Consent for Research Participation

Title: **Study evaluating efficacy of a non-invasive pelvic floor muscle trainer for treatment of stress urinary incontinence**

Investigator/Researcher(s): **Jeremy Wiygul, M.D.**
Investigator/Researcher Contact Information: **347-684-0176/jeremy@pelex-med.com**
Sponsor: Pelex, Inc.

KEY INFORMATION FOR YOU TO CONSIDER:

We (the researchers) are asking if you would like to be in a research study. Some key information is provided in the boxes below to help you decide if you want to participate or not. Read the entire form and ask questions before you decide. The researchers will go over this form with you and you can ask any questions.

What is the purpose of this research?	This main purpose of this study is to learn whether the Pelex Upp, a non-invasive biofeedback device, can successfully treat stress urinary incontinence The research will also give insight into ease of use of the Pelex Upp as well as factors that help make it more comfortable. The Pelex Upp is not approved by the Food and Drug Administration for treatment of stress urinary incontinence
What will happen to you during the study?	[You are being asked to be in this research study because the researchers want to know if the Pelex Upp, a medical device, can successfully treat stress urinary incontinence. When enrolled in this study, you will receive a Pelex Upp and accompanying materials to guide you through use. You will be asked to use the Pelex Upp to complete pelvic floor exercises five times a week for ten minutes a day. You will also be asked to fill out surveys characterizing any urinary incontinence symptoms you may have both at the beginning and end of the study, and participate in scheduled weekly checkup phone calls during the study to ensure appropriate device function.
How long will you be in the research?	You will be in this study for four weeks. We will keep the data collected in the study for three years.

Could being in this research harm you?	You should understand the risks of this research study before you decide to participate. If you participate in this study, you might experience some risks and discomforts that might include the following: • S*kin irritation* • *Muscle fatigue* This research is no more than minimal risk. The level of risk is expected to about the same as risks of daily life or a physical exam. The treatment under study also may involve risks to you which are currently unforeseeable.
Will being in this study help you in any way?	No benefits are promised. Some benefits might include improvement in stress urinary incontinence symptoms. You also may notice an improvement in any pelvic organ prolapse symptoms you have.
Are there any costs to participate?	It does not cost anything to be in the study. Your insurance or third-party payer will be billed for any routine care in this study. The study team can explain your costs to you if your insurance does not pay. You will pay your usual co-payments or deductibles. You will not be charged for use of the Pelex Upp or any of the accompanying educational materials.
How do researchers protect your information?	Researchers keep your personal information confidential and stored securely. Only the researchers approved to be on this study may see your information. Any identifying information such as name or birthdate will be removed before entry of data into a secured, password protected database.
Will you get any test results?	No
What other choices do you have besides taking part in this research?	There are no alternatives to this research at this site. You may choose not to participate in this research study.

ADDITIONAL DETAILED INFORMATION:

What should you do if the research causes any injury or need for medical treatment?

Call 911 if you suffer a medical emergency. If you are not sure, go and ahead and call. It is better to be safe.

Call the researchers if you receive emergency treatment.

How many people will participate in this research study?

Up to 20 people will be screened to determine if they can be enrolled.
The researchers hope to enroll up to 5 people.

Who can you talk to about the research?

Contact the researcher listed on the first page if you have questions, concerns, complaints, or get hurt.

Pearl Institutional Review Board (IRB) oversees this research. You may call (317) 899-9341 to speak to the IRB for any reason, such as:

- You have questions about your rights.
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get more information.
- You want to provide your input about this research.

Are there any conflicts of interests reported for this study?

Dr. Jeremy Wiygul is a founder of the sponsor Pelex, Inc., and has equity ownership. The outcome of this research study could be of interest to Pelex, Inc. The IRB oversees the conflict of interest policies. In accordance with these policies, the IRB has determined that Dr. Wiygul's interests create no significant risk to the welfare of participants in this study or to the integrity of the research. If you want more information about this, please contact the IRB.

How do researchers protect your information?

The researchers will keep information about you in a secure location with limited access. If the results of this study are made public, information that identifies you will not be used.

There is a section at the end of this consent form that asks for your permission to use or share your information for future research. Your information will only be used or shared if it is coded or your identifiers are removed and if you agree. If you agree to this today, we will not ask for your permission in the future. This is optional. You do not need to agree to participate in any future research in order to be in the current study.

What Protected Health Information will be used or disclosed?

Federal law protects your right to privacy concerning PHI. There are certain things you need to know. PHI is any information from your medical record or obtained from the study linked to you and that refers to your mental or health conditions in the past, the present or the future.

By signing this form, you give permission to the researchers approved on this study to use or disclose (release) your Health Information that identifies you for the research described within this form.

This authorization is valid on the date the form is signed until the research is complete
The PHI that we may create, use, report, or disclose (release) for this research includes:

- Health information collected during the research
- Results of physical examinations
- Medical history

The researchers will not use unsecure e-mail for any research communications involving PHI unless you specifically authorize us to do so.

This information will be used and/or given to others to:

- Do the research,
- To do clinical testing,
- To study the results, and
- To see if the research was done right.

The **PHI** listed above may be used by and/or disclosed (released) to:

- The Institutional Review Board(s) (IRB) that have oversight of this research.
- The following research sponsor(s) and/or its agents: Pelex, Inc.
- The researchers and their staff approved by the IRB.
- Collaborating research sites, outside laboratories, cooperative study groups, or contracted research organizations that are approved by the IRB
- Other administrative staff who supervise the way research is done, such as auditors or monitors.
- The Federal agencies that supervise the way research is conducted, such as the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), the National Institute of Health (NIH) or other government agencies.
- Data Coordinating Center(s).
- The Data Safety Monitoring Board that reviews the safety of this study.

You may change your mind and revoke (take back) this authorization in writing at any time. You may discontinue participation in the study at any time without penalty or loss of any benefits to which you are otherwise entitled.

To withdraw, please write to Dr. Jeremy Wiygul, 38-60 Douglaston Parkway Douglaston NY 11363. Your PHI collected before you withdraw your authorization will still be used and reported to the extent that those noted above have taken action in reliance of this authorization, including

as necessary to maintain the integrity of the research or to conduct investigations or to report adverse events (bad effects).

If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

Participation in this study is voluntary, and you have a right to refuse to sign this form. If you do not sign this form, your health care treatment, your enrollment for benefits, your payment for the health care outside of the study, and your health care benefits are not affected, and will otherwise not involve any penalty or loss of benefits to which you are otherwise entitled. However, you will not be able to participate in the research described in this consent form if you do not sign this form.

The researchers cannot share with you some of the PHI obtained in this study during the research; however, it can be shared at the end of the study. This includes improvement in pelvic floor muscle strength.

You need to know that some of the individuals or groups mentioned above who may receive your health information may not be required by federal privacy laws to protect your PHI. They may share your information with others without your permission if permitted by the laws governing them. For example, the sponsor *Pelex Inc* does not have the same obligations as your research team and may no longer protect your PHI.

The research team may share your PHI as required by law, for example, to:

- Comply with a court ordered subpoena,
- Report suspected child abuse or neglect,
- Report certain communicable diseases,
- Report a possible threat or harm to yourself or others, or
- Comply with other laws.

What information about this study is available to the public?

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.

Can your participation end early?

Your participation in the research study may end for any of the following reasons:

- If you are a female who becomes pregnant
- If the research becomes harmful
- Whenever it is determined that it is not in your best interest to continue
- If you do not follow the instructions or adhere to the research requirements given to you by the study doctor or study staff
- You do not take medication as instructed
- You do not keep study appointments

What additional information should I know?

The researchers will inform you of any significant new information that may affect you in a timely manner. Such information may help you decide if you want to stay in the study. The researchers will share any new information with you if it affects your ability to stay in the study.

Does this research include whole genome sequencing?
NoPa

You will NOT receive any gifts, rewards, compensation, or reimbursement for your participation in this research study.

You will NOT receive any type of rights for discoveries, patents or products developed from this research.

Will the researchers obtain additional information about you from others?

No other information about you will be obtained from others.

OPTIONAL RESEARCH ACTIVITIES

This section provides a description of optional research activities. Please indicate if you agree or do not agree with the options below. Your decision will not affect your participation in the current study.

May the researchers contact you after your participation in this research is over to invite you to consider other research studies? • Your decision will not affect your participation in the current study. • The study team may contact you to see if you are interested in other studies.	
Please initial the ONE option that you choose below:	
_____ *(initials)*	YES.
_____ *(initials)*	NO.

SIGNATURES:

You have read this document and were told of the risks and benefits and a member of the research team answered questions to your satisfaction. A member of the research team will answer any future questions. You voluntarily agree to join the study and know that you can withdraw from the study at any time without penalty. You do not waive any legal rights by signing this form.

You will receive a signed copy of this document.

_____ **Print the Name of the Adult Research Participant** (18 years of age or older)	_____ **Signature of the Adult Research Participant**	_____ **Date Signed**
Completed by the Investigator obtaining informed consent: ☐ In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be, associated with this research, and to answer any further questions. ☐ Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered. *Check options pertaining to remote consent if applicable:* ☐ Check if remote consent (conference call or video conference). ☐ Check if the informed consent document was not retained, due to contamination of the document by infectious material. ☐ Check to confirm participant was asked to mail, fax, or e-mail a copy of the signed consent to the research team.		
_____ **Print Name of Investigator Obtaining Informed Consent**	_____ **Signature of Investigator Obtaining Informed Consent**	_____ **Date Signed**