**Clinical Trials.gov ID:**

NCT04605198

**Study title:**

Mindfulness-based Intervention to Address PTSD in Trauma-exposed, Homeless Women **Principal Investigator**:

Dana Rose Garfin

# INFORMED CONSENT

Updated: 1/15/2021

# UNIVERSITY OF CALIFORNIA, IRVINE
# CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Wellness-intervention to Address PTSD in Trauma-exposed, Homeless Women

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Nicholas Arce, BA
Elaine Tannouz, BA
Amada Laura Cipres, BA
Alexandra Amador
Krista Sadiwa Ruivivar

**STUDY LOCATION(S):**
HealthRight 360

Prototypes Women's Center 845 E Arrow Highway, Pomona, CA 91767
North County Serenity House 1341 N Escondido, CA 92026

**STUDY SPONSOR(S):**
National Institute of Health
Institute for Minority Health and Health Disparities

If you have urgent concerns, you may call our 24-hour number:
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**SUMMARY OF KEY INFORMATION:**

**The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.**

***Participation is Voluntary***
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

***Study Purpose***
The purpose of this study is to evaluate the benefit of a wellness-based intervention (Mindfulness-based Stress Reduction [MBSR]) to address posttraumatic stress disorder (PTSD) in trauma-exposed homeless women. The benefit of this intervention on your stress response, substance use, and depression will also be evaluated.

***Study Procedures***
In this study, you will provide information via a questionnaire that you will fill out on an iPad and participate in a brief stress task. Our research staff will be available to answer any questions you might have. You will then come to wellness classes (either MBSR or a Health Promotion course) once a week for 8 weeks, then repeat the measures you took before immediately after the last class and again 6 months after your first assessment.

***Expected Duration***
The assessments will take about one hour. The classes will be once a week for 8 weeks and are about 2 hours. There is one longer class that is 3-4 hours.

***Risks of Participation***
The more notable risks of participation include loss of confidentiality of your answers or things you talk about during the wellness classes. Meditation can be boring or distressing for some people sometimes. Some people do not like spitting in a container, which is part of the stress task.

***Benefits to Participants***
Taking part in this study may or may not make your health better. While researchers hope that mindfulness and other components of Mindfulness-based Stress Reduction (MBSR) will help people with PTSD, there is not proof of this yet.

If you are in the group that receives the MBSR and it proves to treat your PTSD, depression, substance use, and stress response, you may benefit from participating in the study, but this cannot be guaranteed. If you are in the group that receives the Health Promotion Wellness Classes, you may receive information and training that could improve a number of health outcomes (such as infectious disease, heart disease, and diabetes), but this cannot be guaranteed.

***Benefits to Others or Society***
This study will help researchers learn more about mindfulness-based interventions and the benefit they could have to reduce PTSD and other outcomes. It is hoped that this information will help in the treatment of future patients with PTSD and trauma exposure.

***Alternative Procedures or Treatments***
There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

**WHY IS THIS RESEARCH STUDY BEING DONE?**
The purpose of this research study is to see if a mindfulness-based intervention (a modified Mindfulness-based Stress Reduction [MBSR] course) can help women who have experienced trauma, PTSD, and homelessness improve their PTSD symptoms. We also want to find out if the MBSR program helps women with other problems such as physical health, depression, and substance use.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**
Approximately 450 participants will take part in the research, 225 from each of two residential drug treatment facilities in Southern California that are run by HealthRight 360: Prototypes, in Pomona, CA or Serenity House in Escondido, CA. HealthRIGHT 360 provides compassionate, integrated care that includes primary medical, mental health, substance use disorder treatment and re-entry services for individuals in California. HealthRight 360 operates several programs in Southern California that serve women suffering from substance use disorders and related problems. Two of these program locations will be participating in the present study: Prototypes (located in Pomona, CA) and North County Serenity Hours (located in Escondido, CA).

A total of 450 participants will be asked to participate across all study sites. There will be about 12-14 women in each group each time we run the programs; everyone at your residence will get the same program in the particular group that you are in (either MBSR or Health Promotion Classes).

**AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?**
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

***Inclusion Requirements***
You can participate in this study if you are female, have been homeless in the last 6 months, are over age 18, have experienced a trauma and have symptoms of PTSD

***Exclusion Requirements***
You cannot participate in this study if you don't speak English

**HOW LONG WILL THE STUDY GO ON?**
This study includes up to 12 sessions (three assessments and nine classes). The sessions are between 1-2 hours over a 6 month period. The classes will take place over 8 weeks, and one class will be a little longer (3-4 hours).

The researchers will want to assess you 6 months after your first session. Since you might not be living here anymore, we will do our best to keep in touch with you. If you living in prison or jail at that time, we will not conduct a 6 months follow-up session with you.

**WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?**
***Before you can participate in the main part of the study...***
You will need to have "screening" procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include filling out a short survey about your PTSD and trauma exposure and a measure of cognitive issues.

***During the main part of the study...***
If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include:

1. First session: fill out questionnaires about your physical and mental health as well as your life experiences. We will take a picture of you to help us locate you for a follow-up session, although you can still be in the study if you don't want us to take your picture. You will complete a urine test for drug use, and participate in a short stress task where we will collect your saliva before and after the stress task.

   Your saliva will be collected by the 'passive drool' collection technique. This technique is an accepted, non-invasive method and will require you to sit, lean forward, and allow saliva to pool at the bottom of your mouth. You will then use your tongue to slowly push the saliva into a straw-like collection tool that leads into a tube until you have collected roughly 1 teaspoon of saliva.

   In the stress task, you will be asked to describe a traumatic experience that you had in the past. You will do this in writing or aloud to one of the researchers. If you talk about it out loud, it will be recorded, and we will play it back to you via headphones. The recording will then be deleted.

2. Sessions 2-10: you will participate in one of two wellness classes that will meet 9 times over 8 weeks. You have been assigned to participate in the Health Promotion Wellness course.

   In the Health Promotion Wellness Classes, you will participate in nine sessions that will cover the following topics: Introduction, Envisioning Health through Art, Chronic Disease Prevention, Nutrition, Infectious Disease Prevention, Skin Care, Oral Health, Promoting Social Integration (including jobs as Community Health Workers). You will have activities that you will do on your own in between the classes.

**Randomization:** You will be assigned to a study group by chance (like a coin flip). This will depend on which site you are staying at (Prototypes in Pomona, CA or North County Serenity House in Escondido, CA). Everyone at the site will get the same program. The class you take may have different benefits for you. You will still be receiving the same care you would normally be getting through HealthRIGHT 360 at Prototypes/ North County Serenity House. These classes are extra to what you normally do as part of your treatment. Importantly, participation in this study will not impact your current treatment in anyway. You will be receiving the same treatment and opportunities through HealthRIGHT 360 that you are already receiving or would receive in the future.

***After you complete the main part of the study*****,** you will again fill out questionnaires, complete a urine test for drug use, and participate in a short stress task where we will collect your saliva (again, you will push your saliva into a tube until you have collected roughly 1 teaspoon of saliva). This will occur either right after session 10 or a few days after. Six months after the first session, you will fill out questionnaires, complete a urine test for drug use, and participate in a short stress task where we will collect your saliva (again, you will push your saliva into a tube until you have collected roughly 1 teaspoon of saliva).

**RETURN OF RESULTS**
You will not be provided clinically relevant information as part of the study.

**WHAT ARE THE POSSIBLE RISKS RELATED TO THE STUDY?**
You should talk to the research team about any problems you experience while taking part in the study.

Risks and side effects related to MBSR and participation in the wellness classes include those which are:

**Likely**
- None. We believe the risks associated with this study are rare.

**Less Likely**
- Anxiety or distress that arises as part of the meditation instruction
    - You will be asked to sit still for a period of time, which can be hard for some people
- Anxiety or distress that arises as part of the stress task
    - We expect a stress task to be a little bit stressful, but the stress task has been used in other studies without a lot of problems and we don't think the stress will last very long.
- Loss of confidentiality (< 1%)
    - Since all your information will be uploaded onto a secure server on the UCI server as you fill out the questionnaire and your responses will be recorded separately from your name, we think this is not very likely.
- Although we will not report your answers to anyone affiliated with your treatment facility or the court, you might be worried that some of your information will be disclosed.
- Pain or discomfort while doing yoga
    - We will provide instructions, but it is a very gentle yoga and you can still be in the study if you are not comfortable doing the yoga. You can sit in a chair and listen as an alternative.

**Rare but serious**
- We do not believe there are any serious risks associated with participating in this study

**Psychological discomforts:** Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop. You might experience a little psychological discomfort as a result of the stress task, but we do not believe it will last long. You don't need to finish the stress task if you don't want to. You can still be in the rest of the study if you skip any part of it.

## WILL I BE PAID FOR TAKING PART IN THIS STUDY?
You will be paid for taking part in this study.

### *Compensation*
You will be paid up to $153 over the course of the study at specified time points over the course of the study (including the $3 paid as part of the screener). There are between 11-12 visits in this study. You will be paid $3 dollars for completing the screener, $15 for completing the baseline measures, $10 for each wellness class you attend, $15 dollars for the first follow-up session (right after the 9$^{th}$ session), and $30 for the second follow-up session (6 months after the baseline). Total compensation for participation in the entire study is $153. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits and/or procedures that you have completed.

You will also receive a certificate of completion if you attend at least 6 of the classes. If you come to all 9 classes you will receive an additional certificate for your perfect attendance. You will get materials that are associated with the classes (for example, MP4 players, yoga mats if you are part of the MBSR class, facial scrubs if you take part in the wellness classes).

### *Reimbursement*
If you are no longer living at Protoypes/ North County Serenity House, we will reimburse you for any out of pocket expenses you incur as part of your transportation back to the site.

## WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?
There is no cost to you for participation in this study.

**WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?**
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any severe symptoms that we did not anticipate or that are listed above or your health worsens you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for the follow-up visits if you would like to complete those assessments.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

**HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?**
***Subject Identifiable Data***
Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. The reason that we link your actual name with a code is so that we can link all your data for the three assessments with each other. The list will be destroyed at the end of the study.

We will also take a picture of you and take down some information to help us find you for the follow-up assessments if you move away from Prototypes/ North County Serenity House. This is part of a Locator Guide but it will not be linked with your responses.

***Data Storage***
Research data will be stored electronically via REDCap, a data capture software program, on a secure server at the University of California, Irvine in an encrypted file with a password that only the Principal Investigator (Dr. Dana Rose Garfin) or senior research staff will have access to.

Your responses to the script driven imagery task will be destroyed at the end of the study.

***Data Retention***
The researchers intend to keep the research data indefinitely. However, the identifiable information that links you to your responses will be destroyed after the final data collection

**WHO WILL HAVE ACCESS TO MY STUDY DATA?**
The research team, authorized UCI personnel, the National Institute of Health, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

<u>We will not report any information regarding your participation or your answers to our questions to your parole or probation officer or anyone involved in the courts. Participation in this study will have no effect on your probation or parole, if applicable, in any way</u>

***Future Research Use***
Researchers will use your saliva and information to conduct this study. Once the study is done using your saliva and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

***ClinicalTrials.gov***
ClinicalTrials.gov is a Web site that provides information about clinical trials. 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.

***Certificate of Confidentiality***
To help us protect your privacy are in the process of obtaining a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institute of Health which is funding this project or for 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 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else including child abuse, severe domestic violence, elder abuse, sexual assault, or hard to yourself or others.

**ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?**
***Use of Specimens***
Biospecimens (saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research conducted at UCI. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them. Once you provide the specimens you may not have access to them.

***Investigator Financial Conflict of Interest***
Douglas Granger has financial interests in Salimetrics & SalivaBio, companies with interests related to this study. Douglas Granger is the founder of, serves as the Chief Scientific and Strategy Advisor for, owns stocks in, and receives owner distributions from both companies, which is in addition to their salary from the University of California, Irvine.

The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee (COIOC). The COIOC has determined that the researcher's financial interests are appropriately managed as to avoid compromising the quality or reliability of the study and furthermore, the UCI Institutional Review Board has determined that appropriate safeguards are in place to avoid adversely affecting your safety and welfare.

**WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

**What is an IRB?** An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

**HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?**
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep.
**Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

**Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.**

***I agree to participate in the study.***

_____ _____
**Subject Signature** **Date**

_____
**Printed Name of Subject**

_____ _____
**Signature of Person Obtaining Informed Consent** **Date**
*(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)*

_____
**Printed Name of Person Obtaining Informed Consent**

***A witness signature is required on this consent form only if:*** ***(Researchers: check which one applies)***

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

**For the witness:**
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
**Witness Signature** **Date**
Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

_____
**Printed Name of Witness**

**UNIVERSITY OF CALIFORNIA, IRVINE**
**Experimental Subject's Bill of Rights**

**The rights listed below are the right of every individual asked to participate in a research study. You have the right:**

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

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If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

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**WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?**
***Before you can participate in the main part of the study...***
You will need to have "screening" procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include filling out a short survey about your PTSD and trauma exposure and a measure of cognitive issues.

***During the main part of the study...***
If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include:

1. First session: fill out questionnaires about your physical and mental health as well as your life experiences. We will take a picture of you to help us locate you for a follow-up session, although you can still be in the study if you don't want us to take your picture. You will complete a urine test for drug use, and participate in a short stress task where we will collect your saliva before and after the stress task.

   Your saliva will be collected by the 'passive drool' collection technique. This technique is an accepted, non-invasive method and will require you to sit, lean forward, and allow saliva to pool at the bottom of your mouth. You will then use your tongue to slowly push the saliva into a straw-like collection tool that leads into a tube until you have collected roughly 1 teaspoon of saliva.

   In the stress task, you will be asked to describe a traumatic experience that you had in the past. You will do this in writing or aloud to one of the researchers. If you talk about it out loud, it will be recorded, and we will play it back to you via headphones. The recording will then be deleted.

2. Sessions 2-10: you will participate in one of two wellness classes that will meet 9 times over 8 weeks. You have been assigned to participate in the Mindfulness-based Stress Reduction (MBSR)

   You will participate in 9 sessions that consisted of the following: Week 1: Introduction; Week 2: Understanding Perceptions; Week 3: Hatha Yoga, Sitting Meditation, Walking Meditation; Week 4: Concentration & Awareness; Week 5: Unhealthy Patterns &Getting Unstuck; Week 6: Transformational Coping Strategies; Week 7: Mini-retreat; Week 8: Maintaining Discipline & Flexibility; Week 9: Course Review. Participants are assigned brief homework assignments (e.g., Pleasant/Unpleasant Event Calendar; mindful eating) and participate in guided meditations (pre-loaded on a MP4 player) in between sessions.

**Randomization:** You will be assigned to a study group by chance (like a coin flip). This will depend on which site you are staying at (Prototypes in Pomona, CA or North County Serenity House in Escondido, CA). Everyone at the site will get the same program. The class you take may have different benefits for you. You will still be receiving the same care you would normally be getting through HealthRIGHT 360 at Prototypes/ North County Serenity House. These classes are extra to what you normally do as part of your treatment. Importantly, participation in this study will not impact your current treatment in anyway. You will be receiving the same treatment and opportunities through HealthRIGHT 360 that you are already receiving or would receive in the future.

***After you complete the main part of the study*****,** you will again fill out questionnaires, complete a urine test for drug use, and participate in a short stress task where we will collect your saliva (again, you will push your saliva into a tube until you have collected roughly 1 teaspoon of saliva). This will occur either right after session 10 or a few days after. Six months after the first session, you will fill out questionnaires, complete a urine test for drug use, and participate in a short stress task where we will collect your saliva (again, you will push your saliva into a tube until you have collected roughly 1 teaspoon of saliva).

**RETURN OF RESULTS**
You will not be provided clinically relevant information as part of the study.

**WHAT ARE THE POSSIBLE RISKS RELATED TO THE STUDY?**
You should talk to the research team about any problems you experience while taking part in the study.

Risks and side effects related to MBSR and participation in the wellness classes include those which are:

**Likely**
- None. We believe the risks associated with this study are rare.

**Less Likely**
- Anxiety or distress that arises as part of the meditation instruction
  - You will be asked to sit still for a period of time, which can be hard for some people
- Anxiety or distress that arises as part of the stress task
  - We expect a stress task to be a little bit stressful, but the stress task has been used in other studies without a lot of problems and we don't think the stress will last very long.
- Loss of confidentiality (< 1%)
  - Since all your information will be uploaded onto a secure server on the UCI server as you fill out the questionnaire and your responses will be recorded separately from your name, we think this is not very likely.
- Although we will not report your answers to anyone affiliated with your treatment facility or the court, you might be worried that some of your information will be disclosed.
- Pain or discomfort while doing yoga
  - We will provide instructions, but it is a very gentle yoga and you can still be in the study if you are not comfortable doing the yoga. You can sit in a chair and listen as an alternative.

**Rare but serious**
- We do not believe there are any serious risks associated with participating in this study

**Psychological discomforts:** Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop. You might experience a little psychological discomfort as a result of the stress task, but we do not believe it will last long. You don't need to finish the stress task if you don't want to. You can still be in the rest of the study if you skip any part of it.

**WILL I BE PAID FOR TAKING PART IN THIS STUDY?**
You will be paid for taking part in this study.

***Compensation***
You will be paid up to $153 over the course of the study at specified time points over the course of the study (including the $3 paid as part of the screener). There are between 11-12 visits in this study. You will be paid $3 dollars for completing the screener, $15 for completing the baseline measures, $10 for each wellness class you attend, $15 dollars for the first follow-up session (right after the 9$^{th}$ session), and $30 for the second follow-up session (6 months after the baseline). Total compensation for participation in the entire study is $153. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits and/or procedures that you have completed.

You will also receive a certificate of completion if you attend at least 6 of the classes. If you come to all 9 classes you will receive an additional certificate for your perfect attendance. You will get materials that are associated with the classes (for example, MP4 players, yoga mats if you are part of the MBSR class, facial scrubs if you take part in the wellness classes).

***Reimbursement***
If you are no longer living at Protoypes/ North County Serenity House, we will reimburse you for any out of pocket expenses you incur as part of your transportation back to the site.

**WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**
There is no cost to you for participation in this study.

**WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?**
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any severe symptoms that we did not anticipate or that are listed above or your health worsens you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for the follow-up visits if you would like to complete those assessments.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

**HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?**
***Subject Identifiable Data***
Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. The reason that we link your actual name with a code is so that we can link all your data for the three assessments with each other. The list will be destroyed at the end of the study.

We will also take a picture of you and take down some information to help us find you for the follow-up assessments if you move away from Prototypes/ North County Serenity House. This is part of a Locator Guide but it will not be linked with your responses.

***Data Storage***
Research data will be stored electronically via REDCap, a data capture software program, on a secure server at the University of California, Irvine in an encrypted file with a password that only the Principal Investigator (Dr. Dana Rose Garfin) or senior research staff will have access to.

Your responses to the script driven imagery task will be destroyed at the end of the study.

***Data Retention***
The researchers intend to keep the research data indefinitely. However, the identifiable information that links you to your responses will be destroyed after the final data collection

**WHO WILL HAVE ACCESS TO MY STUDY DATA?**
The research team, authorized UCI personnel, the National Institute of Health, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

We will not report any information regarding your participation or your answers to our questions to your parole or probation officer or anyone involved in the courts. Participation in this study will have no effect on your probation or parole, if applicable, in any way

***Future Research Use***
Researchers will use your saliva and information to conduct this study. Once the study is done using your saliva and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

***ClinicalTrials.gov***
ClinicalTrials.gov is a Web site that provides information about clinical trials. 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.

***Certificate of Confidentiality***
To help us protect your privacy are in the process of obtaining a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institute of Health which is funding this project or for 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 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else including child abuse, severe domestic violence, elder abuse, sexual assault, or hard to yourself or others.

**ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?**
***Use of Specimens***
Biospecimens (saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research conducted at UCI. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them. Once you provide the specimens you may not have access to them.

***Investigator Financial Conflict of Interest***
Douglas Granger has financial interests in Salimetrics & SalivaBio, companies with interests related to this study. Douglas Granger is the founder of, serves as the Chief Scientific and Strategy Advisor for, owns stocks in, and receives owner distributions from both companies, which is in addition to their salary from the University of California, Irvine.

The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee (COIOC). The COIOC has determined that the researcher's financial interests are appropriately managed as to avoid compromising the quality or reliability of the study and furthermore, the UCI Institutional Review Board has determined that appropriate safeguards are in place to avoid adversely affecting your safety and welfare.

**WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

**What is an IRB?** An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

**HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?**
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep.
**Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

**Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.**

***I agree to participate in the study.***

_____ _____
**Subject Signature** **Date**

_____
**Printed Name of Subject**

_____ _____
**Signature of Person Obtaining Informed Consent** **Date**
*(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)*

_____
**Printed Name of Person Obtaining Informed Consent**

***A witness signature is required on this consent form only if:*** ***(Researchers: check which one applies)***

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

**For the witness:**
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
**Witness Signature** **Date**
Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

_____
**Printed Name of Witness**

**UNIVERSITY OF CALIFORNIA, IRVINE**
**Experimental Subject's Bill of Rights**

**The rights listed below are the right of every individual asked to participate in a research study. You have the right:**

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

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If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.