional distress. Identities of participants in the focus groups and the information exchanged should be kept confidential. However, the researcher cannot assure that participants will respect the confidentiality of others in the groups. The benefits which may reasonably be expected to result from this study are none. We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your medical care. The alternative is not to participate.

**TIME INVOLVEMENT:** The total viewing time of Bladder Basics is about 1 hour (7 short videos). You will have 4 weeks to complete the viewing. Before accessing Bladder Basics, you will fill out a pre-intervention survey. During viewing Bladder Basics, you will fill out a post-lesson survey after watching each video. You will also fill out a post-intervention survey at the completion of the entire Bladder Basics and 3 months after the completion.

**PAYMENTS/REIMBURSEMENTS:** You will receive up to $80 Amazon gift card via email upon completion of the study, as follow: 1) receive $60 after completing the pre-intervention survey, post-lesson surveys, and post-intervention survey at ≤4weeks, (2) then receive $20

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after completing the post-intervention survey at 3 months. The Societies for Pediatric Urology is providing financial support and/or material for this study.

**PARTICIPANT'S RIGHTS:** If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to refuse to answer particular questions.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, you and your child's identity will not be disclosed. 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 Web site at any time.

## Authorization To Use Your Health Information For Research Purposes

Because information about you and your child's health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how you and your child's health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

### What is the purpose of this research study and how will my health information be utilized in the study?

Pediatric lower urinary tract symptoms significantly impact children's health as well as their emotional, social, physical, and academic domains due to associated urinary symptoms, lowering their quality of life. Behavioral modifications have been identified as an effective measure to educate children and their families on strategies to rehabilitate the bladder and sphincter function to achieve more sustainable voiding habits and have been shown to reduce pLUTS in 40-70% of patients. Hence, the Bladder Basics was created through the Stanford Department of Urology in 2020. It is self-guided digital health platform to increase accessibility to patients and their families named BRAVE. This study aims to understand the

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retention, engagement, knowledge, behavior change, and user experience among potential Bladder Basics stakeholders.

**Do I have to sign this authorization form?**
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke it or withdraw from the research later?**
If you and your child decide to participate, you are free to withdraw your authorization regarding the use and disclosure of you and your child's health information (and to discontinue any other participation in the study) at any time. After any revocation, you and your child's health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:
Kathleen M. Kan,
300 Pasteur Dr
S-287
Stanford, California 94305-2200

**What Personal Information Will Be Obtained, Used or Disclosed?**
You and your child's health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to,
Full Name
Geographic subdivisons smaller than a state
Dates (except year) directly related to an individual
Demographics (age, sex, etc.)
Health information relating to your child's bladder health obtained by the health survey.

**Who May Use or Disclose the Information?**
The following parties are authorized to use and/or disclose you and your child's health information in connection with this research study:

- The Protocol Director Dr. Kathleen M. Kan
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

- Research Staff

**Who May Receive or Use the Information?**
The parties listed in the preceding paragraph may disclose you and your child's health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Urology Provider
- The Societies for Pediatric Urology

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**
Your authorization for the use and/or disclosure of you and your child's health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

*The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).*

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____

Print Name of LAR

_____

LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

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**WITHDRAWAL FROM STUDY:** The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- No longer meets inclusion/exclusion criteria.
- Did not complete watching the Bladder Basics Curriculum.
- Did not watch the Bladder Basics Curriculum.
- You have previously enrolled in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

If you are withdrawn from the study for one of the above reasons, you will not be sent the 4-week and 3-month follow-up survey, and will not be able to receive the $80 Amazon gift card. If you have already been sent the 4-week survey, you will not be sent the 3-month survey and will not receive the $20 Amazon gift card. You will receive an e-mail notification on your withdrawal and access to the Bladder Basics curriculum will be removed.

**CONTACT INFORMATION:**

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Kathleen Kan at (650) 497-8000. You should also contact them at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Chenxi Liu at chenxil@stanford.edu

**FUTURE STUDIES:**

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

The extra copy of this signed and dated consent form is for you to keep.

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_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

*The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).*

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Print Name of Other Parent or Guardian