PRINCIPAL INVESTIGATOR: Dawn M. Johnson, Ph.D.

Treatment of PTSD in Residents of Battered Women's Shelters

You are being asked to take part in this study because you are a resident of a battered women's shelter seeking counseling for the traumatic effects of the abuse you experienced. If you decide to join this study, you will be taking part in a clinical research trial funded by the National Institute of Mental Health.

WHY IS THIS STUDY BEING DONE? The purpose of this study is to evaluate a new counseling program called HOPE that aims to help you with some of the emotional difficulties you may have from being in a relationship with an abusive partner. In this study, HOPE will be compared to traditional counseling. You will not know which form of counseling you will be receiving; both forms of counseling will be referred to as HOPE.

The researcher will give you a verbal and written explanation of the purpose of the study, what participation means for you, and the potential benefits and possible risks of participation. You may ask her any questions you have to help you understand the study. A basic explanation of the project is written below. Please read this entire consent form, discuss any questions you might have with the researcher, and take your time to making your decision to participate in the study. We encourage you to talk to shelter staff, your family, and/or your friends before you decide.

YOU MAY PARTICIPATE IN THIS STUDY IF YOU:

(1) have experienced abuse from an intimate or romantic partner in the month before you came to the shelter; and
(2) are currently experiencing emotional difficulties typically associated with abuse (for example, symptoms of posttraumatic stress)

YOU CANNOT PARTICIPATE IN THIS RESEARCH STUDY IF YOU:

(1) are currently receiving any other mental health treatment besides medication management;
(2) have Bipolar Disorder or symptoms of psychosis;
(3) have recent alcohol or drug dependence; or
(4) are actively suicidal

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY? A total of 194 women will be invited to participate in this project. All participants will receive treatment, with half of participants receiving HOPE and half receiving traditional counseling. Which type of counseling you receive will be determined by chance (i.e., like flipping a coin). As stated above, you will not know which form of counseling you will be receiving.

WHAT IS INVOLVED IN THE STUDY? If you wish to participate in the study you will be asked to sign this consent form. If it is determined that you are not a good candidate for the program, we will provide referrals for alternative treatment. Additionally, if at any time during this study it is discovered that you did not meet these conditions, you will be given an appropriate referral and will no longer be able to take part in the counseling program. At the end of today's assessment (or shortly after) we should know if you meet criteria for our program. The next step would be for you to meet with a counselor.

The interview to determine eligibility will take place at the shelter and will involve an interview and responding to some questionnaires on a computer about the relationship that brought you into the shelter, emotional difficulties you may be experiencing, stressful events that you may have experienced and how they affected you, and other treatment and services you have received. This session will take approximately3-4 hours. You will also be asked to collect saliva samples during the first two mornings after this interview. These saliva samples will allow us to measure the levels of the hormone cortisol in your body, one of the primary stress hormones. These samples will not be used for any other testing (such as drug or alcohol). We will ask you to provide us with 4 samples over a 1 hour period, as well as answer some questions about foods and medications you may be using that may impact cortisol levels, as well as questions about the times you took the samples. We will ask you to repeat this procedure on the very next morning. We will again ask you to collect saliva 1-week and 1-year after you complete treatment. Research staff will provide you detailed instruction on how to take the samples and answer any questions you may have. You have the right to refuse collection of these saliva samples. We will offer to call or text you on the mornings you are taking the saliva samples as a reminder. You have the

right to refuse such calls or texts.

There are essentially two parts to this study: the HOPE or traditional counseling sessions and the assessments of the effectiveness of the programs. If you participate in the study, study personnel will set you up with a study therapist and schedule you for your first therapy session. Which counseling program you receive will be randomly determined (like flipping a coin). You will not know which program you are receiving. If at any time you choose to drop counseling or do not attend all your counseling sessions, you may still participate in the assessment part of the study.

HOPE or traditional counseling sessions. You will participate in a maximum of 16 individual counseling sessions. The first set of sessions (up to 10) will take place while you are at the shelter. All sessions will be free of charge and childcare will be provided if needed. It is expected that you will attend one to two 1-hour sessions each week until you finish the 10 shelter-based counseling sessions or leave the shelter. You will not receive any money for attending these therapy sessions. Counseling will also continue during the first 3 months after you leave the shelter. These sessions will occur one to two times per week at a safe, convenient and confidential location determined by you and your counselor. Additionally, you will be reimbursed $10 for each session you attend after leaving shelter to cover your transportation costs. **For quality assurance purposes, all counseling sessions will be audio recorded. You have the right to refuse to have your session recorded. In order to best assess the impact of HOPE, it is important that you do not share any information you may learn in counseling (e.g., handouts from your counseling workbook) with other women in the shelter. Thus, we ask you to not discuss the details of your treatment with other women in the shelter.**

Assessment of counseling program. You will either be interviewed or complete a questionnaire at a variety of time points both during your shelter stay and after you leave the shelter. Interviews after you leave the shelter will take place at a safe, convenient and confidential location agreed upon by you and research staff. You will be reimbursed for each interview Again, for quality assurance purposes, all interviews will be audio recorded. You have the right to refuse to be recorded. **To make sure we are as objective as possible, we ask that you do not talk to the staff member completing any of your follow-up assessments about your counseling program (including providing the name of your therapist). If you need to discuss something relating to your counseling program, please call Dr. Johnson at 330-972-6821.** A summary of all the assessment time points, the time-commitment, and the reimbursement schedule is below. Please note that you can do each assessment even if you decide not to continue with counseling. We still want to know how you are doing

	Assessment	Time Commitment	Reimbursement
During Shelter Stay			
Time 1	Initial evaluation at shelter	3-4 hours	$40
	Saliva Samples & Questionnaires	1 hour for 2 mornings	$10/each ($20 for both)
Time 2	Mid-shelter treatment period - Questionnaires	15 minutes	$20
Time 3	1-week after shelter treatment – Questionnaires	15 minutes	$20
As needed	If remain in shelter – Questionnaires every 5 weeks after completion of shelter treatment	15 minutes	$20
After Leaving Shelter			
Time 1	1-week after leaving the shelter - Interview, Questionnaires	1-2 hours	$50
Time 2	Mid post-shelter treatment period - Questionnaires	15 minutes	$20
Time 3	1-week after entire treatment period (approximately 3 months after leaving shelter) Interview, Questionnaires	2-3 hours	$50
	Saliva Samples & Questionnaires	1 hour for 2 mornings	$10/each ($20 for both)
Time 4	3 months after entire treatment period (approximately 6 months after leaving shelter) - Questionnaires	15 minutes	$20

Time 5	6 months after entire treatment period (approximately 9 months after leaving shelter) - Interview, Questionnaires	1-2 hours	$50
Time 6	9 months after entire treatment period (approximately 1 year after leaving shelter) Questionnaires	15 minutes	$20
Time 7	1 year after entire treatment period (approximately 1 year and 3 months after leaving shelter) Interview, Questionnaires	2-3 hours	$50
	Saliva Samples & Questionnaires	1 hour for 2 mornings	$10/each ($20 for both)
Bonus	If complete all available assessments	n/a	$25
Bonus	If complete 75% of all available assessments	n/a	Enter in raffle to win 1 of 2 $250 Wal-Mart gift cards

In order to contact you after you leave the shelter, we will ask your permission to contact people close to you or agencies you may work with to find out where you are. You do not have to give any contact information you do not want to give. Your written consent will be obtained to contact anyone about your location after you leave the shelter. We will also contact you in between appointments to see how you are doing and to update your contact information. You have the right to request that we do not contact you.

HOW LONG WILL I BE IN THE STUDY? This research study will continue approximately 1 year and 3 months after you leave the shelter.

Participation in this study is voluntary and you may stop participation at any time. Participation in this project or your decision not to participate will in no way affect any of the current or future services you may receive from any battered women's shelter. You may stop participation in this research study at any time, without penalty or loss of benefits. If you do decide to stop participating in this research study, we encourage you to discuss your decision with shelter staff, your therapist, or any other mental health providers you may have.

You may be discontinued from the counseling provided by this study if at any time it is determined that you no longer meet research study criteria or require more treatment than can be provided by the study (if you become suicidal or if your symptoms become significantly worse). If this were to happen, an appropriate referral for psychiatric treatment will be provided for you. If you are discontinued from your counseling program, you will still be invited to participate in all of the follow-up assessments described previously.

WHAT ARE THE RISKS OF THE STUDY? There may be risks associated with participation in this study. If your abuser finds out that you are participating in this study, it may put you at increased risk for future abuse. Therefore, we will continue to evaluate your safety needs and negotiate the safest methods for contacting you during your participation in this study. We will also provide information on safety planning during each contact with you. It is also possible that the questionnaires and interviews that contain items of a personal nature will cause you some discomfort. You always have the option of choosing not to answer any questions that you do not want to answer. All interviews will be administered by research assistants trained to deal sensitively with these issues. You may also experience some discomfort from being audio recorded during your interviews. You have the right to refuse to be recorded at any time. You also have the right to ask that any recordings be deleted or erased immediately or at any time during or after the study.

There are some risks that may be associated with the counseling program. One expects that the counseling will address sensitive personal issues. Sometimes counseling may stir up emotions or cause more distress in the short term. In more extreme cases, thoughts or urges to harm yourself, an increase in emotional problems, or a relapse of alcohol or drug problems may result. If you should have these feelings it would be important to discuss them with shelter staff or your counselor so we can make sure to provide you with appropriate treatment. Additional risks may also be associated with the counseling program. The counseling program is brief (16 sessions). You may find it difficult to stop counseling at the end of the program. Your therapist is trained to deal with these issues and will help you with whatever difficulties you are having at the end of the program.

It is always possible that you will experience further abuse from your partner or other new traumatic events during your participation in this study. If you do, please tell research staff so that they can provide you with appropriate referrals. **There may also be risks in your taking part in this research study that we do not know about.** You will be told about any new risks that are identified as part of this study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY? We cannot promise or guarantee any particular benefit from participating in this study. We hope the information learned from this research study will further our understanding of the mental health needs of women who have been abused and how we can help them. One benefit you may have from the counseling program is learning more effective ways to lessen distress and cope with your current emotional difficulties.

WHAT OTHER OPTIONS ARE THERE? Currently there are other counseling programs for the emotional effects of trauma, however to date, no standard counseling program exists for battered women in shelters. Counseling may or may not be offered through the shelter at which you are staying, but counseling is always available to you through traditional community resources. Research staff can provide you with a referral for alternative treatment if you choose.

WHAT ABOUT CONFIDENTIALITY? Your research and counseling records will be kept in strictest confidence as required by law. Confidentiality will be maintained during and after your participation in the study. You will be assigned a code number and all your data will be analyzed by this code number only. All reports related to this study will not contain any specific or individual answers, only the total as a group. Records of your therapy progress while in this study will be kept on a confidential form in locked files in the office of your therapist. These files are only accessible to research staff directly involved with this study. All records in which your name appears will be kept confidential. The results of this study may be presented at meetings or in publications; however, no information by which you can be identified will be released or published.

Research staff will not discuss any information you provide in interviews or counseling sessions with shelter staff without your written permission. In order to contact you for interviews after you leave the shelter, research staff will request contact information for you and people who will always know how to contact you. You do not have to provide information that you do not want to give. Your written consent will be obtained to discuss your contact information with anyone other than yourself. All contact information you provide will be held in the strictest confidence.

Audio recordings of counseling sessions and interviews will also be kept confidential. Recording labels will not include your name and will be stored on password protected computers only accessible to research staff directly involved in this research project. All audio recordings will be erased or deleted after all the data for this research study has been analyzed.

We will do everything we can to keep others from learning about your participation in this research study. To 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 personnel of the United States Government that is used for auditing or evaluation of federally funded projects. 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 does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project to prevent serious harm to yourself or others. If you tell a research team member or therapist or it is determined that you are in danger of hurting yourself or others, research staff will contact the appropriate persons or authorities necessary to protect the safety of yourself or others. **Additionally, if you provide information to a member of the research team or therapist that gives them reason to believe that you or someone else has committed child abuse or neglect or elder abuse or neglect, they will contact the appropriate agencies necessary to protect others from harm. This includes both your participation in and knowledge about current or past abuse or neglect to any child or elder person.**

WHAT ARE THE COSTS? There is no direct cost associated with participation in this research study. However, if you are referred for additional or alternative treatment you or your insurance company will be charged for this treatment. You will be reimbursed for your time for all interviews in which you participate as explained above. No additional reimbursements are available other than those described within this document.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS? You have the right to ask any questions concerning the potential and/or known risks of this study at any time. You will be informed of any significant new information pertaining to your

safety. If you have any questions concerning this research study please contact Dr. Dawn M. Johnson, Ph.D. Principal Investigator, at (330) 972-6821. This project has been reviewed and approved by The University of Akron Institutional Review Board (which is a group of people who review the research to protect your rights). If you have any questions about your rights as a research participant, you may call the IRB at (330) 972-7666. If at any time you are in crisis while a resident of the shelter, please use the standard services available through the shelter for emergencies.

WHAT ARE MY RIGHTS AS A PARTICIPANT? Taking part in this study is voluntary. You may also leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

WHAT ARE MY RESPONSIBILITIES AS A PARTICIPANT? You will be expected to keep all scheduled visits required for the counseling program and follow-up appointments and follow all research procedures. In addition, if your contact information would change, please inform the research staff.

SIGNATURE LINES

By signing this consent form, I am stating that I have been informed about the study, all my questions have been answered, and I willingly give consent to participate. A copy of this signed consent form will be provided to me for my records.

Date	Participant Name (printed)	Participant Signature
Date	Witness Name (printed)	Witness Signature

I also give permission to have my counseling sessions and/or interviews audio recorded.

Date	Participant Signature

APPROVED
IRB
Date 5/6/15
The University of Akron