Project Title:	**Women's Treatment Preferences Study**	
Principal Investigator:	**Katherine Iverson, Ph.D.**	**Version #: 4**

1. Overview of the Research Study:

We are asking you to be in a research study that is being supported by the Department of Veterans Affairs (Health Services Research and Development Services), awarded to the VA Boston Healthcare System. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

We are doing the research to compare the effectiveness of two different brief counseling interventions for female VA patients who have experienced past-year intimate partner violence (IPV). IPV refers to physical, sexual, and/or emotional abuse from a current or former intimate partner. If you agree, you will come in and fill out surveys about you, your well-being, and your emotional experiences, receive a brief counseling intervention by a VA-trained clinician, and participate in post-intervention visits to give feedback on the intervention you received. You will be in the study for approximately 4 months if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

You might choose to volunteer in the study because you may learn of resources or tools to help with IPV and related stress, and your feedback may lead to future improvements in IPV care for other women. You will find more information about benefits later in this form.

You may choose not to volunteer to be in the study because you might experience some distress or embarrassment in answering questions about relationships or emotional problems you have experienced. You will find more information about these and other risks later in this form.

Other treatment may include other types of psychotherapy and will be under the supervision of your doctor or caregiver. We are not aware of another intervention at the VA Boston Healthcare System that directly addresses IPV among women. You will find more information about alternate treatment/procedures later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get a second opinion about being in the study. You can do so now or at any time during the study. Another doctor who is not an investigator can give you a second opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

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.

2. WHAT IS THE PURPOSE OF THIS STUDY?

This is a VA-funded research study that will compare the effectiveness of two different brief counseling interventions for female VA patients who have experienced past-year intimate partner violence (IPV). IPV refers to physical, sexual, and/or emotional abuse from a current or former intimate partner. You are eligible to participate in this study if you are a female VA patient over the age of 18 who is currently enrolled in the VA Healthcare System. This study is taking place at VA Boston Healthcare System, and participation via telehealth is available during COVID-19. We plan to enroll up to 68 female VA patients at the VA Boston Healthcare System who have experienced IPV. This study involves participation in an individual brief counseling intervention to address health concerns of women who have experienced IPV within the previous year.

3. HOW LONG WILL I BE IN THE STUDY? WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

This study includes three primary components and will last for approximately 4 months. These components are initial assessment, treatment, and follow-up assessments.

Initial Assessment. You will be asked to complete a series of surveys that ask you about your well-being and emotional experiences. The surveys ask about things such as your self-esteem, relationship experiences, health symptoms, and health care use. After you sign this form, and while you are finishing your initial assessment, you will be randomly assigned to one of the two treatment conditions (described next). This assessment will take approximately 60 minutes to complete. You will be compensated $25 for participating in the initial assessment.

Treatment. You will be randomized to one of two brief counseling intervention conditions. Both interventions are delivered by a trained clinician, such as a social worker or psychologist, and take place at the VA Boston Healthcare System or virtually via telehealth (during COVID-19 crisis). If you agree to participate, you are agreeing to be randomly assigned to one of two conditions. This means that you do not get to choose which of the two treatments you will receive. During COVID-19, you will be sent intervention materials via email initially (at an email address provided by you), and you will have the option to receive intervention materials via USPS mail as well. During the COVID-19 crisis, you will have the option of having your intervention session(s) via telephone or through a VA-approved virtual platform. One of the interventions is called RISE (Recovering from IPV through Strengths and Empowerment). This treatment is a variable length intervention, in which you will have between one and six sessions. In this intervention you will focus on guided activities and discussion of topics such as coping skills, safety planning, self-care, and resources. In the RISE condition, you will complete brief questionnaires at the beginning of each of your sessions (approximately 10-15 minutes to complete). You will need to complete your treatment within approximately 10 weeks. Your first RISE session will be up to 60 minutes, while subsequent sessions are approximately 45 minutes. The other intervention is called Make the Connection, and consists of one 60-minute supportive counseling session in which you learn about the different types of IPV and the ways in which IPV may be impacting your physical, emotional, and social health. This counseling session includes discussion of

safety planning, resources, and referrals that may be of interest to you. Regardless of which intervention condition you are assigned to, you will receive your initial RISE session or your single Make the Connection session today.

Follow-up Assessment. Regardless of condition, you will be asked to complete a post-treatment assessment in approximately 10 weeks from today and an additional follow-up assessment in approximately 14 weeks from today. You will complete the same types of surveys that you did for the initial assessment, including questions about your self-esteem, relationship experiences, health symptoms, and health care use. You will also complete a brief audio-recorded interview to provide feedback on your treatment experiences. Each of these assessments is expected to take approximately 60-75 minutes. You will be compensated $50 for the post-treatment assessment and $75 for the additional follow-up assessment. You will complete these assessments in person or by phone.

Throughout the study you will be reminded that your participation is voluntary and you need not answer any questions that you find uncomfortable. Similarly, during each of the assessments you may refuse to answer any question that you do not feel comfortable answering. You are free to withdraw from the study at any time. You will not have to tell the staff your reasons for ending your participation. As desired, you will be provided by study staff with possible resources within the VA and the community that may be of assistance to you at any time during your participation in this study. Your participation in the study may be ended by the researchers even if you consent. If the researchers end your participation you will be able to know why.

For supervision purposes, we need to digitally audio record all treatment sessions. We will also audio record the posttreatment interviews. Only study providers and study personnel will have access to the recordings. All recordings will be marked only by subject identification codes and will be saved in a digital audio file on a limited access folder on a secure VA server. **As digital audio recording is required for this study, if you refuse to be audio recorded, you will not be able to participate in this study.**

You will *not* be eligible to participate in the study if you have symptoms of mania, psychosis, or intoxication at the time of initial assessment or subsequent sessions, or if you lack the capacity to consent to the study for any other reason. During the COVID-19 pandemic when all enrollment is virtual via telehealth, you will not be eligible to participate if you are unable or unwilling to provide and receive study-related materials at a personal email address, physical mailing address, and/or if you decline to do the enrollment session virtually via VA Video Connect (VVC). If you feel that it is not safe for you to take part in this study virtually because, for example, you do not have a safe place to participate without fear of your partner finding out, you will not be eligible to participate in this study, but our study team would be happy to connect you resources that might feel safe to contact during this time.

If you are not eligible to participate in the study, you will be given appropriate referrals and resources.

4. WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
This study involves answering questions about you of a personal nature (e.g., questions about your emotional health and relationship experiences), and you may experience discomfort in answering them. Additionally, this treatment requires you to confront thoughts, feelings, and behaviors related to your emotional experiences and your safety in intimate relationships. It is also important to consider any risks you may have related to an intimate partner (past or current) finding out that you are participating in a research study focused on IPV or accessing IPV-related resources you learned about in treatment. We will discuss safe ways of contacting you and you do not have to take any study-related materials home with you if you think they could increase risk. During COVID-19 when enrollment is virtual, we will ask if it is safe to mail materials to an address specified by you, as well as whether it is safe to receive emails regarding telehealth (VVC) appointments and intervention materials. Consenting to receive materials by mail and to use your private email to receive intervention-related materials may pose risks to your privacy (e.g., if a partner were to find out about your study participation). Talking about safety planning and resources available to you is a focus of both treatment conditions. Please raise any concerns you may have regarding your safety with study staff and your provider. Although you may have input into the focus of treatment, you may feel uncomfortable thinking about these issues. However, please raise concerns about increasing distress or changes in relationship safety with your provider or study staff. Additionally, you may feel uncomfortable about the assessments and treatment sessions being audio recorded. However, this is required for adequate supervision of the clinicians and will not be shared with anyone outside the research team. You may prefer to receive one intervention over the other; however, it is not possible for you to select your treatment. Randomization is a requirement of the study and you may only have the intervention to which you are assigned. This may be mildly distressing or disappointing to you.

You might also experience some distress or embarrassment in answering questions about any relationship or emotional problems you are having. If at any point you are uncomfortable with the procedures, you have the right to stop participation. If you become extremely distressed during the study, you will be asked to meet with Dr. Katherine Iverson, the Principal Investigator, or another licensed psychologist, to discuss your feelings. You may also be asked to wait a half hour before leaving the session, so that your level of distress can be monitored. It is also possible you may experience distress related to your relationship or the IPV, including being more aware of IPV behaviors and dynamics and how IPV may be impacting your health. The goals of this study are not to tell you what do in terms of staying in or leaving an abusive relationship, though you may want to discuss your options and desires about this during treatment. It is possible that if you return to or continue to have contact with an abusive partner you may be at increased risk for abuse if the partner were to find out about participation in the research project or if you are more assertive as a result of receiving the intervention. This is a standard and unavoidable issue when providing treatment for women experiencing IPV. Please raise concerns and discuss this risk with your provider or study staff. Both interventions focus on safety planning and providing resource information if you feel unsafe or

have concerns about the safety of your loved ones or pets. In addition, there are possible social or legal consequences due to revelations of IPV (e.g., in the event of mandated reporting of a provider if s/he gains knowledge that a child or elder is being abused through the course of the intervention or if a provider gains knowledge that children are witnessing severe IPV). The treatment or procedure may involve risks that are currently unforeseeable.

5. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Possible benefits from participating in the study include a greater understanding of ways to help with IPV and stress. You may also find it satisfying to participate in a study that may lead to future improvements in IPV care for other women. But, there is no guarantee that you will receive any direct benefits from your participation.

6. DO I HAVE TO TAKE PART IN THE STUDY?

Your participation is voluntary and you do not have to take part in this study. If you do take part, you may withdraw at any time. If you refuse to take part or if you decide to withdraw from the study, you will not suffer any penalty, loss of rights, or loss of VA or other benefits that you have a right to receive. You will also still receive the same standard of care that you would otherwise receive. If you are an employee of the VA or a student, refusing to partake or withdrawing from the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

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

Other treatment to that described above may include other types of psychotherapy and will be under the supervision of your doctor or caregiver. We are not aware of another intervention at the VA Boston Healthcare System that directly addresses IPV among women. There are services in the community that address IPV (e.g., local hospitals and the National Domestic Violence Hotline). Although you can only participate in the treatment to which you are randomly assigned (RISE or Make the Connection), you may participate in any other treatment or services within VA or the community throughout the course of this study.

8. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way: We will store your information in ways we think are secure. Only the research team will have access to the information collected from you for this study. The paper data collected from this study will be kept in a locked cabinet in a locked office, while the electronic data will be coded and stored without personal identifiers. The sessions will be audio recorded. These will be saved in a digital audio file on a limited access folder on a secure VA server with only your subject number as a label. Any personally identifiable information (i.e., this signed Informed Consent Form) will be kept separate from your other information in a locked cabinet or in a secure drive of the computer with password protection.

Your research records will be kept indefinitely or until the law allows their destruction in accordance with the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Records will be destroyed, when allowed, in the following manner:

- Paper records will be shredded.
- Electronic records will be destroyed in a manner in which they cannot be retrieved.
- Digital images (photographs, x-rays, scans, video/audio recordings, etc.) will be destroyed in a manner in which they cannot be retrieved.

Your research records and the information within them will not be used for any purpose other than that which is described in the study as approved by the IRB.

To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from the personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for the information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality (CoC) does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: in the event that you report engaging in behavior that constitutes child abuse or elder abuse as defined by the Commonwealth of Massachusetts; or, you are deemed at immediate risk of suicide; or, you are deemed to be at risk for doing bodily harm to a specifically identifiable individual.

We will record information from this study in your medical record, such as information related to your medical care. This will include the name of the study as well as dates of participation and payments. There will be no reference to IPV in the study notes that will be posted in your medical records. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways.

For active-duty military participants, a CoC only protects research information; it does NOT protect study-related information that is included in the VA medical record, which is subject to access by DOD personnel.

Your research records and the information within them will not be used for any purpose other than that described in this study as approved by the IRB.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, diagnoses, progress notes, medications, and treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Research & Development Committee, Research Compliance Officers, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Iverson and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

To comply with laws and regulations, we may need to share safety-related information such as that relating to child abuse or neglect; elder or disabled person abuse; harm to self or others.

An unsigned copy of this consent form will be posted on clinicaltrials.gov or Regulations.gov after all study participants have completed the study.

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.

9. WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

10. WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

You will be compensated $150 for your time and effort taking part in this study. The payment schedule is described next.

You will be compensated $25 for completion of your pretreatment assessment today, $50 for completion of the posttreatment assessment (approximately 10 weeks from today), and $75 for completion of the additional follow-up assessment (approximately 14 weeks from today) as a token of appreciation for your time and effort taking part in this study. Payments will be provided via cash or by mail via check at a safe address provided by you.

You consent to the release of personally identifying information about you including your name, address, and the last 4 of your social security number to the Fiscal Office of the VA Boston Healthcare System so that we may provide compensation to you.

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If payment is made to you by the VA (whether by check or cash voucher), an IRS Form 1099 will be generated regardless of the amount you are paid.

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

In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

12. WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

I understand that if I have any medical questions about this research study, I can call **Dr. Katherine Iverson at 857-364-2066** during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr. Katherine Iverson at 857-364-2066** during normal working hours.

I understand that if I have any medical problems that might be related to this study that **during the day** I can call **Dr. Katherine Iverson at 857-364-2066** and **after hours** I can call the Medical Center Operator at 617-323-7700 and ask for the fellow on call for Psychiatry.

I understand that, if at any point during or after this study I have any questions about my rights as a research participant or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857) 364-4182.

I understand that, if at any point during this study I have any questions about my rights as a research participant, I may contact the Employee Relations Specialist at (857) 364-5564.

13. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read or have had read to me all of the above. Study staff have explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

Participant's Signature **Month Day Year** **Name (print)**

For virtual enrollment during COVID-19: after signing this form, please hold it up to your web camera during your VVC appointment with our study staff so that we can take a screen shot of your signed consent form, which will be saved directly to our secure project folder (in a file separate from any other data collection) behind the VA firewall. Please then mail back this signed consent form to our study team at VA Boston using the pre-stamped and addressed envelope. Please feel free to keep the extra copy of the consent form that has been mailed to you for your own records.