Participant Name: _____ **Date:** _____

Title of Study: The Brief Relationship Checkup: A 3-session program to support Veteran relationships

Principal Investigator: Dr. Peter Britton **VAMC:** Finger Lakes Healthcare System

Consent Version Date: (3/13/2020)

Dr. Crasta is involved as an investigator in this research study. As both a postdoctoral psychology fellow and a research investigator, he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

KEY INFORMATION

What key information do you need to know?

- This study investigates a new 3-session relationship program, which will require you and your partner agreeing to participate together.
- Before and after the program, partners will complete separate assessments which offer up to $100 compensation for each partner ($200 per couple), in addition to the $15 for each partner already earned for completing the initial screening. *You may not be eligible to participate in all aspects of the study*, but you will be compensated for the parts you have completed.
- Participation in this study is *completely voluntary*. You may withdraw consent and discontinue participation at any time. Declining will not affect your eligibility for services.
- Audio recordings will be made of sessions for training staff and improving the program.
- There are risks of participating in this study (e.g., sharing of information; emotional distress). There also measures we have taken to address those risks.
- As a new program, we cannot guarantee any benefits to your relationship or well-being.

PURPOSE OF THE STUDY

You are being asked to take part in a research study at the Canandaigua Veterans Affairs Medical Center (VAMC) or Rochester Community-based Outpatient Clinic (CBOC) because you are at least 18 years old, can understand English, and are in a committed relationship at least 6-months length. Additionally, you or your partner report mild relationship concerns or are a Veteran experiencing mood, stress, or behavioral concerns that are commonly asked about in primary care.

Our research team is conducting a preliminary study of a 3-session couples program that is meant to help Veterans and their partners begin to improve their relationships by sharing their concerns with one another and with a professional and then deciding on a plan of action. This trial will help us evaluate this program for Veterans and their families, gather feedback to continue improving this program, and help us determine whether we should conduct a larger study.

This study is sponsored by the Center of Excellence for Suicide Prevention.

DESCRIPTION OF THE PROCEDURES AND APPROXIMATE DURATION OF THE STUDY

If you and your partner agree to participate in this research study, you will be asked to participate in 4 additional meetings (3 in-person, 1 by phone) over the next 1-3 months. The in-person meetings will involve you and your partner attending *together* and can take place at the Canandaigua VAMC or the Rochester CBOC based on what is mutually convenient for both you and your partner. The follow-up phone interview will be scheduled separately with each partner.

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Approximately 40 subjects (20 couples) will participate in the larger trial. Your participation in this study will last 1-3 months. The activities below can be conducted in-person, by phone, or over VA Video Connect, an application that uses encryption to ensure a secure and private session between our study computers and nearly any device that has an internet connection and a web camera.

Here is what you can expect if you decide to participate in this study:

- An initial assessment (Baseline), which will take approximately 1-2 hours. You will be asked to fill out a few questionnaires and complete interviews on topics such as:
  - Relationship functioning
  - Depressed mood, suicide-related thoughts and behaviors
  - Traumatic experiences and their possible impact on you
  - Alcohol and drug use
- If both partners are found eligible during their Baseline Assessment, you and your partner will be asked to attend three sessions together across a 30-day time period. These sessions will cover relationship strengths, relationship concerns, and will help build a plan of action to address these concerns. These sessions will be audiotaped for supervision and to continue refining and improving this program.
- After completing the program, you will be asked to complete an additional Follow-Up Assessment including Questionnaires and Interview. This Interview can be completed in-person or by phone based on your preference and convenience and will help give feedback for improving the program.

Each *individual* participant will be compensated up to $100 for completing the assessment according to the following schedule:

Baseline Assessment	$50
Follow-up Assessment (post-treatment)	$50

In total, a couple can earn $200 in total compensation ($100/person) if both partners are eligible for and participate in the entire study. But your compensation at each stage will simply depend on your participation in each assessment. This would be in addition to the $15 payments each partner has already earned for participating in the eligibility screen prior to the baseline.

Compensation will be in the form of electronic funds transfer (EFT) or a Direct Express prepaid debit card. If you are not currently enrolled in EFT or the Direct Express debit card, research staff can help provide the information for enrollment in EFT or the Direct express card along with the appropriate forms to you (either directly or by mailing them to your address). If there are any issues with receipt of compensation, you may contact research staff at 585-393-7537 to work towards a resolution.

During the study, voice recordings will be obtained while you are (1) completing portions of the interview during the Baseline, (2) completing the 3 couples sessions, and (3) completing the Follow-Up Interview. This is for the following purpose(s): supervision and training of study staff; evaluation of the program; gathering feedback to improve the program.

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NOTE: The information requested in this consent form is solicited under the authority of title 38, United States Code. The execution of this information consent form does not authorize disclosure of the materials specified above except for the purpose(s) stated. The specified material may be used within the VA for authorized purposes, such as education of VA personnel or for VA research activities. It may also be disclosed outside the VA system as permitted by law. If the material is part of a VA system of records, it may be disclosed outside the VA as stated in the 'Routine Uses' in the "VA Privacy Act Systems of Records" published in the Federal Register. A copy of the 'Routine Uses' is available upon request to the administrative office of the VA facility involved. You do not have to consent to have your picture or voice taken, recorded, or used. Your refusal to grant your consent will have no effect on any VA benefits to which you may be entitled.

As a research participant, you will NOT be required to pay for the relationship program received in this research study. However, at the end of the program, you might discuss possible benefits of enrolling in VA treatment programs as part of your standard patient care. As these services are part of your standard clinical care available to you even if you were not a research subject, your insurance carrier may be responsible to pay for you and you may be responsible to make a co-payment for any such service depending on your VA patient category and means test. As part of discussing any services, we will explain any specific eligibility criteria including whether the service is available to non-Veteran family members of Veterans.

At any time, you can choose to discontinue the entire study, including any remaining sessions, or you can choose to discontinue the couples program but still continue to participate in the study assessments.

DESCRIPTION OF THE DISCOMFORTS, INCONVENIENCES, AND/OR RISKS

Most individuals will experience little, if any risks from their participation in this study. Responding to questions during interviews may cause distress. Examples of distress include anxiety symptoms (e.g., shortness of breath, fear) or feeling down. If you experience distress during the interview, please discuss this with your interviewer. You may decide to stop the interview or talk to the on-call clinician. The interviewer will discuss with you what to do if you experience distress after the interview, which will include calling the on-call clinician. You also may find that discussing your relationship with your partner becomes distressing or lead to arguments. If you experience distress during these sessions, please discuss this with the study staff member. They will help pause the conversation, stop the session, or talk to the on-call clinician. If needed, partners can do this in separate rooms. The interviewer will also discuss with you what to do if you experience distress or worsening conflict after the sessions, which will include on-call resources and hotlines you can use during off-hours.

One potential issue where confidentiality will be broken is if you report wanting to harm yourself, others, or child abuse. If this is disclosed to research staff, we would be mandated to report this information to the appropriate parties in order to protect the safety of yourself and/or other persons.

There may be other unforeseen risks.

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FOR STUDY PARTICIPANTS WHO ARE VETERANS:

As a Veteran subject you will not be required to pay for any treatment received as a research participant, which is being done solely for the purpose of this research study. However, your insurance carrier will be billed for all routine care and clinical procedures, if applicable. If you are in a "priority group # 6, 7 or 8 veteran category" you are subject to making a co-payment for all non-research related medical care as indicated by a means test. Your doctor should be able to provide you with this information or refer you to the appropriate individual for any questions you may have.

As a Veteran, you will receive medical care and treatment for injuries suffered as a result of participating in a VA research program in accordance with Federal Law*** (see below)**. You will incur no additional charges for additional medical care and treatment that may result from injury or complications that are a direct result of your participation in this study. Money has not been set aside for pain and suffering compensation.

In case there are any medical problems or questions, or in the event of illness or injury that you believe to be related to the study, you can also call Dr. Peter Britton at (585) 393-7926 during the day and the on-call psychiatrist at 585-263-2668 in Rochester or 585-393-7969 in Canandaigua after hours. In case of emotional crises, both Veterans and family members may use the National Veterans Crisis Line at 1-800-273-8255.

***Federal Law Advisory - VA Disability Compensation Benefits**: As a veteran-participant, you may be entitled to VA disability compensation benefits for "additional disability" incurred or aggravated as a direct result of your participation in this study (*see* 38 U.S.C. Sec. 1151; 38 C.F.R. Sec. 3.358). If you believe you have incurred additional disability as a result of your participation in this study, please contact your Veterans Service Officer for more information regarding your right to file for VA disability benefits.

FOR STUDY PARTICIPANTS WHO ARE NOT VETERANS:

Immediate necessary care will be provided by the Veterans Affairs Medical Center for injuries suffered as a result of participating in this research study. You or your insurance provider will be financially responsible for the costs of this immediate, necessary treatment. The VA will not provide additional medical care or be responsible for the costs of additional medical care beyond immediate necessary care. Further, VA will not be responsible for monetary compensation for such injury.

In case of emotional crisis, both Veterans and family members may use the National Veterans Crisis Line at 1-800-273-8255.

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ANTICIPATED BENEFITS RESULTING FROM STUDY PARTICIPATION

If you agree to take part in this study, there may or may not be direct medical benefit to you in terms of your relationship or any other mental health conditions. Previous studies using this treatment in families without Veteran partners have demonstrated that the risks associated with this program are minimal and that there are potential benefits to relationship quality and mood, but we cannot guarantee any direct benefit for you or your relationship.

Taking part in this study may not personally help you, but your participation may lead to knowledge that will help others. Without conducting research studies such as this one, we cannot identify which treatments can improve the relationship quality and mood of Veterans and their families.

If you are interested in learning more about clinical studies for a wide range of diseases and conditions, you may visit www.clinicaltrials.gov

ALTERNATIVE PROCEDURES/OTHER TREATMENT AVAILABLE

You are not required to take part in this research study. Your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services/other rights. This will not interfere with your regular medical treatment and will incur no penalty or loss of benefits which you are otherwise entitled to as a patient.

Since this study investigates a couples treatment program, if either partner refuses to participate in the study during this baseline, both partners will be discontinued from the study. After beginning the treatment, if either partner chooses to discontinue the treatment, we will discontinue the treatment for both partners. However, either or both partners may still continue to participate in the assessment portion of the study if they wish.

FOR VETERANS: If you choose not to participate in this study, there are some alternative treatments available to you or your partner through VA. Treatment options for Veterans may include: assessments and evaluations, counseling, medication, or referral to specialty care in behavioral health. To learn more about treatment options, speak to your primary care provider.
FOR NON-VETERAN PARTNERS: If you choose not to participate in this study, VA has begun offering limited services for Veterans' family members. You may be able to participate in your Veteran partner's (e.g., couples therapy; family support of Veteran) or may receive limited services from the VA based on specific eligibility criteria. To learn more, you may visit https://www.oefoif.va.gov/familysupport.asp

Since this study involves asking you further information about your mood and issues pertaining to your safety, we want you to know that at any time if we are concerned about your safety, we will discuss it with you, if possible, or seek help from your primary care provider or other emergency services. At the discretion of the primary investigator, participants may be taken out of this study due to unanticipated circumstances, such as extreme distress or severe relationship conflict. In other words, we may withdraw you from the study, should we judge your participation not to be in your best interest.

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CONFIDENTIALITY AND PRIVACY

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Information published or presented about the results of this study will be in a form that does not identify any particular participant. In order to monitor compliance with federal regulations and for purposes of monitoring the accuracy and completeness of the research data, records identifying you may be inspected by representatives of the sponsor or sponsors of this study, the Syracuse VA Medical Center Institutional Review Board (Syracuse IRB), Internal Compliance Auditors, the Office of Human Research Protections (OHRP), VA Office of Research Oversight (ORO), Veterans Affairs contracted agency for accrediting VA Human Research Protection Programs and the Department of Health and Human Services (DHHS). The results of this study may be published but your identity and records will not be revealed unless required by law.

As a couples treatment, we will discuss individual responses to homework assignment questionnaires during joint treatment sessions. Packets intended to be discussed during the joint sessions will be clearly labelled. As with all questionnaires in this study, you may skip any questions you do not want to answer.

The results of this study may be published but your identity and records will not be revealed unless required by law. The only place we will store your name is on the consent form, locator form, and master tracking log. All data will be assigned an identification number and stored in locked file cabinets in secure research offices, to which only IRB-approved research staff will have access. Digital files such as audio-recording or questionnaire data will be stored on secure VA servers. Research personnel are carefully trained to maintain the confidentiality of the information collected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

What will happen to your information (data) at the end of the study?

At the end of the study your VA information will be retained in your research record in accordance with Veterans Health Administration (VHA) and Federal Records Control Schedule policies.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

How will your information be used in the future?

Your information could be used for future studies or by another investigator for future research studies without your or your legally authorized representative's consent. Should this happen, information that could identify you will be removed.

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RESEARCH RESULTS

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study.

CONTACT INFORMATION

If you have questions about this study or to report a research-related injury, you can contact: Dr. Peter Britton at 585-393-7926. If you have general questions about giving consent or your rights as a participant in this study or you would like to speak with an individual who is unaffiliated to this specific research study to discuss problems, concerns, and questions; obtain information or offer input you may call the Chairman of the Syracuse VAMC Institutional Review Board or the Human Research Protection Program Administrator, at (315) 425-4400 x 53607or the Syracuse VA Patient Advocate at (315) 425-4345 You can also contact your local Patient Advocate: Amy Enderle at (585) 463-2653 in Rochester or Kerry Hall at (585) 393-7612 in Canandaigua.

STATEMENT OF PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY

I have read (___) this consent form or have had it read to me (___). (Check one).

Research staff have explained the study to me and all of my questions have been answered. 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 told my rights as a research subject, and I voluntarily consent to participate in this study. I have been told what the study is about and how and why it is being done. All my questions have been answered. If I do not take part in this study, my refusal to participate will involve no penalty or loss of rights to which I am entitled.

I agree to authorize voice recordings to be made of my Baseline interviews, my Couples Sessions, and my Follow-up Interview while I am participating in this research study. I authorize the disclosure of these voice recordings to all parties mentioned in the HIPAA release. I understand that said voice recordings are intended for the purpose of supervision/training of study staff and evaluation/improvement of the program for the duration of this study.

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I have been told that I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. **I may withdraw consent and discontinue participation at any time, without prejudice to my care, by informing Dr. Britton of my decision to withdraw**. I also have been told that my participation also may be stopped by the study sponsor, study doctor, FDA, OHRP, ORO, or the Syracuse IRB, *without my consent*.

If any important information is found during this study that may affect your wanting to continue your participation in this study, you will be told about it right away.

You will receive a copy of this consent form and the original will be placed in the investigator's research files. Additional copies will be filed in your medical chart and in the Syracuse VAMC's RCO Office.

NOTE: CONSENT FORM SHOULD NOT BE SIGNED IF THE APPROVAL STAMP IS MISSING.

SUBJECT'S STATEMENT: I, the undersigned, hereby agree to participate as a subject in this research study.

	___ - ___ - ___		
Subject's Signature	**Subject's Social Security Number**		
Subject's Name (Printed)	**Telephone Number**	**Date**	**Time**