RUTGERS
School of Health Professions

Dr. Suchismita Ray, ph# 732-445-4261
Ray Lab
65 Bergen St
Newark, NJ 07107

**Title of Research:** Guanfacine and Mindfulness for Opioid Use Disorder
**Principal Investigator:** Suchismita Ray, PhD

**RESEARCH SUMMARY:** This consent form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want to take part in this **research**. It is your choice whether to take part or not.

P**URPOSE**: The purpose of this research is to see if the experimental study medication called Guanfacine extended release combined with mindfulness therapy reduces the desire to use opioids in individuals who have opioid use disorder. In this study, you will be one of 80 people on buprenorphine taking part. You will be randomly assigned to take either study medication or a placebo for 6 weeks. A placebo is a pill that looks like medicine but doesn't have any active ingredients. After that, you will be placed into one of four groups.

1) Support Group: You will take the placebo and attend support group (SG) therapy sessions.
2) Medication Group: You will take study medication (Guanfacine) and attend support group (SG) therapy sessions.
3) MORE Group: You will take the placebo and attend mindfulness therapy (MORE) sessions.
4) Combined Group: You will take study medication (Guanfacine) and attend mindfulness therapy (MORE) sessions.

If you agree to join the study and are eligible, you will be randomly assigned to one of these groups. In the support group therapy, you will talk about topics related to opioid use. In the mindfulness (MORE) therapy, you will learn mindfulness techniques and ways to express your emotions to help reduce the chance of opioid relapse.

If you join the study, you will also complete the following: Intake #1 (2 hrs) session to assess your overall health. Intake #2 remote session (1 hr) you will complete questionnaires. A pre-treatment laboratory session (2 hr), which will include you putting on headphones and a voice, will guide you through three different scenarios, while heart rate and mood will be monitored. You will also provide saliva samples at this session to test your cortisol levels. Six weeks of treatment with 2 times per week remote sessions using zoom. During these sessions, we will ask about your opioid use, mood, and stress and ask you to produce a urine sample, after which you will hold the test strip to the camera so a member of the research team can see the results. You will be trained in how to take your heart rate and blood pressure so we can monitor your vitals throughout the study. One of the remote sessions will include support group therapy or MORE Mindfulness therapy. After six weeks treatment, you will complete a post-treatment laboratory (2 hr) session. Like pre-treatment will include you putting on headphones, and a voice will guide you through three different scenarios, and you will rate your level of stress, cravings and mood. The following week, you will take a reduced amount of medication (taper week), and the next week, you will complete the final interview to check your vitals and urine sample. Your total time in the research study will take 9 weeks to complete.

**RISKS/BENEFITS:** Possible harms or burdens of taking part in the study may be an initial reaction to study medication. The most common symptoms are mild and include fatigue, sedation, light-headedness, and dizziness. Exposure to stress imagery might remind you of a personally stressful event. During blood draw, you might experience bruising. Possible benefits of taking part might be you experience weekly support from therapy sessions. However, there are no long-term benefits for you.

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**ALTERNATIVES:** Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

**Who is conducting this research?**
Suchismita Ray, PhD is the Principal Investigator for this research. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Suchismita Ray may be reached at ph# 732-445-4261, 65 Bergen St, Suite 160, Newark, NJ 07028.

The Principal Investigator or another study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

**Sponsor of the Research**: National Institutes of Health

**Why is this research being done?**
The study is designed to look at the effects of a study medication called Guanfacine combined with Mindfulness therapy on your craving, thinking, and opioid use. Guanfacine also called Intuniy which is commercially available drug being used off label in the study.

**Who may take part in this research and who may not?**
To be eligible for to participate in this study, you must be:

- Age 18-55 years old
- On Buprenorphine treatment
- Have a positive urine toxicology screen for non-prescription opioids
- Be in good health as verified by screening examination
- Able to read English and provide informed consent
- Woman who agrees to use reliable forms of birth control such as condoms, birth control, vaginal rings, skin patch
  On blood pressure medication if you have high blood pressure

You are not eligible to participate in this study if you:

- Meet the criteria for moderate to severe substance use disorder
- You are experiencing severe mental health issues, like being psychotic or having serious psychiatric problems (for example, feeling suicidal or currently having mania)
- Have uncontrolled high blood pressure
- Are a woman who is pregnant or nursing or refuse to use a reliable form of birth control
- Your initial EKG shows any serious heart rhythm problems

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**Why have I been asked to take part in this research?**
We are asking you if you want to be in this study because it is our understanding that you have Opioid Use Disorder and on Buprenorphine.

**How long will the research take and how many participants will take part?**
Participation will last 9 weeks. We will enroll 80 participants for this study.

**What will I be asked to do if I take part in this research?**
If you agree to be in the study, you will complete:
Intake #1 (approximately 2 hrs): This will be in person at University Hospital, Newark. At this visit, you will:

- Complete a physical examination (which will include blood draws and an EKG) with the study nurse to ensure that you are free of major medical illnesses. The total volume of blood collected for all blood draws will be 40mL of blood for women (approx. 8 teaspoons or 1/6 of a cup) and 20mL for men (approximately 4 teaspoons or 1/12 of a cup).
- Be asked to provide a urine sample to see if you have recently used opioids.

Intake #2 (approximately 1 hr): This will be a remote visit via Zoom, you will:

- Complete clinical surveys and questionnaires asking you about your demographics (age, race, etc), mood, stress, and substance use, and other psychological and physical problems that you may have now or in the past.
- Develop two different 5 minute personalized scripts. 1) Mental picture script, on your description of a recent personal event that you found "most stressful," rating it above 8 on a 10-point scale. This could be something like a breakup or job-related stress, but it can't be related to opioid us. 2) Relaxing script will come from a personal, non-arousing, non-opioid-related relaxing situation. Examples include lying on a beach or reading a book on a fall afternoon.

A pre-treatment laboratory session (approximately 2 hrs): This will be in person in the Ray Lab at SHP 65 Bergen St, Newark for the following:

- You will arrive at PI Ray's lab in Newark at 11am and get a light lunch. Before the lab session, you will receive visual imagery and relaxation training to help you visualize well and use relaxation techniques. At 12pm, you will sit in a comfy recliner chair, and a pulse oximeter will be attached to your finger to monitor your heart rate.
- You will listen to three different scripts (stress cue, opioid cue, neutral cue) through headphones randomly. You will be asked to imagine each scenario as if it were happening right now. You will rate your opioid craving, anxiety, stress, mood, and emotion reappraisal before and after each script on a tablet.
- You will listen to a 5-minute relaxation exercise through headphones before each imagery session and follow with a 10-minute recovery period, then a 15-minute break. The relaxation exercise quickly reduces craving and improves mood back to normal levels.
- You will also provide saliva samples right before, directly after, and 15 minutes after each script for a total of 9 samples to test your levels of cortisol.
- Saliva samples will be collected utilizing the Salimetrics Clinical Laboratory Salivary Cortisol EIA Kit. The kit contains swabs, tubes, a box for storage, and sample labels. To collect the saliva, the

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study personnel will open the pouch and remove the Saliva (SCA). The ribbed-end of the SCA will be placed securely into a pre-labeled collection vial. The research staff will then hand the vial to you. You should allow saliva to collect in your mouth and then gently guide saliva through the SCA into the vial. Try not to spit or blow into the tube to avoid creating foam and bubbles. After the vial is filled to the required volume, you will hand the vial back to the study personnel who will then remove and discard the SCA and attach the cap to the collection vial and tighten it.

- You will be given a study medication packet specific to your group assignment. Study medication or an inactive substance, also known as a placebo. A placebo is a dummy pill that does not contain any medication and is used for the comparison purposes of this study.

Six Weeks of treatment phase: During 6- weeks, you:

- Take one dose of the assigned medication every morning for 6-weeks. We ask that you video yourself each morning to indicate that you have taken the medication. We will show you how to do this by using HIPAA-compliant, encrypted software App on your phone.
- Attend 2 remote visits each week for 6 weeks. One visits will be approximately 60 minutes long and will involve answering brief questions about your opioid use since the last visit, mood, stress withdrawal symptoms and any potential side-effects. You will also provide a urine sample and check your vitals. If you do experience any side effects from taking study medication, you will meet with the research nurse or doctor, who will check your symptoms and may adjust your dose if required. Secondly weekly visit will include an individual therapy session with a qualified therapist. Therapists are trained in support or MORE therapies. You will also do daily mediation exercises or journaling. The therapists will monitor how well you stick to the treatment.
- You will be asked about your opioid use, mood, stress, and ask you to produce a urine sample, after which you will hold the test strip to the camera so a member of the research team can see the results. You will be trained in how to take your heart rate and blood pressure so we can monitor your vitals throughout the study.
- Post-treatment laboratory (2 hr) session like pre-treatment which you will listen to three different scripts (stress cue, opioid cue, neutral cue) through headphones randomly. You will be asked to imagine each scenario as if it were happening right now. You will rate your opioid craving, anxiety, stress, mood, and emotion reappraisal before and after each script on a tablet. You will also provide saliva samples right before, directly after, and 15 minutes after each script for a total of 9 samples to test your levels of cortisol. The same procedure will be repeated as in the pre-treatment session.

After week 6 of treatment you take a reduced amount of medication (taper week) and the following week you will complete final interview to check your vitals and urine sample

**What are the risks of harm or discomforts I might experience if I take part in this research?**
Study medication: When taking study medication, you may have initial reactions most common symptoms are mild and include fatigue, sedation, light-headedness, and dizziness.

Exposure to mental picture: You might be reminded of a personal stressful event.

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Blood draw: You might experience some bruising. However, infection is rare. Research phlebotomists will follow hospital procedures to minimize discomfort.

Answering personal clinical assessments may make you feel uncomfortable. We will do all we can to mitigate this by ensuring that your data is confidential and that you are in a compassionate and non-judgmental environment.

There may be a risk of a breach of confidentiality regarding your data. We take every precaution to ensure that the confidentiality of your data is maintained using encrypted databases and web-based platforms. Additionally, we de-identify your data using a number or code instead of your name or other personal identifiers. Despite this, we cannot completely guarantee that your identity may not become known due to an unlikely breach in the security of the computer systems.

**Reproductive Risks of Harm**
If you become pregnant while taking part in this study, you should notify the Principal Investigator of this fact as soon as possible, since the risks to the fetus or to yourself are unknown.

**Are there any benefits to me if I choose to take part in this research?**
There are no known benefits to you currently. You may experience some support from the weekly counseling. However, there are long-term benefits to society from research such as this, which would result from increased knowledge about opioid use treatments.

**What are my alternatives if I do not want to take part in this research?**
There are no alternative treatments available. Your alternative is not to take part in this research.

**How will I know if new information is learned that may affect whether I am willing to stay in the study?**
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

**Will I receive the results of the research?**
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

**Will there be any cost to me to take part in this study?**
There are no costs to you for participating in this research, however you must have access to a smartphone.

**Will I be paid to take part in this study?**
Payment for participating in this study will be made using ClinCard, a pre-paid Visa card that works like a debit card. We will give you one card that will be used to pay you at each visit/in accordance with the schedule above for the duration of the study. Your ClinCard will come with an information sheet about how to use the card and who to call if you have any questions. You may use this card online or at stores that accept Visa. Please see the ClinCard Cardholder FAQ sheet or the Rutgers ClinCard Information Page: https://sites.rutgers.edu/clincard-users/ for

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important details about how to use the card, about fees that may apply and what to do if your card is lost or stolen.

ClinCard is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study that you are participating in.

In order to compensate you for your time and effort in participating in this study, you will be paid $50 for each visit that you complete and $40 for a follow up visit, according to the schedule below for a total of $440.

Pre-treatment Laboratory session 1 ($50)
Completion of week 1 sessions ($50)
Completion of week 2 sessions ($50)
Completion of week 3 sessions ($50)
Completion of week 4 sessions ($50)
Completion of week 5 sessions ($50)
Completion of week 6 sessions ($50)
Post-treatment Laboratory session 2 ($50)
Follow up visit ($40)

In addition you will earn chances to win a prize (Visa gift card) ranging $10-25 for each scheduled 6 week treatment session you keep.
It is important for you to know that payments for participating in research are considered taxable income. In accordance with Rutgers Tax Policy, study teams are requested to collect your social security number (SSN) or tax identification number (TIN) if any single payment exceeds $100.00 or if there is a possibility that you will earn more than $300 on any given study in a calendar year, which is the case with this study. Your SSN or TIN will be entered into the ClinCard system, where it will be securely maintained and accessible only to the individuals at Rutgers who have an absolute need to see it.

If you earn $600 or more in payments through ClinCard at Rutgers during any calendar year, and if you have provided your SSN or TIN, the Rutgers Tax Office will issue you an IRS-1099 form (or 1042-S form if you are a non-resident alien), and you will be required to report this as income on your taxes.

If you do <u>not</u> provide an SSN or TIN, Rutgers' Tax Policy requires, once you have earned more than $300 in payments on a study in a calendar year, that 24% of your next payment (or portion of any payment that takes you over $300) and the remainder of payments you receive for the year, be withheld from the payment. For example, if you have already earned $300 in payments on this study in one year, and your next study visit payment would be $100, you will receive $76 on your ClinCard instead of the full $100. The Rutgers Tax Office will send that $24 to the

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United States Internal Revenue Service (IRS) in order to comply with US tax law. Note that the payment from Rutgers to the IRS will not identify you in any way, therefore, you will not be able to receive a refund or credit against that withholding for any other taxes.

Please also note that if, during your study participation, your situation changes and you are able to provide an SSN or TIN, you are asked to let the study team know at your next study visit. If you provide a valid SSN or TIN, funds will not be automatically withheld from that point forward. If you then go on to earn $600 or more in the calendar year, an IRS Form 1099 will be issued to you. You will report this as income on your tax return.

**How will information about me be kept private or confidential?**
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Your information will be collected in a way that will remove information that can identify you, such as your name. Your data will then be entered into a computer used for the study. The data will be analyzed using statistical software.

The research team may use or share your information collected or created for this research with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- Members of the research team and other staff or representatives of UC San Diego whose work is related to the research or to protecting your rights and safety
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Food and Drug Administration
- National Institutes of Health

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**What will happen to my information collected for this research after the research is over?**
After information that could identify you has been removed, only de-identified data is collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you. To “De-identify” data, the data are stripped of the original session ID, and are assigned a new ID, that is generated in a manner that cannot be linked to either your Session ID# or your name. In this manner the data are made anonymous so that not even the original researchers can link the data back to you.

After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

**What will happen if I am injured during this research?**
Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, are listed in risk and harm section of this document. In

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addition, it is possible that during the course of this research, new adverse effects of Guanfacine that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

**What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?**
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Suchismita Ray may be reached at ph# 732-445-4261, 65 Bergen St, Suite 160, Newark, NJ 07028. Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you.

We are required by the Food and Drug Administration to continue to report anything that is related to the safety of the drug used in the research.

If you decide to withdraw from the research for any reason, you may be asked to return for at least one additional visit for safety reasons.

**Who can I contact if I have questions?**
If you have questions, concerns, or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Suchismita Ray, School of Health Profession, Health Informatics may be reached at ph# 732-445-4261.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

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## PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

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**What Is the purpose of the research and how will my information be used?**
You are invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using your health information for this research is to help investigators answer the questions that are being asked in the research.

**What information about me will be used?**
- Medical history or treatment
- Medications
- Laboratory/diagnostic tests
- EKG and/or EEG reports

**Who may use, share or receive my information?**

The research team may use or share your information collected or created for this research with the following people and institutions:
- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Hospital Personnel as Necessary for Clinical Care
  - The University Hospital (UH)
- Non-Rutgers Investigators on the Research Team:
  - Indiana University Medical School
  - The Food and Drug Administration
  - National Institutes of Health

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

**Will I be able to review my research record while the research Is ongoing?**
No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

**Do I have to give my permission?**
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

**If I say Yes now, can I change my mind and take away my permission later?**
Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: Dr. Suchismita Ray, 65 Bergen St, Suite 160, Newark, NJ 07028

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**How long will my permission last?**
There is no set date when your permission will end. Your health information may be studied for many years.

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## AGREEMENT TO TAKE PART IN RESEARCH

**Participant Consent:**

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

**Signature of Investigator/Individual Obtaining Consent:**

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____