Informed Consent Form

Study Title: The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

NCT Number: NCT02736929

Document Date: 1/4/2021

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

CONCISE SUMMARY

The purpose of this study is to learn more about how reducing posttraumatic stress disorder (PTSD) symptoms affect cardiovascular systems that regulate heart and blood pressure. Study participation will last anywhere from eight to 20 weeks. The study requires two to three laboratory visits during which we will draw your blood, monitor your blood pressure, and take ultrasound pictures of the arteries in your arm. The study requires home monitoring of blood pressure and activity, and collection of urine for 24 hours. The study may also require 12 sessions of counseling for PTSD.

If you receive counseling for PTSD, you may benefit by experiencing a decrease in symptoms. This benefit is not guaranteed to you. Risks of participating in the study include fainting or bruising from the blood draw, a temporary increase in anxiety or PTSD symptoms related to participation in counseling, and a risk of loss of confidentiality.

You are being asked to take part in this research study because you may have posttraumatic stress disorder, or PTSD. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. Feel free to ask any questions as study staff discusses this consent form with you. We also encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Watkins' and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Beckham will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
Some individuals who are exposed to traumatic events experience both psychological and cardiovascular changes that affect their health and well-being. The purpose of this study is to learn more about how reducing the psychological symptoms (such as those that occur with PTSD) affect cardiovascular systems that regulate your heart and blood pressure.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 215 people will take part in this study at Duke.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

WHAT IS INVOLVED IN THE STUDY?

The study involves several laboratory visits and several days of at-home monitoring. It requires that you are willing to participate in treatment for PTSD. There is also an optional procedure involving genetic testing.

If you agree to be in this study, you will be asked to sign and date this consent form.

Screening Session: We will ask you to do the following to make sure that you are eligible:

- be interviewed about your current mental health; and
- provide a urine sample so that we can test for substances such as cocaine, heroin, and amphetamines. If you are a woman of child-bearing age and/or potential, we will also use this urine to perform a pregnancy test.

We will also ask you to fill out some questionnaires that will include questions about your age, work status, financial status, exposure to traumatic events, mood, medical history, health habits, sleep, interpersonal relationships, and current psychological symptoms you may be experiencing. We will ask you to provide contact information for yourself, including the names and telephone numbers of family members, friends, etc. who would be able to help us get in contact with you.

If you are eligible to participate in the study, the study coordinator will ask you some questions about your recent health and take your temperature. If you have been sick recently, or if your temperature is not within the normal range, the study coordinator will ask you to wait to schedule Assessment 1 (see below) until it's back to normal.

We will send you home with some additional questionnaires to complete at your convenience. You will be asked to return these on your next visit. If you would prefer to complete these questionnaires in the office instead of at home, you will be allowed to do so. We will also send you home with a small cooler bag and a set of bottles. You will be asked to keep all of your urine for 24 hours in these bottles and cooler. This will need to be done on two to three separate occasions as described below. Each time, you will return the urine to your study coordinator at your next visit. We will use the urine samples to run laboratory tests related to the study.

It is important that you collect urine for the full specified time. If you do not collect every urine sample, you may not receive compensation for that portion of the study.

Altogether, this visit will take about 5 ½ hours to complete. We will pay you $85 for completing this session.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

Assessment 1: You will be asked to come to Duke with your cooler and collected urine between 8 am and 11 am after fasting overnight (not eating anything, starting at 12:00 AM). At Duke, we will ask you to do the following:

- Complete some questionnaires about your PTSD symptoms and sound sensitivity.
- Have your temperature taken. If your temperature is not within the normal range, the study coordinator will ask you to reschedule this first assessment.
- Have your blood pressure taken several times first using an arm blood pressure cuff and then using a finger blood pressure cuff. While wearing the finger blood pressure, you will be asked to lie quietly for 10 minutes and then to stand for 5 minutes. You will also be asked to do a one minute breathing exercise during this time.
- A trained technician will draw 18 ml (about 1 ½ tablespoons) of blood. After this blood draw, we will check your weight and offer you a light breakfast. You will then be asked to fill out some questionnaires about your exercise and about hassles in your life. Then, in a different room, we will ask you to lie quietly again while we take an ultrasound picture of the artery in your arm. This test will allow us to measure the function of your blood vessels. We will also take pictures after a cuff has been inflated on your arm for 5 minutes.

It is very important that you fast before attending this appointment. If you report that you have not fasted, the study coordinator may not allow you to participate in the assessment. You will be paid $100 for completing Assessment 1.

In this session, the study coordinator will provide you with a hospital gown, and you will be asked to disrobe from the waist up and wear the hospital gown. The study coordinator will measure your hips and waist while you are wearing this monitor. Then, he/she will hook you up to a Holter monitor, which is a device about the size of a credit card that records the electrical activity of your heart through electrodes (small sticky discs) placed on your chest. You may be asked to allow the study staff to shave hair from a small portion of your chest in order for the electrodes to work. You will be asked to wear this monitor for one full day and one full night (about 36 hours). We also will ask that you refrain from drinking alcohol while wearing the Holter monitor. You will be provided with a pouch for the Holter recorder that you may wear on a shoulder strap or on a belt.

At the end of the recording period, you will take the Holter monitor off. You will return the equipmentto the study coordinator via FedEx. We will provide you with a pre-paid FedEx mailer for their return. If you choose to have FedEx pick up the equipment directly from your home, FedEx will be provided your name and address. No health information about you will be given to FedEx.

You will be paid an additional $100 for completing the urine collection after the screening session and wearing the Holter monitor. It is very important that you wear the Holter monitor during the entire 36 hour period. If you remove the Holter monitor, you will not be paid for that portion of the study.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

Counseling Sessions: You will then be assigned to one of two groups using a process like drawing numbers from a hat. You will have a 2 out of 3 chance (about 66% chance) of being assigned to the first group and a 1 out of 3 chance (about 33% chance) of being assigned to the second group. If you are assigned to the first group, you will receive twelve sessions of a treatment for PTSD called Cognitive Processing Therapy (CPT). CPT involves changing learned ways of thinking that may interfere with psychological recovery in individuals exposed to trauma. If you're assigned to this "active treatment group," you will receive about one hour of counseling with a therapist twice weekly. Your counseling sessions will be videotaped so that a trained supervisor can make sure that the therapy is being done correctly. During these sessions, you will be asked to complete questionnaires related to your psychological symptoms and mood. You will complete additional questionnaires at the first and last sessions of CPT. You will be paid $45 if you complete all of the questionnaires at each time point.

If you are assigned to the second group, which we call the "waitlist group," you will receive weekly telephone calls for six weeks to assess how you're doing psychologically. The counselor who calls you may provide supportive, brief counseling if needed. After you finished the six weeks of being in the "waitlist group", you will be given a chance to participate in CPT as part of the "active treatment group". If you're assigned to this group, the study coordinator will contact you **six times (once every week)** to ask you some questions about your PTSD symptoms while you are in the "active treatment group" or in the "waitlist group". You will be paid $45 if you participate in all six calls.

Assessment 2: After you have completed your counseling sessions **or** the six week waiting period, we will ask you to repeat the temperature measurement, urine collection, blood pressure measurements, blood draw, and arm ultrasound imaging that you did for Assessment 1. We will once again ask you to collect your urine for 24 hours before coming in for this visit. You will be asked to fast overnight and to come in between 8 am and 11 am with your urine samples. It is very important that you fast before attending this appointment. If you report that you have not fasted, the study coordinator may not allow you to participate in the assessment. We will hook you up to the Holter monitor again after the lab visit, and you will be asked to wear the monitor for one full day and one full night (about 36 hours), just as you did before. You will be asked to remove the monitor yourself and return it to Duke using a pre-paid Federal Express mailer that we provide to you. You will be paid $130 for completing the blood pressure measurements, blood draw, and arm ultrasound imaging, and you will be paid $200 for the urine collection and for wearing the monitor. You will not be paid for these tasks until the urine, and monitor is returned to us. It is important that you wear the heart rate monitor and collect urine for the full specified time. If you take off the heart rate monitor early or if you do not collect every urine sample, you will not receive compensation.

If you were assigned to the active treatment group, your study participation will be complete after you return the study equipment. If you were assigned to the waitlist group, you will be given the opportunity to receive CPT for 12 sessions and participate in the study assessments. You are not required to participate in this therapy or the study assessments; it is completely voluntary. If you do decide to

participate in the CPT part of the study after being in the waitlist group for 6-weeks, you will be compensated for completing assessments after the CPT ends ($130 for the blood pressure measurements, blood draw and arm ultrasound imaging, $200 for completing the urine collection and wearing/returning the monitor, and $45 for completing all three telephone interviews during CPT).

If you are a Duke patient, Dr. Watkins and/or her study team may review your medical records at Duke to become informed about your medical history.

While you're in the study, you may find that you'd like to refer another person to participate. In order to encourage you to refer other people to the study, we'll give you six referral coupons that are marked with an identification number that is unique to you. You can give these referral coupons to any person you think might be interested in the study. If that person comes in for a screening visit and brings us his/her coupon, we'll offer you a $20 payment for taking the time to make the referral. Please note that we won't be able to tell you whether or not a specific person uses your coupon. We ask that you not discuss with others whether you think/believe a person you have referred may be participating in the study. You can choose not to distribute the coupons we give you, and you can refuse to even receive the coupons.

Optional Study Procedures:

Option 1:

We are asking you to participate in genetic testing as part of this study. If you agree to participate in this portion of the study, during your blood draw at the screening session and after treatment (or your waiting period), we will draw an additional 16 ½ ml (about 1 tablespoon) of blood each time. We will use your blood to run genetic analyses. Your genes are made up of DNA. DNA is short for deoxyribonucleic acid. DNA contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child. RNA is made from DNA. RNA is short for ribonucleic acid. RNA is a genetic material that has a major role in making proteins. Proteins are the building blocks of your body, cells, and organs.

We will store your blood at the Durham VA Medical Center. We will protect your privacy and confidential information by labeling your samples and genetic information only with a code number. Your blood will be combined with other information from this study, including your PTSD diagnosis before and after treatment. It will be combined with other genetics studies being run at the Durham VA Medical Center and Duke University's Molecular Physiology Institute (DMPI). We will use your blood to run genome-wide association studies (GWAS). GWAS look at the genetic differences between individuals that may be found in the human genome (the complete set of all human genes) to find out if there is a relationship between certain traits (such as blood pressure) and the presence or absence of a disease or condition. We will also be testing for cortisol, other steroids and possibly proteins and small molecules that may be linked to PTSD and/or how you respond to treatment.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

The genetic studies described are for research purposes only. Therefore, you will receive no results from this study. It is not the purpose of this study to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. The research tests are not being used as diagnostic tests for any disease or illness. Your participation in this study is not a substitute for your regular medical care or check-ups.

Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information; this risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family. You should discuss your participation in this study with your family and ask the study doctor about any questions or concerns you may have.

I would like to participate in the optional genetics testing portion of this study. I agree to my blood being stored at the Durham VA Medical Center and to it being combined with other studies at the Durham VA Medical Center and DMPI.

☐ Yes ☐ No Initials: _____

Option 2:

We would like to maintain your blood samples indefinitely. By agreeing to participate in this portion of the research, you authorize DUHS and members of its staff to use your blood for the purposes described in this consent form. DUHS will maintain these samples indefinitely or until they are exhausted. Your blood or tissue samples may be used to generate cell lines that can be cultured and used for a longer period of time than the original samples. These cell lines will only be used as described in this consent form and will be destroyed once the research has been completed. These samples will not be available to you for diagnostic or therapeutic purposes. Therefore, for any future diagnostic testing or treatments, a new sample will be obtained from you.

Blood collected as part of this study may be valuable for scientific, research, or teaching purposes or for the development of a new medical or commercial product. DUHS and/or the developers will assert all rights of ownership in the samples and all rights arising from use of the samples. There is no plan to compensate you for any use of the samples.

With your permission, your blood samples may be shared anonymously with other investigators for research purposes. The samples may be used for study of disorders unrelated to PTSD. Such research will be strictly anonymous, in that no identifying information that would link the samples to you is provided to the researcher. An ethics board will review any such research prior to access being given to your samples. This secondary use will in no way compromise the use of your samples

as part of this study. Your samples and genetic information may be used for research for many years in the future.

We will protect your privacy and confidential information by labeling your samples and genetic information only with a code number. Researchers outside of Duke University will not be given a link between the code number and your name or any other identifying information. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.

I agree to long-term storage of my blood and the DNA coming from it. I allow the study staff to share my blood samples with other investigators outside Duke University for research purposes as described above.

☐ Yes ☐ No Initials: _____

HOW LONG WILL I BE IN THIS STUDY?

If you are in the active treatment group and you attend your therapy sessions as recommended (that is, twice per week), your participation in this study will last about eight weeks. If you attend your therapy sessions less often (for example, once per week) your participation will last about 3 ½ months. If you are in the waitlist group, your participation will last anywhere from eight weeks to 20 weeks, depending on whether or not you wish to participate in the CPT treatment group after Assessment 2. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Clinically relevant results of this research will be communicated with you and/or your primary care provider if your Holter monitor readings identify an abnormal heart rhythm.

WHAT ARE THE RISKS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Risks of Drawing Blood: Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Risks of Completing Paper and Pencil Measures, Interview, and PTSD Treatment: There are no known psychological hazards or risks associated with completing paper and pencil measures. There is a possible risk of temporary anxiety associated with discussing past traumatic experiences or symptoms that are stress-related for you. There is possible risk of an increase in anxiety or in symptoms related to stress that are associated with discussing stressful or traumatic events and symptoms related to these events. There is the potential risk of loss of confidentiality. Every effort will be made to keep your

information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Risks of Other Procedures: When we take pictures of your blood vessels, since the blood pressure cuff will be inflated for 5 minutes, your arm may feel uncomfortable and may tingle or feel "asleep."

The Holter monitor is not painful to wear. However, if shaving of your chest is required, there is a small risk of minor cuts. Removing the electrodes (small discs) may sting slightly, similar to removing a Band-Aid. You may experience skin irritation at the sites where electrodes are placed.

Risks Related to Genetics Testing: It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at DUHS, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Other Risks:
There is a potential risk of loss of confidentiality. If you are in the active treatment group, your therapy sessions will be videotaped. We will use a Duke-owned, password-protected and encrypted iPhone or iPad to record the sessions. After recording, the sessions will be loaded from the iPhone or iPad to a

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

Duke computer using a direct connection. These recordings will later be moved to Box@Duke, a cloud storage area to which only our study staff members have access. From there, they will be reviewed by one of our staff members. After they are reviewed, they are deleted from Box@Duke. Every effort will be made to protect your confidential information but this cannot be guaranteed. Any device that is not in use will be stored in a locked filing cabinet in Dr. Watkins' office. If you express feelings about wanting to harm yourself or others, we will need to refer you for appropriate care.

If you are a female: Because pregnancy may impact measurement of cardiac risk factors, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a urine pregnancy test will be done, and it must be negative before you can continue in this study. If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

Drug and Food Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking/using before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions, or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct benefit to you. If you receive counseling for PTSD, you may experience a decrease in symptoms. However, this benefit is not guaranteed to you. We hope that in the future the information learned from this study will benefit other people who have PTSD.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
There may be other treatments for PTSD available to you in the community. Please talk to your doctor about these and perhaps other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum

necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the DUHS Institutional Review Board, National Institutes of Health, the Office for Human Research Protections, and/or the Food and Drug Administration. If any of these groups review your research record, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Your therapy sessions will be recorded and moved to Box@Duke, a cloud storage area with access limited to study team members. The recordings will be reviewed by a Duke staff member and/or a Duke-paid consultant. These video recordings will include protected health information, because your voice and face are recorded.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

All of the urine and blood laboratory tests are being done only because you are in this study. Your urine samples and a portion of your blood samples will be sent to Lab Corporation of America for analysis. Another portion of your blood samples will be sent to Duke Molecular Physiology Institute for genetic analysis. Your samples will be identified only by the unique code number described above. The study

results will not be given to you to send OR sent to your physician to include in your medical record. If your Holter monitor readings identify abnormal heart rhythms, the readings will be sent to the study cardiologist (heart doctor), who may review them. If we observe clinically significant arrhythmias (irregular heart beats), we will send these results to your primary care physician. At that time, your primary care physician will decide whether to further evaluate and/or treat you."

If you have an existing mental health provider, we will encourage you to inform your provider if you participate in CPT. There may be situations in which your study therapist believes it would be beneficial to talk to your existing mental health provider about your participation. If your study therapist wishes to contact your mental health provider, he/she will obtain your written permission to do this.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Watkins**.** At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

If you receive CPT, Duke University Medical Center will provide the treatment free of charge. The laboratory testing and monitoring will be provided to you free of charge. If you choose to withdraw from the study, Dr. Watkins may request that you return for a visit if she thinks that stopping may harm you. She may also ask you to complete the tests that would ordinarily occur when a person completes the study.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $660 for completing the assessments and at-home monitoring before and after participating in either the active CPT treatment group or after 6 weeks of participation in the waitlist control group**.** You can receive up to $120 for referring other participants to the study.

If you are assigned to the waitlist control group and choose to participate in the active CPT treatment group afterward, you will be reimbursed up to $1155because you are eligible to receive an additional $375 if you complete all assessments and at-home monitoring at the end of the CPT sessions.

You will be paid for partial participation, too and payment for each session is listed in the description of that session in this consent form. We will provide you with a bus pass or parking pass at each appointment.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to any individual exceeds $600 in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Watkins at 919-681-4087 during regular business hours. After hours and on weekends and holidays, you may contact Dr. Beckham by calling 919-286-0411 and ask the operator to contact Dr. Beckham at home.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Watkins in writing and let her know that you are withdrawing from the study. Her mailing address is Dr Lana Watkins, Ph.D., Dr. Lana Watkins, Dept. of Psychiatry and Behavioral Sciences, Box 3119, Duke University Medical Center, Durham, NC 27710. If you are doing home monitoring when you withdraw from the study, you will be asked to return the monitoring equipment.

If you participate in the genetics testing portion of the study, you will not have access to the sample once it is obtained. Samples may be stored indefinitely. If you decide to withdraw your permission to use your samples in this research project, please contact Dr. Watkins in writing and let her know you are withdrawing your permission for your samples to be stored and used for this or future research. Her mailing address is Dr. Lana Watkins, Dept. of Psychiatry and Behavioral Sciences, Box 3119, Duke University Medical Center, Durham, NC 27710. We ask you to indicate in writing if you want your unused samples destroyed or if your samples (with all identifying information removed that would link the sample to you) could be used in research. Data collected using your sample before your withdrawal will continue to be used as part of the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. Reasons why this might occur include failure to follow the instructions of the study staff, inability to complete the study requirements, or inability to attend study visits as scheduled. If this occurs, you will be notified and your study doctor will discuss other options with you.

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.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Watkins at 919-681-4087 during regular business hours. After hours and on weekends and holidays, you may contact Dr. Beckham by calling 919-286-0411 and ask the operator to contact Dr. Beckham at home.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Effect of Reducing Posttraumatic Stress Disorder Symptoms on Cardiovascular Risk

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time