Participant Name: _____ Date: _____

Title of Study: Optimizing Remote Access to Urinary Incontinence Treatment for Women Veterans (PRACTICAL)

Principal Investigator: [redacted] VA Facility: [redacted]

**WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?**

This study is about assessing the helpfulness of two treatment delivery methods for bladder leakage or urinary incontinence. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn which treatment method is the most helpful remote delivery method for treating bladder leakage.

**WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?**

Your participation in this research will last about 6 months. During the first 8-12 weeks of the study, you will receive standard of care from an online educational program (MyHealtheBladder) or a video visit with a provider through VA Video Connect. You will be selected by chance to receive MyHealtheBladder or VA Video Connect. About half-way through the study, we will ask you about your bladder symptoms. If your bladder symptoms are not better, you will be selected by chance to receive your first video visit or a second video visit with a provider. Throughout the study, you will be asked to answer questions related to your health, bladder leakage, costs due to bladder leakage, and track your behavioral training.

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**

The most important reason to join this study is that your bladder leakage may improve while you are in this study. For a complete description of benefits, refer to the Detailed Consent.

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**

The most important reason to not join this study is if you are unwilling to receive treatment for bladder leakage via remote delivery. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

You are eligible to receive treatment for your bladder leakage in clinic with a VA provider. For a complete description of alternate treatment/procedures, refer to the Detailed Consent.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?**

The person in charge of the study is [redacted], Principal Investigator, of this study at the [redacted] Veterans Affairs Medical Center ([redacted]). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted].

Participant Name: _____ Date: _____

Title of Study: Optimizing Remote Access to Urinary Incontinence Treatment for Women Veterans (PRACTICAL)

Principal Investigator: [redacted] VA Facility: [redacted]

## RESEARCH DETAILS

### WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn more about the usefulness of two different remote delivery treatment methods for treating bladder leakage in women Veterans. Both treatment delivery methods involve standard of care treatment that is currently used in the VA Continence Clinic.

### HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 4 years. Your individual participation in the project will take a total of 24 weeks (6 months). During the 6 months, you will complete 8-12 weeks of an intervention. There will be 86 participants enrolled at the [redacted] site.

### WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you agree to participate in this study, you will be asked to complete either an online educational program (MyHealtheBladder) or VA Video Connect (remote provider visits) for 8 - 12 weeks. You will not have to come to the VA for any study visits. All visits will occur on the internet or via telephone. In order to use either program, you will need a computer/mobile device and access to the internet. You will be randomly assigned, so you have a 50/50 chance of being assigned to Group A or Group B. After 8-weeks, you may be re-assigned to receive an initial video visit or second video visit. During the 24 weeks, you will also be asked to complete surveys at different time-points throughout the study. When you complete the intervention, you will be asked if you would like to participate in an interview about your experience. You do not have to participate in the interview, if you do not want to. Finally, you will be asked to complete a final set of questionnaires surveys at 24 weeks.

As a participant, you are allowed to skip any questions that you prefer not to answer.

| **Telephone Visit** | **Timing** | **Schedule of Telephone visit goals, procedures, and assessments** |
|---|---|---|
| Consent | | • You will complete a consent interview with the study coordinator and sign. |
| 1 | Week 1 | • This visit will last 30 minutes<br>• After consent is received, you will answer demographic and bladder leakage questions to determine which group you will have a chance of being assigned to. |
| 2 | Reminder Call | • The coordinator will contact you to remind you of your randomization visit scheduled for the following day. |
| 3 | Week 2 | • This visit will last up to 1 hour and 45 minutes<br>• You will have a 50/50 chance of being assigned to Group A or Group B – like the flip of a coin. You will be told what group you were assigned to participate in. After you are assigned, you will receive an educational session on either Group A or Group B |

Participant Name: _____ Date: _____

Title of Study: Optimizing Remote Access to Urinary Incontinence Treatment for Women Veterans (PRACTICAL)

Principal Investigator: [redacted] VA Facility: [redacted]

| | | | |
|---|---|---|---|
| | | • You will answer surveys pertaining to your health, bladder leakage, costs due to the bladder leakage, stress, and sleep. | |
| | | **Study Arm: MyHealtheBladder** | **Study Arm: VVC** |
| 4 | Week 3 | • These sessions will last 5-10 minutes each day.<br>• You will begin using MyHealtheBladder.<br>• You will login in MyHealtheBladder daily to receive education about your bladder and complete behavioral training sessions. | • This session will last 1 hour<br>• You will complete a VA Video Connect visit with a study medical provider.<br>• You will receive a booklet to review the self-management program. |
| | Weeks 4-5 | • These sessions will last 5-10 minutes each day.<br>• You will continue to use MyHealtheBladder to receive education about your bladder and complete behavioral training sessions. | • These sessions will last 5-10 minutes.<br>• You will continue following the booklet and complete activities within booklet. |
| 5 | Week 6 | • These sessions will last 5-10 minutes.<br>• You will continue to use MyHealtheBladder to receive education about your bladder and complete behavioral training sessions.<br>• You will receive a phone call from the study coordinator to remind you to complete a 4-week assessment about your bladder.<br>• You will also tell us how often you have been completing your pelvic exercises. | • These sessions will last 5-10 minutes.<br>• You will continue following the booklet and complete activities within booklet.<br>• You will receive a phone call from the study coordinator to remind you to complete a 4-week assessment about your bladder.<br>• You will also tell us how often you have been completing your pelvic exercises. |
| | Weeks 7-9 | • These sessions will last 5-10 minutes each day.<br>• You will continue to use MyHealtheBladder to receive education about your bladder and complete behavioral training sessions | • These sessions will last 5-10 minutes.<br>• You will continue following the booklet and complete activities within booklet. |
| 6 | Week 10 | • This is your last week of MyHealtheBladder. These sessions will last 5-10 minutes each day. | • This is your last week of the VVC booklet. These sessions will last 5-10 minutes each day.<br>• You will receive a phone call from the study coordinator to remind |

Participant Name: _____ Date: _____

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Principal Investigator: [redacted] VA Facility: [redacted]

| | | | |
|---|---|---|---|
| | | • You will receive a phone call from the study coordinator to remind you to complete an 8-week assessment about your bladder. You will also tell us how often you have been completing your pelvic exercises.<br>• Depending on your responses to the assessment, you may be re-assigned to a new group.<br>• You may also be asked if you would like to participate in an interview about your experience. This will take 1 hour. | you to complete an 8-week assessment about your bladder. You will also tell us how often you have been completing your pelvic exercises.<br>• Depending on your responses to the assessment, you may be re-assigned to a new group.<br>• You may also be asked if you would like to participate in an interview about your experience. This will take 1 hour. |
| 7 | Week 11 | • If you are identified to be re-assigned, you will have a 50/50 chance of being assigned to Group B (VVC visit) or Group C (self-management).<br>• You will continue practicing what you learned in the previous 8 weeks for the next 4 weeks. | • If you are identified to be re-assigned, you will have a 50/50 chance of being assigned to Group B (VVC visit) or Group C (self-management).<br>• You will receive your 1st VVC visit or Booster VVC visit. This session will last 45 minutes.<br>• After your VVC visit, you will continue practicing what you learned in the previous 8 weeks for the next 4 weeks. |
| 8 | Week 12-14 | • You will continue practicing what you learned in the previous 8 weeks for the next 4 weeks.<br>• You will receive a phone call from the study coordinator to remind you to complete a 12-week assessment about your general health, bladder, and experience using the platform.<br>• You may also be asked if you would like to participate in a 2nd interview about your experience. This will take up to 1 hour. | • After your VVC visit, you will continue practicing what you learned in the previous 8 weeks for the next 4 weeks.<br>• You will receive a phone call from the study coordinator to remind you to complete a 12-week assessment about your general health, bladder, and experience using the platform.<br>• You may also be asked if you would like to participate in a 2nd interview about your experience. This will take up to 1 hour. |
| | Weeks 15-23 | • You will continue practicing your behavioral therapy exercises. These should take you between 5 to 10 minutes to complete each day. | |
| 9 | Week 24 | • You will receive a phone call from the study coordinator to remind you to complete a 24-week assessment about your general health and bladder. This will take you between 45 minutes to 1 hour to complete. | |

**Participant Responsibilities**

- Complete your assigned sessions: daily on MyHealtheBladder or the initial or additional VA Video Connect visits as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

**WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?**

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described below you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

- **Randomization**: You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.
- **Surveys**
  Some people become uncomfortable at being asked questions about sexual trauma; if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.
- **Photographs, audiotaping, or videotaping**
  The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study investigators while you are participating in this study. You also authorize disclosure of the voice recording to Centralized Transcription Services Program, Department of Veterans Affairs, [redacted]. The said voice recording is intended for the following purposes: Audio-recording will be used for participant interviews. After the interview is completed, the Centralized Transcription Service Program will write out your interview word-for-word. When the text is complete, our team will analyze the interviews from participants to look for common thoughts or statements.

  The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any

VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may withdraw your consent for up to a reasonable time before the voice recording is used.

Signature: _____ Date: _____

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include improving your bladder leakage symptoms and being enrolled in two treatment modalities not normally offered by the VA.

**WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?**

You may choose not to participate in this study. If this is your decision, there other choices such as behavioral treatment, medication, surgical treatment, etc. You may discuss these options with your doctor.

**HOW WILL MY PRIVATE INFORMATION BE PROTECTED?**

For purposes of this research, study data will be stripped of all patient identifiers and each participant will be given a unique code for the study. Paper and electronic patient records will be stored in a secure folder or locked cabinet in a locked office. These records will only be accessible to the Principal Investigator, Interventionist, and Research Coordinator. Computer-based records will be maintained through the Veterans Administration Computerized Patient Record System (CPRS), a secure network with password-protection.

Identifiers might be removed from the identifiable private information that are collected. After that 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 or your legally authorized representative.

We will include information about your study participation in your medical record.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?**

There will be no cost to you for care you receive as a participant in the VA research project. The treatments used in this study will be provided to you at no charge for the 24 weeks of the intervention. This is no guarantee that the treatments you receive during this study will be

continued after your participation ends. You will continue to receive the same treatments after the study, only if they are routinely available at the Birmingham VA Medical Center and your medical provider decides that it is the most appropriate treatment for you.

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

**Compensation/Payments**

To compensate you for your time, you will receive a check for $20 by mail four to six weeks after you consent, again at around the midway point of the study (approximately 8 weeks after enrollment), and then again at your completion of the study (around 24 weeks after enrollment). If you are selected to complete an interview(s), you will receive an additional $20 for each interview (up to $40 total if participate in two interviews). The total amount you can receive through the study is $100. If you withdraw from the study early, you will be paid for the visits you have completed.

Your SSN # will be utilized to process your payment for the study visits. Due to limitations in the Financial Management System, payments made to you through Austin Financial Services Center generate Internal Revenue Service Form 1099, regardless of the amount.

**WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?**

If you are eligible for medical care at a VA Medical Center, and if you are injured as a result of your participation as a research study in this study, the VA medical facility will provide you with necessary medical treatment in accordance with Federal regulations. Any cost of care will be in accordance with your eligibility for care at the VA. Care outside of the VA may not be free and VA may not pay for that care. VA will not necessarily be responsible for injuries that result from noncompliance with study procedures although veterans injured as a result of such participation may be eligible for care from VA under other statutory and regulatory provisions.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: [redacted] at [redacted], and

AFTER HOURS: [redacted] paging at [redacted] ask to page [redacted]. If you are unable to reach the health care provider listed and need immediate medical assistance for a research-related injury, please call the VAMC Emergency Room at [redacted] to obtain advice.

Emergency and ongoing medical treatment will be provided as needed.

**DO I HAVE TO TAKE PART IN THE STUDY?**

Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and discontinue participation at any time. If you decide to withdraw from this study, you are asked to contact [redacted] at [redacted] during the day. Evenings or weekend, call [redacted] paging [redacted] and ask them to page [redacted]. Stopping the study will in no way affect or threaten the quality of care you receive now or in the future at this institution or your opportunity to participate in future studies. Your personal doctor, or the study doctor ([redacted]), may also withdraw you without your consent for medical or other reasons if s/he believes it is in your best interest or if you do not follow study instructions.

If you are a VA employee, refusal to take part in the study will in no way influence your employment, ratings, or subsequent recommendations. You may discontinue taking part of the study at any time without penalty or loss of benefits. You may withdraw and receive standard of care that you would otherwise have received.

If you chose to withdraw from the study, the study doctor will continue to review the data collected prior to withdraw. However, the study cannot collect further information, expect from public records, such as survival data.

**WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?**

If you have any questions regarding the study, please call [redacted] at [redacted] during the day. Evenings or weekends, call [redacted] paging at [redacted] and ask them to page [redacted] or the Geriatric physician on call.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the study coordinator at [redacted], if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

**WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?**

Any significant new findings that develop during the course of the research study that in the opinion of the investigator may affect your willingness to continue to participate will be provided to you as soon as possible.

**FUTURE USE OF DATA, RE-CONTACT, AND TEXT MESSAGES**

We would like your permission to keep your private information (data containing personal information) collected in this study for future research on incontinence. Your private information will be stored indefinitely or until used.

Your private information will be labeled with a code that only the study doctor can link back to you. Results of any future research will not be given to you or your doctor.

You can take part in this study even if you decide not to let us keep your private information for future research.

If you give us permission now to keep your private information, you can change your mind later and ask us to destroy it. However, once we have analyzed your private information, we may not be able to take it out of our future research.

We may share your private information, so that others can use it in their research. Their research may be similar to this study on incontinence. Once we have shared your private information with other researchers, we will not be able to get it back.

Future research use of your private information will be conducted in compliance with applicable regulatory requirements. Paper and electronic patient records will be stored in a secure folder or locked cabinet in a locked office. These records will only be accessible to the Principal Investigator, Interventionist, and Research Coordinator.

You will not find out the results of future research on your private information. Allowing us to do future research on your private information will not benefit you directly.

The private information used for future research may be used for commercial profit. There are no plans to provide financial compensation to you should this occur.

Initial your choice below:

___ I agree to allow my private information to be kept and used for future research on *incontinence.*

___ I do not agree to allow my private information to be kept and used for future research.

We would like to contact you in the future to see if you would be interested in participating in future VA research studies. Please indicate below if you are willing to be contacted about any future studies.

If you agree to be contacted about future studies, your name and last 4 of Social Security will be placed on a “Future Research” list. Paper and electronic patient records will be stored in a secure folder or locked cabinet in a locked office. These records will only be accessible to the Principal Investigator, Interventionist, and Research Coordinator.

Initial your choice below:

Participant Name: _____ Date: _____

Title of Study: Optimizing Remote Access to Urinary Incontinence Treatment for Women Veterans (PRACTICAL)

Principal Investigator: [redacted] VA Facility: [redacted]

____ Yes, I agree to be contacted about future research studies.

____ No, I do not want to be contacted about future research studies.

In addition to email reminders you will receive from the program's online platform, you can choose to receive messages from "Annie," a text messaging application developed by the VA that you can use with either a basic cell phone or smartphone. Some text messages will simply be reminders about PRACTICAL. Others will ask you to text back a reply with information, such as whether you would like follow-up from the study team. Your use of Annie is voluntary and will not impact any benefits or care to which you may be entitled. If you choose to receive the text messages, your carrier's standard message and data rates may apply. Contact your cellular provider with any questions.

____ Yes, I want to receive text message reminders from Annie.

___ No, I do not want to receive text message reminders from Annie.

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

The Investigator, Certified Registered Nurse Practitioner, or Study Coordinator has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

| **I agree to participate in this research study as has been explained in this document.** | | |
|---|---|---|
| _____ Participant's Name | _____ Participant's Signature | _____ Date |