STUDY PROTOCOL

Federal Award Project Title: Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD).

Project Director or Principal Investigator: Michael John Gawrysiak, Ph.D.

NCT Number: NCT05042388

Unique Protocol ID: R15DA050102

STATEMENT OF COMPLIANCE / PROTOCOL AGREEMENT

I have read the protocol specified below. In my formal capacity as Investigator, my duties include ensuring the safety of the study participants enrolled under my supervision and providing complete and timely information, as outlined in the protocol. It is understood that all information pertaining to the study will be held strictly confidential and that this confidentiality requirement applies to all study staff at this site. Furthermore, on behalf of the study staff and myself, I agree to maintain the procedures required to carry out the study in accordance with accepted GCP principles and to abide by the terms of this protocol.

Protocol Title: Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD).

Sponsor - Investigator Signature: 

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List of Abbreviations

CAMS-R	Cognitive and Affective Mindfulness Scale – Revised
DTCQ	Drug Taking Confidence Questionnaire
LEC-5	The Life Events Checklist for DSM-5 (LEC-5)
MAT	Medication Assisted Treatment for Opioid Use Disorder
MBRP	Mindfulness-Based Relapse Prevention
MCS	Mindfulness of Craving Scale
MINI	Mini-International Psychiatric Interview
OCS	Opioid Craving Scale
OUD	Opioid Use Disorder
PCL-5	PTSD Checklist for DSM-5
PEDQ	Perceived Ethnic Discrimination Questionnaire
PROMIS	Patient-Reported Outcomes Measurement Information System
PTSD	Posttraumatic Stress Disorder
RPI	Reward Probability Index
TAU	Treatment-As-Usual
TLFB	Timeline FollowBack
TSDS	Trauma Symptoms of Discrimination Scale
TUQ	Therapeutic Resource Use Questionnaire
UDS	Urine Drug Screen
URM	Underrepresented Minorities

1. PROTOCOL SUMMARY

A. PROTOCOL TITLE: MINDFUL MAT ADHERENCE: MINDFULNESS-BASED RELAPSE PREVENTION (MBRP) TO IMPROVE EXTENDED-RELEASE NALTREXONE (XR-NTX) ADHERENCE AND DRUG-USE OUTCOMES FOR OPIOID USE DISORDER (OUD)

GRANT NUMBER: 1 R15 DA050102-01
GRANT NUMBER: 3-R15-DA050102-01A1S1

B. PRINCIPAL INVESTIGATOR: MICHAEL JOHN GAWRYSIAK, PH.D.

2. Summary of the protocol

a. Brief description of the protocol (Schematic of Study Design):

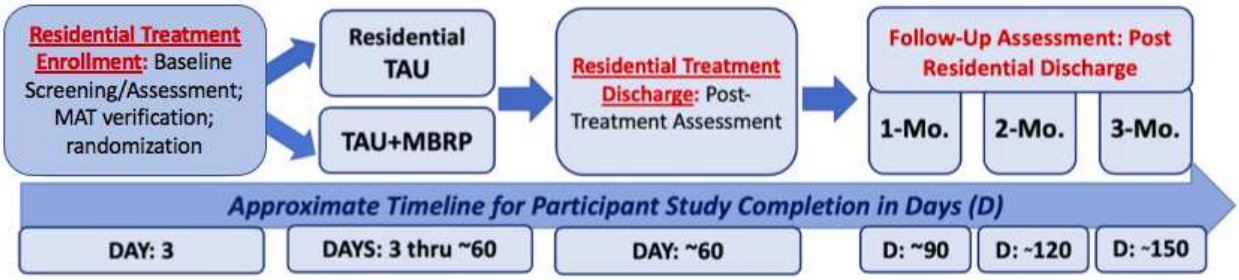

Figure 1: Overview of original study design. Please note that in days for screening, MAT induction, and randomization are approximations based on prior study procedures and clinical feasibility.

This is a phase II, randomized-controlled study designed to examine whether adjunctive Mindfulness-Based Relapse Prevention (MBRP) delivered to patients during their residence in an inpatient addiction recovery facility 1) increases adherence to opioid use disorder (OUD) Medication Assisted Treatment (MAT) and 2) decreases opioid misuse in individuals with OUD following discharge from the residential unit. Follow-up assessments assessing items will be assessed monthly across three consecutive months following patient discharge from residential treatment. The MBRP condition will be tested against treatment-as-usual (TAU; i.e., patients receiving standard residential care and follow-up discharge services provided by the treatment agency partnering with this PI). Participants will be randomized to treatment condition (MBRP/TAU n = 100; TAU n = 100) based on OUD severity, posttraumatic stress severity, and MAT prescribed by the treatment site (i.e., buprenorphine, naltrexone, methadone).

After enrollment, individuals will participate for approximately 16 weeks; the MBRP program will be delivered across approximately 8 sessions for subjects enrolled in the experimental condition will be approximately 4 weeks. The study has 2 distinct phases (see schematic above): 1) Enrollment and treatment phase (approximately 4 to 7weeks); 2) Follow-Up Phase (approximately 3 months). Please see Table 1 Overview of Study Assessment below for a schedule of study procedures.

b. Primary and secondary outcome measures:

The primary behavioral outcome measure is the impact of MBRP (vs. TAU) on MAT adherence and drug-use. Standard discharge procedures for the study-site treatment facility (i.e., Gaudenzia, Inc.) include scheduling follow-up appointments for MAT prescribed OUD patients. These follow-up appointments entail the collection of urine drug screen analysis (UDS) and distribution of MAT. Results of follow-up appointments are entered into patient electronic health records (EHR), to be later accessed by the study team (i.e., UDS results, MAT

adherence). Patient-participants will also be contacted through use of email and telephone to complete secondary self-report outcome measures, including opioid craving, past 30-days drug use, mindfulness, reward probability, and past 30-days utilization of therapeutic resources. Additionally, to ensure that primary outcome data (i.e., MAT adherence, drug-use) is recorded, participants will be contacted by study staff to complete brief phone interviews about their MAT adherence and past 30-days drug use. While it is anticipated that the majority of participants will continue their residential discharge treatment within the Gaudenzia, Inc. continuum, it is possible that some participants will elect to pursue post-residential discharge treatment with providers external to the Gaudenzia continuum. In such cases, follow-up phone contact will be the most viable option for collecting data on continued MAT adherence and drug-use.

In addition to the parent-study aims outlined above, this project has been expanded with support of an Administrative Supplement to Existing NIH-NIDA Grants proposal is to enhance the focus on racial health equity issues. The supplemental aims will examine race and nuanced experiences common to many underrepresented minorities (URM), including racial discrimination trauma symptoms, in relation to treatment outcomes (i.e., drug-use, adherence to medication assisted treatment, MAT). This supplemental proposal aims to address critically important issues relevant to OUD treatment for individuals identifying as Black/African American (henceforth referred to as Black Americans) in an effort to promote racial health equity in OUD treatment. Executing this supplemental research proposal will fill important knowledge gaps by clarifying the role that race and race-based trauma plays in OUD severity and treatment response and will further solidify research collaboration and activities needed to promote health equity for URM, specifically Black Americans.

TABLE 1. Overview of Study Assessment

ASSESSMENT SCHEDULE	Consent/Screening Enrollment/Baseline	MBRP Phase	Discharge	1-Mo.	2-Mo.	3-Mo.
Screening Variables						
Demographics	X					
Primary OUD Diagnosis Verification	X					
MAT Verification	X					
MINI (psychiatric interview)	X					
Primary Outcomes						
MAT Adherence	X		X	X	X	X
Labs: Urine Drug Screen (UDS)	X			X	X	X
Timeline FollowBack (Past 30-Days)	X			X	X	X
Opioid-Craving (OCS)	X		X	X	X	X
Secondary Outcomes						
Cognitive & Affective Mindfulness Scale (CAMS)	X		X	X	X	X
PROMIS-Mental Health	X		X	X	X	X
Mindfulness of Craving Scale (MCS)	X		X	X	X	X
The Reward Probability Index (RPI)	X		X	X	X	X
Drug Taking Confidence Questionnaire (DTCQ)	X		X	X	X	X
Therapeutic Resource Use Questionnaire (TUQ)				X	X	X
Outcome Predictors & Follow-Up AE/SAE						
Trauma Exposure (LEC-5)	X					
PTSD Symptom Severity (PCL-5)	X		X	X	X	X
Adverse Events/Serious Adverse Events				X	X	X
Treatment Adherence						
MBRP Practice Form (MBRP cohort only)			X	X	X	X
*MBRP-Adherence Competence		X				
SUPPLEMENTAL URM Assessment (only URM participants)						

Exposure to Discrimination (PEDQ)	X					
Discrimination based Trauma Symptoms (TSDS)	X		X			

Note: **Items in blue font indicate data collected via review of patient EHR when possible.** All other items reflect patient-participant completion of self-report data administered and collected via Qualtrics Survey Portal (i.e., follow-up assessment), with exception for screening-baseline completion of TLFB and MINI, which is administered via paper-hard copy and entered into participant electronic database.

c. Assessment Measures

Baseline Assessment Only:

i. **Demographics:** A basic questionnaire will record participant demographics (i.e., age, race, sex, gender).
ii. **The MINI-International Neuropsychiatric Interview** (MIN Version 7.0.2; Sheehan, 1998): Completed by a trained clinical psychology graduate student to record psychiatric diagnoses and to determine an OUD severity rating (i.e., total number of symptoms endorsed from OUD diagnosis section.
iii. **Medication Assisted Treatment (MAT) for OUD:** Determination of participant MAT status will made via participant self-report and corroborated by review of participant EHR.
iv. **Drug Use:** The Timeline FollowBack (Sobell & Sobell, 1992), completed by a trained clinical psychology graduate student to record the types of drugs used, past 30 days use, and years of use.
v. **Trauma Exposure:** The Life Events Checklist for DSM-5 (LEC-5; Weathers, Blake, et al., 2013), 17-item self-report questionnaire used to record exposure to conventional traumatic stressors.
vi. **Exposure to Discrimination:** The Brief Perceived Ethnic Discrimination Questionnaire-Community Version (PEDQ; Brondolo et al., 2005), 17-item self-report questionnaire to record perceived frequency of exposure to racial and ethnic discrimination (used exclusively for underrepresented minority participants as part of supplemental grant initiative), higher scores reflect greater exposure to discrimination.

Pre-Post Treatment and Follow-Up Assessments:

vii. **Opioid Craving:** The Opioid Craving Scale (OCS; McHugh et al., 2014), 3-item self-report questionnaire used to record participant opioid craving via a visual analogue scale ranging from 0 to 10, with higher scores reflecting greater craving.
viii. **Mindfulness:** Cognitive & Affective Mindfulness Scale (CAMS-R; Feldman et al., 2007), 10-item self-report questionnaire to record participants' dispositional mindfulness using language that does not reference meditation, with higher scores reflecting greater mindfulness.
ix. **Global Mental Health:** The PROMIS-Mental Health (PROMIS-MH; Hays et al., 2009), 4-item self-report questionnaire used to record general mental health based on a brief assessment of quality of life, mental health, satisfaction with social activities, and emotional problems, higher scores reflect greater mental health.
x. **Posttraumatic Stress Symptom Severity:** The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5; Weathers, Litz, et al., 2013), 20-item self-report questionnaire to record PTSD symptom severity.
xi. **Reward Probability:** The Reward Probability Index (RPI; Carvalho et al., 2011), 20-item self-report questionnaire to record the two RPI scales: reward probability (RP; i.e., I feel a strong sense of achievement) and environmental suppression (ES; i.e., I wish I could find a place to live that brought more satisfaction to my life), higher scores on each subscale reflect healthier reward probability.
xii. **Abstinence Self-Efficacy:** The Drug Taking Confidence Questionnaire (DTCQ; Sklar et al., 1999), 8-item self-report questionnaire to record abstinence self-efficacy using a percentage (0%: not at all confident to 100%: very confident) to reflect participants' ability to resist drug use, higher scores reflect healthier abstinence self-efficacy.

xiii. **Mindfulness of Craving:** The newly created (non-validated) Mindfulness of Craving Scale (MCS), 10-item self-report questionnaire to record the perception to which one is mindfully aware of subjective experiences of drug-craving, higher scores reflect greater mindfulness of craving.

xiv. **Trauma Symptoms of Discrimination:** The Trauma Symptoms of Discrimination Scale (TSDS; Williams, Printz, et al., 2018), 21-item self-report questionnaire to record dysfunctional anxiety and avoidance due to fears of discrimination (used exclusively for underrepresented minority participants as part of supplemental grant initiative), higher scores reflect more severe discriminatory related traumatic stress.

Post Treatment and Follow-Up Assessments:

i. **Meditation Practice Form:** Mindfulness Practice Log (Roos et al., 2019; exclusively for MBRP participants), 5-item self-report questionnaire to record average formal and informal mindfulness meditation practiced in the past week using responses ranging from 0 (no days practiced) to 8 (practiced every day). Higher scores reflect more frequent practice.

ii. **Post-Treatment Mental Health Engagement:** Therapeutic Resource Use Questionnaire (TUQ), 3-item self-report questionnaire to assess the average frequency of weekly engagement in individual therapy, group therapy, and/or narcotics anonymous services, higher scores reflect greater engagement in supportive mental health services during post-treatment follow-up period.

iii. **Adverse Events/Serious Adverse Events (AE/SAE):** AS/SAE Questionnaire, 3-item (TAU) or 10-item (MBRP) self-report questionnaire to record past-month experiences of adverse or serious adverse outcomes directly related to the study intervention/participation. The 3-item TAU questionnaire records categorical responses (i.e., Yes, No) to items querying hospitalization, emergency department visits and drug-overdose. The 10-item MBRP questionnaire includes the 3-items from the TAU questionnaire and additionally records responses on a 5-point Likert-Scale ranging from 0 (strongly disagree) to 4 (strongly agree) to prompts querying challenges related to the MBRP intervention with item responses endorsed as agree or strongly agree denoting a potentially adverse or seriously adverse reaction to treatment.

iv. **Post-Treatment Drug Use (Monthly, 3-month follow-up period):** Determination of drug use based on the integration of three sources of data: (1) participant self-report via telephone completion of the TLFB recording categorical drug-use (i.e., did or did not use), types of drug(s) used, and past 30-days use, (2) correspondence with participant after-care provider (if after-care services external to Gaudenzia, Inc. and a release-of-information obtained) regarding participant UDS status recording categorical drug use and type of drug, and/or (3) review of participant EHR (if participant receiving aftercare mental healthcare within Gaudenzia, Inc.), categorically recording drug(s) used. Any discrepancies recorded between healthcare provider (e.g., positive UDS results indicating opioid use) and participant self-report (e.g., no drug-use) coded as drug use.

MBRP Treatment Fidelity

v. **The MBRP Adherence and Competence Scale** (MBRP-AC; Chawla et al., 2010): A validated rating tool for MBRP fidelity, assessed therapists' delivery of MBRP-RA with an additional adherence item included to evaluate for the presence of discussion focused on MAT adherence. The competence evaluation assessed for overall quality of the session. Adherence items were measured using a dichotomous scale (i.e., present vs absent; no evidence vs more than sufficient evidence of adherence). Competence items were measured using a Likert-type scale (0 = Not satisfactory/mediocre, 1 = Satisfactory, 2 = Good/excellent). Two trained psychology graduate students independently evaluated MBRP-RA adherence and two licensed clinical psychologists, experienced in MBRP, independently evaluated MBRP-RA for adherence (no evidence vs sufficient evidence) and competence components. Two iterations of each of the eight MBRP-RA session modules were randomly selected for review.

d. Inclusion/exclusion criteria:

- Inclusion Criteria:

  1. An informed consent document voluntarily signed and dated by the subject.
  2. Subject must understand and be able to read and write in English.
  3. Enrollment in residential treatment at study site (Gauedenzia, West Chester House).
  4. Physically healthy males and females, aged 18 or older, who meet criteria for opioid use disorder (based on DSM-V criteria) as their primary diagnosis, who are enrolled in residential treatment at the collaborating study site (Gaudenzia, Inc.).
  5. Subject must be willing to be randomized to treatment condition.
  6. Subjects who are willing and able to comply with scheduled visits and other study procedures.

- Exclusion Criteria

  1. Meets current or lifetime DSM-V criteria for schizophrenia or any psychotic disorder or organic metal disorder, including dementia-related psychosis as determined by the semi-structured interview.
  2. Presence of any other psychiatric disorder that in the opinion of the PI will interfere with completion of the study or place the patient at heightened risk through participation in the study.

e. Power calculation and sample size:

The primary aim of this study is to determine whether participation in MBRP results in increased MAT adherence and reduced drug-use assessed over a three-month follow-up assessment period (Aim 1). Statistical analyses will compare MBRP to TAU conditions through an evaluation of MAT adherence, UDS status, and self-reported drug-use and drug-craving. A secondary aim (Aim 2) of this study is to determine if the beneficial effects of MBRP (i.e., improvements in mindfulness) mediate outcomes (i.e., MAT adherence, opioid use, opioid craving).

Determination of the sample involves the control of power for the appropriate statistical test. The power of the test is the probability of observing an association of a given magnitude in the sample of subjects tested if such an association is present in the population. Type-II error is 1 minus the power of the test. For specific aim 1 and aim 2, assessing intervention differences in MAT adherence and drug-use, respectively, and our sample size of 100 per arm with as much as 30% attrition, we have 80% power to detect an effect size corresponding to 2/3 a pooled standard deviation. For Aim 2, Fritz and MacKinnon (2007) documented sample size requirements to guarantee 80% power under the sequential regression framework (i.e., Baron & Kenny, 1986). Under the assumption of a medium effect for intervention with the mediator and a medium effect for intervention on outcome covarying the mediator, the sample size is 118. Therefore, our design consisting of a sample size of 200, with an anticipated dropout rate of 35%, is sufficiently powered to detect mediation.

3. Trial Management

a. List of participating enrolling clinics or data collection centers:

The study site where all participants will be consented, screened, enrolled into the study, and receive the study intervention (i.e., MBRP) will be Gaudenzia Inc., West Chester House (GWCH), located at 1030 S. Concord Rd, West Chester, PA 19382. For follow-up assessment data collection, subject EHR data will be accessed using a computer workstation located at this site. Patients discharging from the GWCH residential facility primarily receive aftercare services through MAT and behavioral services at GWCH. However, a proportion of patients also receive aftercare follow-up services through alternative Gaudenzia treatment facilities. Gaudenzia Inc., is comprised of approximately 50 treatment service facilities regionally located in Pennsylvania, New York, Delaware and Maryland. Subjects receiving aftercare follow-up services at an alternative Gaudenzia treatment

site will have their information (i.e., follow-up assessment data) recorded in their EHR, which will be accessible to this study team through the GWCH workstation. Participants electing to pursue post-discharge treatment services external to the Gaudenzia continuum of care will coordinate treatment planning with Gaudenzia staff at the Gaudenzia West Chester House facility (i.e., discharge treatment planning). No external providers (i.e., SUD/Mental Health services outside of Gaudenzia, Inc.) will be included in data collection procedures for this study. However, release-of-information documentation will be obtained by the study team to enable the PI to contact external providers in the event that the participant experiences an AE/SAE during the study follow-up phase to address all study-related concerns (see below for details).

a. Projected timetable:

- May/August 2021: Obtain final IRB and NIH-NIDA approvals.
- August/May 2021 – June 2023: Initiate recruitment, informed consent process, treatment implementation, and outpatient follow-up for 200 participants.
- August 2023: Final data clean-up to ensure accuracy and completeness. Final data analysis and progress reports for n=200 cohort.
- No Cost Extension: Through August 2024

Supplemental Health Equity Project Timetable

- Upon approval of the modifications by the WCU-IRB, prospective URM participants will immediately begin completion of supplemental measures (anticipated start-date: November, 2021).

b. Target population distribution (e.g., women, minorities, etc):

For this study, we will focus on male and female subjects aged 18 and older. Individuals will not be excluded based on gender, religion, race, or socioeconomic status. Our estimated inclusion of women and minorities are based upon prior demographic data analysis of individuals seeking treatment for opiate use disorders at GWCH. Regarding sample inclusion for the entire study, we anticipate that approximately 67% of our sample will be males, with the majority identifying as Non-Hispanic White (50%), Hispanic White (5%), Non-Hispanic Black (40%), Hispanic Black (5%). Based on GWCH data collected between January through December of 2018, we anticipate these distributions will be comparable across male (67%) and female (33%) participants. We will make every effort to diversify our study sample based on the targeted distribution indicated. Children under the age of 18 will be excluded. This study is inappropriate for children as neither efficacy nor effectiveness of the study intervention, MBRP, has been evaluated for children. Moreover, the study site excludes children from enrolling into residential treatment.

Per the award of the NIH supplemental grant (Award Number: 3-R15-DA050102-01A1S1; *Supplements to Support Research on Health Equity*), prospective participants that identify as underrepresented minorities will be asked to complete two additional self-report questionnaires during eligibility screening. Only prospective participants identifying at URM (e.g., African American, Hispanic) will be requested to complete these measures and the results of these measures will not influence inclusion/exclusion of their enrollment into the study.

4. Data Management and Analysis

5. Data acquisition and transmission

a. Electronic Health Record (EHR) Data: Study staff have been granted access to the study site's agency EHR portal (myAVATAR) and have received training from IT Staff on procedures related to completion of signed assent documentation and how to review subject EHR to collect data pertinent to study outcomes (i.e., MAT verification and adherence during follow-up assessment; UDS status collected during residential treatment enrollment and during follow-up assessment). All EHR data will be accessed from a computer

workstation located at the study site and will be directly transposed to HIPAA compliant electronic database (i.e., Qualtrics research management website; WCU held license) to be accessed by the study team at regular intervals to coordinate quality assurance checks on data collection. All data entered into Qualtrics files will be de-identified, with unique ID numbers used to designate subjects.

b. Screening and Baseline Assessment Data: Semi-structured interviews (i.e., MINI, TLFB) will be completed by research staff during screening/baseline assessment using paper-pencil methods. Other initial baseline assessment measures (i.e., self-report questionnaires) will be completed by participants responding to computer presented questionnaires, which will record assessment responses directly to their EHR file. De-identified MINI and TLFB results and self-report questionnaire responses will be transposed from hardcopy to HIPAA compliant electronic database (i.e., Qualtrics research management website; password protected University Sharepoint folder). Access to the Qualtrics database and University Sharepoint folders will be password protected and restricted to study staff. All data entered into Qualtrics and Sharepoint files will be de-identified, with unique ID numbers used to designate subjects.

c. Post-Discharge Follow-Up MAT & Drug Use Assessments: In order to optimally ensure data is routinely and systematically collected on the primary outcome variables (i.e., drug use and MAT adherence) participants will also be contacted by phone to complete a brief (10-15 minute) follow-up interview (3 per participant, corresponding to each of their 3, monthly follow-up assessment time-points). Telephone follow-up assessments will be completed by a clinically trained member of the PI's research lab (i.e., graduate student in clinical psychology), using contact information provided by the participant during the initial screening-baseline assessment. Interviews will focus exclusively on completion of the TLFB and brief MAT adherence questionnaire. All data collected will be entered into the PI's secure and password protected electronic data base (i.e., Qualtrics, Sharepoint University Folder).

- Participants will complete all follow-up measures (i.e., self-report measures and follow-up assessments) through a combination of the two procedures: (1) telephone contact to verify study enrollment and verbal clarification on MAT status and drug-relapse status, (2) emailed web-link to participants containing instructions for how to complete self-report assessments (using a coded ID number; no names recorded). In the event that a participant does not have email or access to a computer, a trained member of the study team will complete the self-report assessments with participants over the phone, recording their questionnaire responses directly into the Qualtrics portal. When necessary, the phone completion of self-report assessments will be conducted in a secure and private location (i.e., the office space located at the study site, GWCH).

- **PHASE-I Data Collection (Enrollment & Treatment Phase):** Participants will complete self-report questionnaires by accessing a private, research staff monitored, workstation in which all responses are recorded directly to subject specific Qualtrics survey portal. Hard copy data collected from structured interviews (i.e., TLFB, MINI) will be stored in locked filing cabinets, in a locked office, located at the study site and later transposed (deidentified) into a centralized database via Qualtrics data entry.

- **PHASE-2 Data Collection (Follow-Up):** After discharge from GWCH, automatic notification scheduling will alert subjects to complete follow-up self-report questionnaires via telephone outreach and emailed message with a web-link enabling direct access to study questionnaires. Self-report assessment data will be recorded in subjects Qualtrics portal accessible to study staff. Participants will also be contacted by study staff to complete brief (10-15 minute) interviews to have information about their MAT adherence and recent drug use recorded. When possible, participants will sign a release of information to enable study staff to contact their healthcare provider (if/when provider is external to Gaudenzia, Inc. network)

to collect corroborating information regarding participants drug-use (i.e., results of UDS) and MAT adherence (i.e., past-month receipt of MAT by provider).

TABLE 2. Data Collection Method

Data Collection	Review of Subject EHR	Subject Entry: Qualtrics	Research Staff Entry: Qualtrics	Hard-Copy
SCREENING & BASELINE ASSESSMENTS				
Demographics	X	X		
Primary OUD Diagnosis Verification	X		X	
MAT Verification	X		X	
MINI (psychiatric interview)				X
Opioid-Craving (OCS)		*X		
Cognitive & Affective Mindfulness Scale (CAMS-R)		*X		
Mindfulness of Craving Scale (MCS)		*X		
PROMIS-Mental Health		*X		
Reward Probability Index (RPI)		*X		
Trauma Exposure (LEC-5)	X			
PTSD Symptom Severity (PCL-5)		X		
Timeline FollowBack (Past 30-Days) - Interview			X	X
Supplemental URM Assessments: - Exposure to Discrimination (PEDQ) - Discrimination based Trauma Symptoms (TSDS)		 X X		
Timeline FollowBack (Past 30-Days) - Interview			X	X
FOLLOW-UP ASSESSMENTS				
MAT Adherence	X		X	**X
Labs: Urine Drug Screen (UDS)	X		X	
Timeline FollowBack (Past 30-Days) - Interview			X	**X
Repeated: *OCS, CAMS-R, PROMIS, MCS, RPI*		X		
Therapeutic Resource Usage Questionnaire (TUQ)		X		
Adverse Events/Serious Adverse Events	X	X		
TREATMENT ADHERENCE & FIDELITY MONITORING				
MBRP-AC				X
Subject Meditation Journal			X	

Note: All hard-copy data collected via semi-structured interview will be transposed to electronic database (i.e., Qualtrics). ***X** = self-report assessments recorded during baseline assessment and prior to residential discharge (i.e., post completion of TAU or MBRP treatment conditions). ****X** = Information collected during telephone interview coordinated by research assistant.

6. Data entry methods

The majority of study data is directly entered into the into subject Qualtrics survey portal or is extracted from subject EHR via chart review. Data acquired on paper that require later transmission into an electronic database are manually entered and subject to a series of quality assurance checks. All data will be subject to intermittent review to ensure that data acquisition is being accurately and efficiently acquired through Qualtrics survey portals. Data collected will be consolidated into a master data spreadsheet (i.e., Qualtrics) through data merge and analytic functions to centralize data and ensure accessibility to the study PI and his research team.

7. Data analysis plan

a. **Behavioral and clinical analyses.** Prior to performing these analyses, standard data screening and cleaning procedures will be applied. These procedures will (1) screen the data for data-entry errors, (2) check for outliers, (3) assess the extent and pattern of missing data, and (4) check that appropriate assumptions of Normality are met whenever necessary. In all analyses, the assumptions underlying the application of all the statistical methods that are used will be examined, principally through the use of standardized residuals, influence diagnostics, and graphical displays.

b. **Data Analytic Plan.** This project proposal aims to enroll 200 participants (TAU *n*=100; TAU+MBRP *n*=100) to be monitored during treatment implementation and on a monthly basis for 3-months following discharge from the residential unit. As a first step, examinations will target missing data, attrition, distributional properties of dependent and other variables, and correlations among study variables. Descriptive statistics and exploratory graphing such as frequencies, means, standard deviations, box and whisker plots, stem and leaf diagrams, and scatter plots will be used to assess the normality of the data in terms of the presence of skew and/or outliers for all outcome domains. The continuous outcome data will be transformed if necessary, by using an appropriate transformation such as the log transform for skewed long tailed data. If deviations of normality are severe, nonparametric methods would typically be applied. But under the study design of repeated measures, application of nonparametric methods is still under investigations (See May and DeGruttola, 2007, for recent research on this topic). Thus, transformations to ordinal levels based on either clinical or statistical cut-points will be made. Intent-to-treat (ITT) analysis will then be conducted on primary analyses. Due to issues with compliance, secondary analyses consisting of As-Treated (AT) analysis (Ten Have et al., 2008), will be conducted. These models will require more advanced statistical methods such as instrumental variable approaches to yield unbiased estimates of the intervention effect, as well as inferences in a mediation/moderation framework as well. Refer to Ten Have et al. (2008) for further details and discussion on ITT and AT models. The research team has experience with these respective methods (Lynch et al., 2008; Ten Have et al., 2004) and will use the respective techniques for these data.

AIM-1 Statistical Analyses: Compare TAU+MBRP to TAU on follow-up MAT adherence and drug-use. We propose to use mixed effects modeling (MEM) as our primary analytical approach, as it will address the nature of the outcome data (binary for adherence and drug-use variables), to accommodate the within-subject variability, and allow for inspection of results for bias due to drop out or missing data. A special class of a mixed model, generalized linear mixed models, will be implemented to accommodate the binary outcomes. Generalized linear mixed models extend standard generalized linear models by including random effects as a part of the linear predictor. With repeated assessments, missing data is inevitable but the key issue is whether the results are impacted by the presence/absence of data. A pattern-mixture models will be used to assess if there is bias due to drop out or missing data. As described by Hedeker and Gibbons (2006), these mixed models allow for an assessment of whether important estimates are dependent on missing data patterns and provide overall estimates of effects by averaging over the various missing-data patterns. If the missing process is deemed informative through the pattern-mixture model, we will fit the shared-parameters model (Gottfredson et al., 2014). The shared- parameters model simultaneously models the outcome and missing data process fitting a correlation estimate between the two processes yielding unbiased parameter estimates and contrast adjusted for the informative relationship between the two processes. The modeling structures of the mixed effects models allow covariates as both time-invariant and time-varying. Variations are expected in the total number of days patients reside within the GWCH facility (e.g., 45-60 days) as well as the total number of MBRP modules attended. Thus, these potentially important covariates will be investigated and included in the model as necessary. All analyses will be conducted using

the latest version of SAS through SAS procedure PROC MIXED for continuous outcomes and PROC GLIMMIX or PROC NLMIXED for binary, count, or ordinal outcomes.

AIM-2 Statistical Analyses: Determine if beneficial effects of MBRP (i.e., improvements in mindfulness, craving, and distress tolerance) mediate outcomes (i.e., MAT adherence, drug-use, craving). A mediation analyses will be conducted to estimate indirect effects using the Monte Carlo Method for Assessing Mediation (MCMAM; Preacher & Selig, 2012) to assess the effects of the *a priori* mediators on the dichotomous primary outcomes (MacKinnon, Lockwood, & Williams, 2004). First, each of the individual mediators will be independently examined, followed by the assessment of multiple mediators simultaneously. MCMAM performs better than the Sobel test and comparably with bootstrapping approaches (Preacher & Selig, 2012). In this approach, a distribution of the indirect effect is used to estimate a confidence interval (CI) around the observed value of the indirect effect (MacKinnon, Lockwood, & Williams, 2014). In the current study, we will compute a 95% CI with 20,000 repetitions. All analyses will adjust for all relevant baseline variables as well as potential covariates such as severity of prior opioid use, homework completion, therapeutic services engaged in during follow-up period). In addition to the path analysis method, we will examine causal mediation approaches, as described by MacKinnon et al., 2007, which provide an adjustment due to potential unmeasured confounding variables. The analysis team has experience implementing these models (Gallop & Tasca, 2009; Gallop et al., 2009; Lynch et al., 2008). To further assess the clinical significance of participant change on a more ideographic level, we will examine the proportion of MBRP participants (relative to TAU participants) through a reliable change index (RCI; Jacobson & Truax, 1991). To assess clinical significance of participant change, reliable change indices will be calculated for each outcome variable, including drug-use (i.e., TLFB; Sobell & Sobell, 1992), opioid craving (McHugh et al., 2014), mindfulness (Baer et al., 2006), and distress tolerance (Simons & Gaher, 2005).

Exploratory AIM-3 Statistical Analyses: Trauma Exposure and PTSD symptoms will moderate Follow-up MAT Adherence and Drug-Use. A moderator is a baseline measure or pre-randomization variable that has a differential effect on outcome across intervention condition (Kraemer et al., 2002). Moderators are typically defined as variables that significantly interact with condition (Baron & Kenny, 1986; Holmbeck, 1997). Because the proposed moderators are present before randomization, they should be uncorrelated with intervention assignment (Kazdin & Weisz, 1998). Therefore, we will first test the association between each proposed predictor and intervention assignment. Assessment of moderation will be made by augmenting our outcome analyses to include the interaction of the effect of intervention with the moderator. Separately for each potential moderator, we will add the effect of the moderator variable to the model and include the moderator x intervention interaction. The variable will be considered a significant moderator of the intervention effect if the interaction term is significant (Kraemer et al., 2002). Statistically significant interactions will be interpreted by plotting simple regression lines for each level of categorical variables or for high and low values of continuous variables (Holmbeck, 1997; Aiken & West, 1991).

Supplemental Specific Aims: To further focus on race, racial-discrimination, and race-based trauma symptoms within this parent design. All statistical analyses will parallel those of the parent study (see above) to test the following aims:

- **AIM 1 (PRIMARY):** Determine the moderating role of race on treatment outcomes (i.e., MAT adherence, drug-use). **Hypotheses 1:** Relative to Black TAU, Black MBRP subjects will evidence a) greater MAT adherence measured during follow-up, b) reduced drug-use (i.e., self-report, urine drug-screens [UDS]) measured during follow-up and c) greater reductions in race-related trauma symptoms from pre- to post-MBRP.

- **AIM 2:** Identify within group variance for Black participants - Determine the effect of experienced racial discrimination and race-based trauma on OUD severity and treatment outcomes for URM subjects. **Hypotheses 2A:** For all Black subjects, pre-treatment levels of experienced discrimination and race-related trauma symptoms will predict pre-treatment OUD severity (i.e., lifetime and past 30-days opioid use). **Exploratory Hypotheses 2B:** More severe history of discrimination and race-based trauma symptoms will result in poorer treatment adherence (i.e., unsuccessful follow-up MAT appointments) and increased drug-use (i.e., self-report, UDS) during each follow-up assessments among TAU but not among MBRP subjects.
- **EXPLORATORY AIM 3:** Among Black subjects, determine whether the beneficial effects of MBRP on outcomes are mediated by reductions in race-based trauma symptoms and increased dispositional mindfulness. Hypotheses 3A: Black MBRP subjects will report greater reductions in race-based trauma symptoms and improvements in mindfulness, relative to Black TAU subjects, which will mediate treatment outcomes (i.e., successful MAT administration, reduced drug use and positive-UDS recordings).

8. Quality Assurance

a. Procedures in place to ensure the validity and integrity of the data.

i. Research assessments/clinical outcome data/structured interviews managed by the PI and study research team in coordination with Gaudenzia, Inc., through utilization of Qualtrics data acquisition platform

- Qualtrics enables a study review prior to study initiation to address data capture and study design issues.
- Study assessments/instruments are entered into the electronic study database and include field (appropriate responses within a given field) and form (cross-checks between fields in a form) validation checks, when possible, to minimize the possibility of invalid data entry.
- Data collected undergo a complete series of data checks through Quality Assurance (QA) checks coordinated by the PI and his research team. Individuals are granted access to the data and assigned quality assurance rights by the study investigators.
- The quality of collected data will be determined by random inspection by a research assistant and any issues will be discussed and resolved with the PI.

ii. **Screening and Baseline Assessment. Semi-structured Interviews**

- Subjects will complete semi-structured interviews administered by trained study staff using paper-pencil record forms (i.e., MINI, TLFB Interview). De-identified MINI and TLFB results will be transposed from hardcopy to HIPAA compliant electronic database (i.e., Qualtrics research management website). Access to the Qualtrics database will be password protected and restricted to study staff.

iii. **Electronic Health Records (EHR):**

- Subject data extracted from the study site's agency EHR portal (myAVATAR) will be accessed from a computer workstation located at the study site and will be directly transposed to HIPAA compliant electronic database (i.e., Qualtrics research management website; WCU held license) to be accessed by the study team at regular intervals to coordinate quality assurance checks on data collection. All data entered into Qualtrics files will be de-identified, with unique ID numbers used to designate subjects.

iv. **Self-Report Questionnaire Completion**:

- Subjects will complete self-report questionnaires across each study timepoint (see above for assessment scheduling). Questionnaires completed during screening/baseline assessment and pre-discharge/post-MBRP will be administered via computer presentation with subjects' responses being recorded directly to their EHR file. Trained study staff will be present during completion of baseline and pre-discharge questionnaires to monitor questionnaire completion, to provide assistance with questionnaire access, and to provide instructions on questionnaire completion.
- Subsequent self-report questionnaire completion (i.e., post-discharge follow-up assessments) will be coordinated through completion of Qualtrics survey portals via email and telephone prompts, enabling subject completion of measures over the phone and/or their electronic device.
    - Follow-up AE/SAE questionnaire responses will be recorded directly into the Qualtrics Survey portal data file. All other follow-up questionnaires will be accessed through a Qualtrics weblink (communicated to subjects via email/phone messaging).
- All self-report questionnaire data will be recorded in Qualtrics data files, and extracted and consolidated to the secure master Qualtrics database.
- Questionnaire data will be backed up regularly through uploading to Qualtrics database. to protect against accidental loss.

v. **Post-Discharge Follow-Up Phone Assessments:**

- A collateral contact form will be completed by participants upon study enrollment. This form will record contact information necessary to use for outreach efforts intended record participant monthly drug use (i.e., TLFB) and MAT adherence (i.e., MAT adherence questionnaire).
- When participants elect to pursue aftercare treatment services outside of the Gaudenzia, Inc. network, they will be asked to sign an electronic release-of-information (ROI) permitting the study staff to contact their provider to collect information on drug-use (i.e., results of UDS) and MAT adherence. This ROI document will be collected and stored in the participants EHR file.
- Good faith efforts will be made to ensure a continuity of contact with participants to enable collection of primary outcome data (drug use, MAT adherence).
- Data collected from follow-up phone interviews will be entered directly into an online master data spreadsheet (i.e., Qualtrics).

vi. Study staff is trained to uphold best practices for collection of all study data as applicable. This includes assuring the data are attributable (the record clearly shows who collected or modified it), legible (for paper-based data), contemporaneous (data is entered at the time the activity is performed), original, and accurate (transcription is minimized to reduce inaccurate data).

vii. All study personal are 1) provided with the protocol and trained on their study-specific roles and relevant SOPs prior to study initiation 2) notified/re-trained, as needed, for relevant protocol/SOP modifications, 3) required to maintain up-to-date study-related training (e.g., CITI Human Subjects Research, HIPAA privacy).

a. Procedures to guarantee the accuracy and completeness of the data, during data collection, entry, transmission, and analysis

i. **Study Assessments/clinical outcome data/structured interviews:** A complete series of data checks is performed intermittently by the study PI and his team of research assistants through a review of subject EHR, and consolidated Qualtrics database.

ii. Screening, baseline, and pre-discharge assessment data:

- Research tech uses checklist during data acquisition that details all procedures required to uniformly collect data throughout study, including scripts used to interact with subjects during data collection.
- Data processing team performs a series of checks to ensure the accuracy and completeness of data prior to and during analysis.
- Prior to analyses, assessment measures are screened for data collection/entry errors and checked for outliers and the extent and pattern of missing data are assessed.

iii. MAT adherence and drug-use monitoring:

- Research tech uses checklist during EHR data extraction and phone interviews that details all procedures required to uniformly collect data throughout study, including detailed guidance on how to access relevant data within subject EHR files.
- Data processing team performs a series of checks to ensure the accuracy and completeness of data prior to and during analysis.
- Prior to analyses, assessment measures are screened for data collection/entry errors and checked for outliers and the extent and pattern of missing data are assessed.
- In the event that participants do not complete follow-up assessments, a member of the PI's study team will endeavor to make continuous good faith efforts (e.g., reaching out to them by phone) to request that they complete the measures.

9. Regulatory Issues

a. Reporting of SAEs

Reporting for SAEs in this behavioral intervention trial is reviewed below. Collection and reporting of SAEs and AEs will be reviewed on a semi-annual basis, and a report will be prepared for the DSMB.

b. Medication trials: N/A

c. Non-medication trials – to the IRB and NIDA:

Reporting of Serious Adverse Events: Death, disability, hospitalization (or prolongation hospitalization), congenital defects, and life-threatening events, and other important medical events, as defined by the FDA will be deemed serious adverse events (SAEs).

SAEs must be reported to the Sponsor-Investigator (Dr. Gawrysiak) and Dr. Kampman (study consultant) within 24 hours of when the event is reported to any of the study staff, and to NIDA's Program Officer, Sarah Duffy, Ph.D. within three working days.

For a study-related, unexpected and fatal/life threatening SAE, a completed SAE report must be filed to the IRB within 3 working days and also entered into NIDA SAETRS.

For a study-related and unexpected SAE (non-fatal/life-threatening), a completed SAE report must be filed to the IRB within 10 working days.

For SAEs that are neither study-related nor unexpected, there will be no expedited reporting to the IRB.

If a previous SAE that was not initially deemed reportable is later found to fit the criteria for reporting, the event will be reported to the IRB as soon as possible based on the IRB reporting requirements and timeline for reporting.

At the time of the initial report, the following information should be provided: Study identifier, study number, a description of the event, date of onset, current status, whether the study treatment was discontinued, the

reason why the event is classified as serious, investigator assessment of the association between the event and the study treatment. Copies of each report and documentation of IRB notification and receipt will be kept in the study regulatory binder.

d. Reporting of IRB actions to NIDA

All IRB actions regarding this protocol related to safety and/or SAEs will be reported to the NIDA Program Officer (PO) Sarah Duffy, Ph.D. in writing as soon as possible, but in no more than three working days. All other IRB actions not related to subject safety or SAEs will be reported to NIDA in the annual progress report. Routine IRB correspondence (e.g., notifications of need for renewals) will not be conveyed to NIDA. Actions by the WCU IRB that impact major aspects of the study design, methods, or operations will be conveyed to NIDA PO in 3 working days and also in the annual progress report for the grant. If the IRB puts a hold on the study or halts the study, this information will be conveyed to the NIDA PO within 3 working days of the IRB decision.

e. Report of changes or amendments to the protocol

Significant changes to the protocol will be discussed with the NIDA PO before submitting them for approval by the local IRB. No change in procedure occurs without approval. The final approval letters for any changes will be retained in the Regulatory Binder and reported annually to NIDA as needed.

If the change to the protocol requires an amendment to the DSM plan, then the revised DSM plan will be submitted to and approved by the NIDA PO. Changes or amendments to the protocol will not be made without IRB approval. Revisions to the protocol will be conveyed to NIDA in the annual progress report. If the investigators decide to end the protocol early, they will notify NIDA within ten days of this decision.

f. Trial stopping rules

In addition to oversight by the West Chester University of Pennsylvania IRB and Office of Human Research, the study will be conducted under the supervision of an Independent Data Safety and Monitoring Board. This independent board will review the study annually. The DSMB is charged with monitoring the safety of subjects and the quality of the data, as well as the appropriate termination of studies either when significant benefits or risks have been uncovered or when it appears that a clinical study cannot be concluded successfully. The DSMB will review all adverse events and will have access to unblinded data in order to determine the association between adverse events and study intervention (i.e., MBRP). If a pattern of significant adverse events is uncovered that suggests that the risks of continuing the study outweigh the expected benefits of the trial then the DSMB will recommend that the study be stopped.

Treatment Discontinuation Criteria: The study team will monitor adverse events during the study period (AE form). If the participant experiences discomfort or adverse events that may be related to the study intervention, the PI (licensed clinical psychologist) will determine if adverse will determine if the adverse events might be related to the study intervention (MBRP) and will correspond with study consultant as needed (physician, Kyle Kampman, M.D.). If determined to be study-related, the behavioral interventions can be discontinued; the patient will no longer be eligible to participate in the MBRP sessions but will continue to participate in the remaining TAU psychosocial treatment related study procedures.

g. Disclosure of any conflict of interest in the DSM

Any apparent or real conflicts of interest will be conveyed to the West Chester University of Pennsylvania Office of Research and Sponsored Programs (ORSP; the University entity that manages conflicts of interest) and the WCU IRB. These steps are required by West Chester University of Pennsylvania. The Principal Investigator and

co-investigators will follow the stipulations set forth by the ORSP. This typically can involve disclosure in communications such as manuscripts and oversight by other faculty not involved in the study as investigators. There are no current conflicts of interest to report for this study.

10. Trial Safety

a. Potential risks and benefits for participants

Men and women participating in the proposed study are considered to be at relatively low risk for adverse reactions to the study procedures. However, because the proposed study seeks to investigate issues of a sensitive nature, one potential risk is emotional discomfort associated with being asked to disclose substance use. Another potential risk associated with participation relates to the confidentiality of information provided.

- **Craving & Emotional Discomfort**

  The MBRP program includes guided discussions on the experiential and conceptual understanding of drug craving and emotional discomfort. It is possible that such discussions can trigger drug-related craving and agitation in patients with a drug-use history. This craving and/or agitation may cause some arousal, but it does not pose a medical risk. Protections: It is our practice for a trained clinician, often the PI, or clinician in training (i.e., clinical psychology doctoral student), to be available in case the patient is still experiencing any continued arousal or discomfort, either from the MBRP sessions, completion of assessment measures, or for any other reason. If the patient is still aroused, the clinician has a number of psychological strategies (deep relaxation; imagery, distraction, consequences tool, etc.) that can quickly help the patient inhibit craving and/or agitation, feeling more comfortable and back in control of her/his feelings. Taking these precautions not only increases the patients' comfort but their safety: it reduces the likelihood that they would abruptly discharge themselves from the residential setting before completing treatment.

- **MBRP Study Intervention**

  It's anticipated that it is a low likelihood that AE/SAEs will be related to the study/study intervention. Adverse reactions to the MBRP study intervention are a (small) potential risk for this study. To date, there is minimal official clinical guidelines about the status of meditation-related risks. The NIH has indicated that there is a small probability that “meditation *could* cause or worsen certain psychiatric problems” and instructs potential mindfulness participants to “check with your doctor before trying meditation” (NCCIH, 2016). The MBCT Implementation Resources (Kuyken et al., 2012) lists potential risks to participants, including increased likelihood of suicidality, depression, negative emotions, and flashbacks during meditation for individuals with trauma histories.

- **Protections**

  Per the directors of the National Center for Complementary and Integrative Health (NCCIH), the most significant potential harm of complementary treatments (e.g., mindfulness-based interventions; MBIs) are *“unjustified claims of benefits”* and the possibility of “adverse events”… “that vulnerable patients with serious diseases may be misled” and diverted from more traditional treatment approaches such as evidence-based pharmacological intervention (Van Dam et al., 2018). Strauss et al., (2014) has cautioned against MBIs being offered as a first line intervention for various psychiatric disorders.

  Note: The study intervention will not be implemented in a manner that would compromise or interfere with medically established interventions for OUD. The MBRP study intervention will be implemented *as a complementary approach for patients already engaged in routine and medically established standards of care*.

Management strategies for potential risks will be enacted through exclusion criteria (i.e., excluding subjects with psychotic spectrum disorders) and informed consent procedures. Both the University of Massachusetts Center for Mindfulness and the Oxford Mindfulness Centre have published recommended exclusion criteria for standard MBIs, both excluding current suicidality and/or any current psychiatric disorder (Kuyken, Crane, & Williams, 2012; Santorelli, 2014). Protection efforts in place include:

a. Excluding subjects from study enrollment on the bases of presentation of psychotic symptoms
b. Restricting inclusion solely to those subjects receiving OUD treatment services from Gaudenzia, Inc. (i.e., not providing MBRP as a first-line treatment for OUD).
c. Restricting inclusion solely to those subjects solely to subjects not endorsing suicidality (i.e., the study-site refers patients with suicidal ideation to alternative treatment facilities for services)
d. MBRP sessions will be delivered by clinically trained instructors and supervised by the study PI (when the study PI is not directly delivering the intervention). All MBRP sessions entail guided discussions in which meditation experiences, pleasant or unpleasant, are discussed and processed. This standardized delivery of MBRP reduces the risk of meditation-related adverse events.

- **Confidentiality**

There is a potential risk for a loss of confidentiality in any research participation. Because our patients carry a substance use diagnosis, this is a risk we take especially seriously. Protections: All study staff receive **Good Clinical Practice** and **Human Participants Protection** training as well as **HIPAA privacy training** before working with any patients and have been instructed to not divulge any information concerning patients to any person or agency without the written and explicit consent of the patients. All electronic data containing PHI is stored on institutionally secured and managed network drives and devices. All EHR and research data may only be accessed by staff engaged in the research project or clinical care of the patients, or by representatives of the National Institute on Drug Abuse or other government agencies as required and permitted by law. Following acquisition, data are transmitted to an institutionally secured and managed network drive). All "hard" copy data is stored in locked cabinets, with access limited to the investigators and data processors. Paper-based data are kept in participant binders, which are stored in secure, locked filing cabinets in locked rooms. Access to these areas is possible only through the investigator or direct research staff. All other research data is collected and stored on institutionally secured network drives, managed by the study PI. If any publication or presentations result from this research, participants will not be identified by name; only de-identified data will be published.

- **Potential Study Benefits**

As prior research has demonstrated the effectiveness and efficacy of MBRP on reducing drug-use relapse, participants randomized to the study intervention condition may benefit from learning new coping strategies to address drug-craving, thereby reducing future drug-use vulnerability. Participants randomized to the TAU control condition, and MBRP participants, may potentially benefit from an increased awareness of their OUD diagnoses and the processes underlying their dependence, the feeling of contributing to medical research, and the potential benefit from substance abuse treatment.

b. Collection and reporting of AEs and SAEs

- **Collection of AEs and SAEs:** All adverse events (AEs) and serious adverse events (SAEs) will be captured on the appropriate adverse event source documents and entered into the database.

  The collaborating study community partner (Gaudenzia, Inc.) adheres to a *Critical Incidents Procedures & Analysis* regulatory plan. Regulatory procedures entail recording AE/SAE information, when appropriate, into patient EHR regarding patients' *Critical Incidents* (i.e., "an unexpected occurrence or significant event of major concern, including but not limited to, death, serious injury, or risk to safety or well-being") and *Adverse Incidents* (i.e., "an unexpected occurrence involving significant issues that disrupt program operations but do not rise to the level of a critical incident but have the potential to do so in the future").

  The study site (Gaudenzia) where the study intervention will be implemented collects information on all patients (EHR) enrolled in residential care. Study staff record AE/SAE information into patients' "*incident management portal*". All enrolled subjects will have their incident management portals reviewed by research study staff on a regular bases (i.e., weekly) to identify AE/SAEs to be recorded. Monitoring of subjects' incident management portal will occur throughout their enrollment in the residential treatment facility (i.e., "treatment phase") as well as during the three-month post-discharge follow-up phase.

  While it is a low likelihood that AE/SAEs will occur as a result of the mindfulness sessions, subjects enrolled in the MBRP condition will be carefully monitored in a manner consistent with the MBRP program. Specifically, all subjects randomized to the MBRP condition will regularly (i.e., during every MBRP session meeting) be queried about their experience with the mindfulness session and corresponding mindfulness meditations practiced in session and in-between sessions. In the event that a subject enrolled in the MBRP condition expresses concern or challenges that may qualify as an AE, they will be followed up with by the study PI to determine the nature, severity, and study-relatedness of their AE.

  During the post-residential discharge follow-up phase of the study, subjects will continue to have their AE/SAEs monitored through regularly scheduled review of their EHR incident management portal. Additionally, all participants will complete a general standardized AE/SAE questionnaire as part of their follow-up monthly assessment packets (administered vie Qualtrics). If a participant evidences concerns that may meet a threshold of AE/SAE, their file will be "flagged", and the PI will make a best effort to immediately contact the subject by phone to assess and resolve the AE/SAE, through the following procedures:

- **AE/SAE questionnaires** (see measures section) will be completed by subjects using Qualtrics questionnaire survey portals. In the event that a subject endorses potential adverse events (i.e., responses notated in red-font on measures section) the PI will contact will (1) endeavor to contact the individual to assess the situation and determine the best course of action (i.e., providing individual with treatment resources/referrals) and, when appropriate, (2) will notify Gaudenzia staff members of the potential need for follow-up contact with the individual. All AE/SAE questionnaire responses will be recorded in the Qualtrics survey portal and made accessible to research study-staff for participant quality assurance measures and data analytics. The study PI regularly reviews (at least 2x per week) responses recorded in the portal to ensure that AE/SAE are routinely monitored.

  a. If the subject is still **within the Gaudenzia's continuum of care** during post-discharge follow-up study phase and the subject endorses a potential AE/SAE, the following activities will occur: **(1)** The study PI will attempt to contact the subject by phone call to ascertain the nature, severity, and outcomes related to the potential AE/SAE. Based on this correspondence, the PI will determine if further follow-up is necessary, in which case, the PI will **(2)** follow-up with

Gaudenzia, Inc. staff to **(a)** notify them of the AE/SAE and **(b)** inform them of the potential need for further substance use/mental health services evaluations and/or services. (**3)** The study PI will record a summary of the potential AE/SAE within the Gaudenzia electronic healthcare record (i.e., progress note) and will communicate, when necessary, all information to NIH-NIDA, to West Chester University institutional review board (IRB), and to the University of Pennsylvania Data Safety Monitoring Board (DSMB).

b. If the subject is **no longer within the Gaudenzia continuum of care** (i.e., has elected to engage in treatment services external to Gaudenzia Inc., or has elected to not participate in any post-discharge treatment services), and the subject endorses a potential AE/SAE, the following activities will occur: **(1)** The study PI will attempt to contact the subject by phone call to ascertain the nature, severity, and outcomes related to the potential AE/SAE. Based on this correspondence, the PI will determine if further follow-up is necessary, in which case, the PI will **(2)** follow-up with the *external provider* to **(a)** notify them of the AE/SAE and **(b)** inform them of the potential need for further substance use/mental health services evaluations and/or services. **(3)** The study PI will also engaged in coordinated efforts to have the subject re-engage in substance use/mental healthcare services in the event that they are no longer engaged in substance use/mental healthcare services through Gaudenzia, Inc. Specifically, the PI's outreach efforts will focus on facilitating the subject's re-engagement in substance use/mental healthcare services at their most recent treatment provider or at a Gaudenzia, Inc. location (e.g., providing Gaudenzia call-center phone number (833-976-HELP(4357)). **(4)** The study PI will record a summary of the potential AE/SAE within the Gaudenzia electronic healthcare record (i.e., progress note) and will communicate, when necessary, all information to NIH-NIDA, to West Chester University institutional review board (IRB), and to the University of Pennsylvania Data Safety Monitoring Board (DSMB).

**NOTE.* Although infrequent, some patients admitted to Gaudenzia West Chester House elect to develop their post-discharge plan to solely include treatment providers external to Gaudenzia, Inc. The post-discharge treatment plan is determined collaboratively between Gaudenzia staff and the patient during their residence within the Gaudenzia West Chester House treatment facility. All patients enrolled into the study that elect to pursue treatment services external to Gaudenzia Inc., will complete signed release of information enabling the study PI's ability to communicate with external treatment providers in the event that AE/SAE issues necessitate further action to resolve.

The study PI will monitor follow-up procedures to verify that potential AE/SAE issues are resolved and will notate events in the study regulatory binder. The PI will also initiate correspondence with the participant directly if/when appropriate for follow-up inquiry based on participant completion of the AE questionnaire. In the event that a subject fails to complete their follow-up assessment questionnaires (which, includes the AE/SAE questionnaire), a good faith effort will be coordinated by members of the study team to contact them to request that they complete these measures.

- **Treatment Phase AE/SAE Collection:** (A) Monitor/record events listed in participants incident management portal; (B) Querying subject experiences related to mindfulness and meditation practices occurring during and in-between.
- **Post-Discharge Phase AE/SAE Collection:** (A) Monitor and record events listed in participants incident management portal; (B) Collect self-report questionnaires assessing AE/SAE related to ongoing mindfulness practices (MBRP cohort) and more general AE/SAE (TAU cohort).

All adverse events occurring during the study period must be recorded. The clinical course of each event should be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause. Any serious adverse event that is still ongoing at the end of the study and/or occurs after the study period and is considered to be possibly related to the study treatment or study participation should be recorded and reported immediately.

Adverse events may be identified by research staff or by one of the study investigators and will be reported according to the criteria and timelines described within this document.

Reporting of AEs: AEs that are study-related and unexpected must be reported to the IRB within 10 working days. If a previous AE that was not initially deemed reportable is later found to fit the criteria for reporting, the event will be reported to the IRB as soon as possible based on the IRB reporting requirements and timeline for reporting.

- **Adverse Event Reporting Period:** The study period during which adverse events must be reported is defined as the day of subject randomization to treatment condition through the end of the study treatment follow-up. For this study, the adverse event reporting period will end after the follow-up visit.
- **Report of Non-Medical Events:**
  The IRB requires prompt reporting of the following events:
  - New information showing increased risk to subjects
  - Unapproved protocol deviation to assure protection of human subject
  - Protocol deviation that places subjects at risk or has the potential to occur again
  - Any serious and continuing non-compliance
  - Breach of confidentiality
  - Premature completion of a study for any reason

c. Management of SAEs or other study risks

Serious adverse events and other study-related events will be initially managed by the study PI (licensed clinical psychologist). When necessary and appropriate, the PI will consult with study consultant, Kyle Kampman, M.D., to verify the determination of SAEs relation to the study and/or study intervention. Staff at the study site (i.e., Gaudenzia West Chester House; GWCH) are trained in CPR and mobile emergency crash carts are available throughout the facility. Additionally, nursing staff are stationed on site, seven days a week, between the hours of 8:00AM to 10:00PM. The study site (GWCH) is located near Chester County Hospital Emergency Department (9-minute drive). In case of a serious adverse event participants may be taken there for immediate care. This hospital is a full-service general hospital.

11. Trial Efficacy

a. Plans for interim Analysis of efficacy data: N/A

12. DSM Plan Administration

a. Responsibility for data and safety monitoring

Responsibility for monitoring data and safety during this clinical study, as well as ongoing clinical monitoring, will reside with the study PI, Dr. Gawrysiak, Ph.D. The PI will be responsible for assuring through personal contact with the research team that everyone clearly understands and accepts the obligations incurred in the undertaking of this clinical trial, including the obligation to obtain informed consent in accordance with 21 CFR Part 50; the obligation to obtain IRB review and approval of a clinical investigation before the investigation may

be initiated and to ensure continuing review of the study by the IRB in accordance with 21 CFR Part 56; and to keep the sponsor informed of such IRB approval and subsequent IRB actions concerning the study. Training will consist of an explanation of the protocol, training in MBRP, and review of the CRF. In addition, the duties of each member of the staff outlined in all applicable regulations will be reviewed. The PI shall coordinate the preparation of semi-annual summary reports to the DSMB regarding adverse events observed during the course of the study, as described in section 10. The PI is responsible for promptly notifying, in writing, the local Institutional Review Board, and the funding agency (NIDA) Program Officer (Sarah Duffy, Ph.D.), if a serious adverse event (SAE) occurs, as discussed in section 6.

b. Frequency of DSM

This study will be internally monitored on an annual basis by the PI or an appropriately trained member of the PI's team of research assistants working at West Chester University of Pennsylvania, using the Principal Investigator Compliance Assessment (PICA). This compliance assessment provides a structured and comprehensive framework for internal monitoring of clinical research.

Multiple items will be assessed including:

1. Informed Consent and HIPAA Authorization: Source document verification (SDV) that consent is on file with signature, date, and proper version for all subjects that consented within the timeframe being reviewed.

2. Inclusion/Exclusion Criteria: SDV eligibility for completeness and accuracy all subjects for that completed or failed screening during the timeframe being reviewed.

3. Safety Review:

a. Serious Adverse Events (SAEs): Verification that study specific reporting requirements were followed for reportable SAEs according to the Reporting of Adverse Events and Serious Adverse Events section above and proper follow-up and resolution of SAE was documented.

b. Adverse Events: Verification that an annual report of all AEs was reviewed by study PI and, when appropriate, M.D. (Kyle Kampman, MD, Study Consultant) and that all AEs collected during the study and classified as serious were reported to appropriate agency and resolved.

4. CRFs: Verification that CRFs are consistent with source documents, and that the CRFs are being completed and Final QA'd in a timely manner.

The compliance assessment will also be used to monitor the Regulatory Binder.

C. Content of DSM report:

The completed annual assessment, which will function as the DSM report, will include a summary of study progress including newly screened participants for enrollment, number of participants newly enrolled into the study, recording of adverse events/serious adverse events (AE/SAEs), summary of challenges related to recruitment if/when relevant, summary of changes to research since last DSMB report. The report will be reviewed by the investigator and filed in the Monitoring Section of the Regulatory Binder, and the visit will be recorded in the study monitoring log. The PI and study staff will address any outstanding issues within 1 month of receiving the report. A summary of the report will be included with the annual IRB continuing review, and any findings that require reporting to the IRB will be reported per local requirements.

10. DSM Board Plan

A safety monitoring board has been established at the Center for the Studies of Addiction with the following purpose (according to NIDA guidelines): to assure that the safety of study subjects is protected while the

scientific goals of the ongoing studies are being met. Specifically, the DSMB is charged with monitoring the safety of participants and the quality of the data, as well as the appropriate termination of studies either when significant benefits or risks have been uncovered or when it appears that a clinical trial cannot be concluded successfully.

a. Members and affiliation: The board is chaired by James McKay, PhD, a faculty member within the Department of Psychiatry at the University of Pennsylvania. Other members of the board include but are not limited to Kevin Lynch, Ph.D. (senior statistician), David Metzger, Ph.D. and Daniel Weintraub, M.D., who are faculty members of the University of Pennsylvania School of Medicine, Department of Psychiatry. All board members meet NIDA requirements regarding background and experience.

b. Frequency of meetings: The board meets every six months (unless more frequent meeting are deemed necessary).

c. Conflict of interest: No board members will have ethical conflicts, including financial interest related to study outcome. Individuals invited to serve on the board disclose any potential conflicts in writing.

d. Protection of confidentiality: See section "e" below.

e. Monitoring activities (initial and ongoing study review): The current study is reviewed using a DSMB Progress Report reviewed in the open session of the meeting, followed by a closed session under the direction of Dr. McKay. Issues related to recruitment, subject safety and efficacy, whether the primary study question is being answered, conflict of interest, confidentiality, and ongoing study review (including AEs, SAEs, and regulatory issues) are assessed. There will be an annual (if the project is still active) analysis of efficacy data by the DSMB and criteria for trial stopping rules as previously described will be evaluated.

f. Communication plan to IRB and NIDA: Following each DSM Board meeting, Dr. McKay will make recommendations to Dr. Gawrysiak, and a final report (edited by all Board members) will be prepared and submitted to NIDA, and the WCU IRB according to each body's reporting requirements. A DSMB report will be issued to the NIDA project officer with the annual progress report.

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INFORMED CONSENT (7-20-2022)

WEST CHESTER UNIVERSITY OF PENNSYLVANIA

INFORMED CONSENT FORM

Project Title: **Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD).**

Principal Investigator: **Michael J. Gawrysiak, Ph.D.**
Associate Professor of Psychology
West Chester University of Pennsylvania
124 W. Rosedale Avenue, West Chester, PA 19382
MGawrysiak@WCUPA.edu

Project Overview: *What is this research study?*

Participation in this research project is voluntary and is being done by Michael Gawrysiak as part of his Faculty-Directed Research. In order to participate in this study, you must meet specific study criteria, which are described in this consent form. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read.

The purpose of this research project is to test whether a behavioral intervention, delivered in a group format, helps reduce drug-use and increase adherence to medications prescribed for individuals in recovery from opioid use disorder. We will be looking at two different treatment programs. Each of these treatment programs will be delivered during your residence at Gaudenzia West Chester House. The first treatment program will be "**treatment-as-usual**" and will be no different from what you would normally receive at Gaudenzia West Chester House. The other treatment program is **Mindfulness-Based Relapse Prevention (MBRP)**. The MBRP program will also be delivered during your residence at Gaudenzia but will be included *in addition to* the other services that you receive. If you are interested and eligible to participate in this study, you will be randomly assigned to enroll into either the treatment-as-usual program or the MBRP program. This means that neither you nor the research team will determine which group you will be assigned to.

The aim of this study is to test whether participation in MBRP helps to reduce drug-use and increase medication adherence (i.e., *naltrexone, buprenorphine, methadone*) after you discharge from the Gaudenzia West Chester House facility.

If you would like to take part, West Chester University requires that you agree and sign this consent form. You may ask Michael Gawrysiak any questions to help you understand this study. **If you don't want to be a part of this study, it won't affect any care you may receive from West Chester University**. If you choose to be a part of this study, you have the right to change your mind and stop being a part of the study at any time.

Who is eligible to participate in this study?

This study is restricted to individuals that identify opioids (e.g., prescription pain-relievers, heroin, fentanyl) as their primary problematic drug-of-abuse. Additionally, this study focuses on individuals struggling with opioid use that are prescribed a medication to help address their opioid addiction during their residence at Gaudenzia West Chester House. However, the study will also include individuals with a history of opioid misuse that are not prescribed medication assisted treatment.

How long will I be in the study?

Your participation in this study will last approximately 4-months (from enrollment to completion). The beginning of your participation starts right now if/when you sign informed consent. The end of the study will occur 3-month following your discharge from Gaudenzia West Chester House. The final study visit will occur during your third follow-up appointment with Gaudenzia health-care providers.

What do I have to do if I participate in this study?

Your participation in this study will entail completing a brief assessment battery, which includes: self-report questionnaires, answering questions to the research-staff interviewer. You will also be asked to provide your consent for the MBRP sessions to be audio recorded and for us to review a portion of your electronic health record (EHR). If you are assigned to the treatment-as-usual condition, you will proceed with your standard treatment program at Gaudenzia West Chester House and will complete a secondary (shorter) assessment battery prior to discharging Gaudenzia West Chester House. If you are assigned to the MBRP condition, you will be asked to attend 8, ~1-hour group sessions where you will learn various skills designed to promote your long-term recovery from opioid usage. Both treatment-as-usual and MBRP conditions will also include (brief) follow-up assessments to occur on a monthly bases, for 3-months, following your discharge from Gaudenzia West Chester House. During these follow-up appointments, you will be asked to complete additional questionnaires. These questionnaires will be forwarded to you through the MeU CARE online survey portal. We will also reach out to you by phone to complete a brief (10-15 minute) interview to ask about your recent drug use and, if applicable to you, your continued adherence to the medication you have been prescribed for opioid addiction.

What is the purpose of this study?

The purpose of this research project is to determine whether a behavioral intervention, delivered in a group format, helps reduce drug-use and increase adherence to medications prescribed for individuals in recovery from opioid use disorder. The overarching aim of this study is to test whether participation in a group behavioral intervention (Mindfulness-Based Relapse Prevention; MBRP) delivered to individuals during their residence at Gaudenzia West Chester House, helps to reduce drug-use. An additional aim is to determine if MBRP increases medication adherence following discharge.

A secondary purpose of this study is to identify factors that relate to drug-use severity. This secondary purpose would include examining information collected from participants during the initial eligibility assessment. To identify factors related to drug-use severity, we intend to examine information collected from all participants regardless of whether they are included in the treatment randomization. Any information included in secondary analyses would not include identifiable information.

If you decide to be a part of this study, you will be asked to do the following:

- Complete self-report questionnaires and a clinical interview now, during your residence at Gaudenzia West Chester House, and questionnaires at each of the three follow-ups.
- Provide written consent permitting research staff (limited) access to your electronic health record to obtain additional information.
- Provide written consent permitting the audio recording of the MBRP sessions. A portion of these recordings will be reviewed to make sure that MBRP sessions are delivered in the manner they were intended.
- Participate in either treatment-as-usual or an 8-session group therapy delivered across 4 weeks.
- Complete brief assessment measures one time per month, for three months after you discharge from Gaudenzia West Chester House.
- This study will take About 4 months (from enrollment to completion) of your time.

Are there any experimental medical treatments?

- No

Is there any risk to me?

Individuals participating in this study are considered to be at relatively low-risk for adverse reactions. However, this study collects information that is sensitive nature. As such, one potential risk is emotional discomfort associated with being asked to disclose information about substance use in general and prior trauma history (during this initial meeting).

There is a chance that discussing this sensitive information may cause some distress. If at any time you are uncomfortable answering any questions, you may skip any question(s). Additionally, your participation in this study is completely voluntary and you may discontinue participation at any time. Furthermore, you will not be penalized in any way for choosing to withdraw or not participate in the proposed study. In addition, should you become distressed during research participation you will be encouraged to speak with your treatment provider at Gaudenzia, West Chester House.

- If you become upset and wish to speak with someone, you may speak with Michael Gawrysiak, Ph.D. or any Gaudenzia staff member.
- If you experience discomfort, you have the right to withdraw at any time.

Is there any benefit to me?

- Benefits to you may include: Learning techniques designed to improve one's ability to more effectively cope with drug-craving and challenging emotions. Prior research has demonstrated that MBRP is an effective treatment and for helping prevent relapse among individuals in recovery from drug and alcohol addiction
- Other benefits may include. The present study is the first study of an adjunctive MBRP intervention for patients receiving medication assisted treatments (MAT). This study is innovative for examining if and how MBRP reduces drug-use and increases adherence to medication assisted treatments for opioid use disorder. This study is also important in terms of contributing to science. In particular, this study will examine how individual patient characteristics (i.e., trauma-history) influence long-term recovery efforts for those struggling with opioid addiction. Thus, the proposed study will help to advance the understanding of potential mechanisms and unique patient factors underlying response to treatment. In all, this study will provide the first findings regarding the use of mindfulness-based interventions for MAT patients, which will provide important information for the treatment of the critical public health problem of opioid misuse. If the mindfulness-based intervention improves MAT treatment adherence and drug-use outcomes, this will provide crucial evidence for disseminating this adjunctive psychosocial intervention across the country to improve substance use outcomes.

How will you protect my privacy?

- The MBRP sessions will be recorded.
  - A small portion of audio recordings (20%) will be reviewed by a member of the study team to determine MBRP sessions are delivered appropriately.
  - These audio recordings will only be accessible to study team members and will be destroyed when no longer needed.
- Your records will be private. Only Michael Gawrysiak and the IRB will have access to your name and responses.
- Your name will **not** be used in any reports.
- Records will be stored:
  - in a locked cabinet in a locked office at Gaudenzia West Chester House (GWCH)

There is minimal risk related to the loss of confidentiality of participant information (e.g., data obtained through survey, interview, biological (i.e., urine toxicology), and EHR (chart review). A number of safeguards will be in place to maintain the confidentiality of participant information. This includes (1) ensuring that no data identifying individual participants will be released to persons other than project personnel, (2) recording all study information with a participant identification code, and (3) maintaining a single master list, separated from all other study data, that connects participant identification codes with personally identifying information (i.e., names). The list that links participant identification codes with identifying information will be destroyed once the required data has been obtained. In addition, the PI will obtain a Certificate of Confidentiality for this study prior to enrolling

participants. Additionally, all research staff associated with this study (i.e., graduate student research assistants) will complete all necessary CITI and HIPAA training prior to participating in research activities.

- Records will be destroyed Three Years After Study Completion

Do I get paid to take part in this study?

- You will not receive any compensation for study procedures completed during your residence at Gaudenzia West Chester House.
- You will receive VISA gift cards for completion of post-discharge/follow-up assessments:
  - You will receive a $10.00 VISA gift card for completing the 1st assessment (1 month post discharge).
  - You will receive a $10.00 VISA gift card for completing the 2nd assessment (1 month post discharge).
  - You will receive a $20.00 VISA gift card for completing the 3rd assessment (1 month post discharge).
- Gift cards will be mailed to you following your completion of the assessments.

Who do I contact in case of research related injury?

- For any questions with this study, contact:
  - **Primary Investigator:** Michael Gawrysiak at 610-436-3339 or MGawrysiak@wcupa.edu

What will you do with my Identifiable Information?

- Identifiers might be removed from the identifiable private information and after removal, the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or the legally authorized representative.
- It is possible that you may share information with the study team that concerns Dr. Gawrysiak (e.g., suicidal thoughts). To support your ongoing health and recovery efforts, Dr. Gawrysiak may decide to share this information with the treatment staff at Gaudenzia West Chester House (GWCH). Dr. Gawrysiak would only share information with the GWCH treatment staff that he believes would benefit your wellbeing. Before sharing with the GWCH staff, Dr. Gawrysiak would first communicate his intentions to do so with you.

For any questions about your rights in this research study, contact the ORSP at 610-436-3557.

I, _____ (your name), have read this form and I understand the statements in this form. I know that if I am uncomfortable with this study, I can stop at any time. I know that it is not possible to know all possible risks in a study, and I think that reasonable safety measures have been taken to decrease any risk.

I, _____ (your name), have read this form and consent to being contacted by the research team to complete monthly assessments once per month for three months after I discharge from Gaudenzia West Chester House.

CHECK BOX:

☐ Yes, I consent to being contacted by researchers to complete the discharge assessment questionnaires. I acknowledge that the research team will use the information that I provide Gaudenzia on my Follow-Up Consent to Contact form.

☐ No, I DO NOT consent to being contacted after I discharge from Gaudenzia West Chester House.

Addressing Potential Adverse Events Following Residential Discharge

If you are **still within the Gaudenzia's continuum of care during post-discharge follow-up phase** the below procedures will be adopted.

a. **Adverse Event/Serious Adverse Event (AE/SAE) Follow-Up Procedures:** In the event that you endorse experiencing a potential AE/SAE (i.e., based on your response to follow-up questionnaires), the following activities will occur: **(1)** Dr. Gawrysiak (study Principle Investigator) will endeavor to follow-up with you via phone call to determine the nature, severity, and outcomes related to the potential AE/SAE. Based on this correspondence, the Principle Investigator will determine if further follow-up is necessary, in which case, Dr. Gawrysiak will **(2)** follow-up with Gaudenzia, Inc. staff to **(a)** notify them of the AE/SAE and **(b)** inform them of the potential need for further substance use/mental health services evaluations and/or services. (**3)** The study Principle Investigator will record a summary of the potential AE/SAE within the Gaudenzia electronic healthcare record (i.e., progress note) and will communicate, when necessary, all information to NIH-NIDA, to West Chester University institutional review board (IRB), and to the University of Pennsylvania Data Safety Monitoring Board (DSMB).

If you are **outside of Gaudenzia's continuum of care during the post-discharge follow-up phase,** then Dr. Gawrysiak will:

2. Obtain a release to coordinate follow-up care with you prior to your discharge from GHWC.
3. Coordinated efforts will be made to have you re-engage in substance use/mental healthcare services in ***the event that you are no longer engaged in substance use/mental healthcare services through Gaudenzia, Inc. or another treatment provider.*** Specifically, the Principle Investigator's outreach efforts will focus on facilitating your re-engagement in substance use/mental healthcare services at your most recent treatment provider or at a Gaudenzia, Inc. location (e.g., providing Gaudenzia call-center phone number (833-976-HELP (4357)).

CHECK BOX:

☐ Yes, I consent

☐ No, I DO NOT consent

This study also includes a sub-aim of better understanding how race and the experience of racism or discrimination influences drug use and treatment engagement. The term 'underrepresented minority' (URM) refers to Black or African American, Hispanic or Latino, American Indian or Alaska Native, Native Hawaiian and other Pacific Islander, or any other underrepresented groups. If you identify as URM we are also requesting that you complete two brief self-report questionnaires as part of your study involvement. Completing these questionnaires will not play a role in determining your eligibility. The information we gather from these questionnaires will help us better understand how to improve treatment efforts for URM.

_____ _____

Subject/Participant Signature Date

_____ _____

Witness Signature Date

GAUDENZIA: RELEASE OF INFORMATION DOCUMENT (electronic format)

Used for access to patient-participant EHR file and, when appropriate, as duplicated to enable communication between the PI and treatment provider external to Gaudenzia continuum of care (i.e., UDS/MAT/treatment resources).

Client's Name TEST,TEST

Client's Date of Birth 01/01/1990

I hereby give Gaudenzia, Inc. permission to RELEASE my health information to:

Name of Individual or Organization

Relationship

Street Address

City

State

Zip

Phone

Fax

Information to Release

- Psychological/Psychiatric Evaluation(s)
- Assessments
- Physical / Medical Records
- Treatment Plan(s)
- Progress Notes
- Discharge Summary
- Case Consultations
- Mental Health Records
- Medication Records
- 255.5 Presence in Treatment
- 255.5 Prognosis
- 255.5 Nature of Project
- 255.5 Brief Description of Progress
- 255.5 Relapse and Frequency

(Staff must document release of above in case consultation note)

Purpose of Release

- Program Compliance
- Continuity of Care
- Legal Purposes
- Social Security

Date of Service Start

Date of Service End

This information has been disclosed to you from records protected by state and federal confidentiality rules (42CFR Part2 and 45 CFR Part 160 and 165). The federal rules prohibit you from making any further disclosures of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42CFR Part2. A general authorization for the release of medical or other information is not sufficient for this purpose. The federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse client. I further understand that the information specified above will be disclosed pursuant to this authorization, and that the recipient of the information may re-disclose the information and it may no longer be protected by the HIPAA privacy law, Federal Law for Drug and Alcohol Confidentiality prohibits the re-release of information. This consent is effective from the date of the client's signature for one year.

This form has been fully explained to me and I certify that I understand its content. Gaudenzia, Inc. may not condition treatment on obtaining this authorization from you. I understand that I may revoke this consent at any time, verbally or in writing to any staff member, except to the extent that action has been taken in reliance on it (e.g. probation, parole, etc.). I understand that the covered entity seeking this authorization may not consider this authorization or my refusal to sign this authorization a condition of treatment, payment, enrollment in the health plan, or eligibility for benefits on whether I sign the authorization. By refusing to sign, I may be faced with the following consequences: The P.O. could discontinue treatment as an option; there may be a delay in authorization for funding; or other possible consequences.

Signature

Client Signature

Get Signature

Date

Authorized Person in Lieu of Consumer Signature

Get Signature

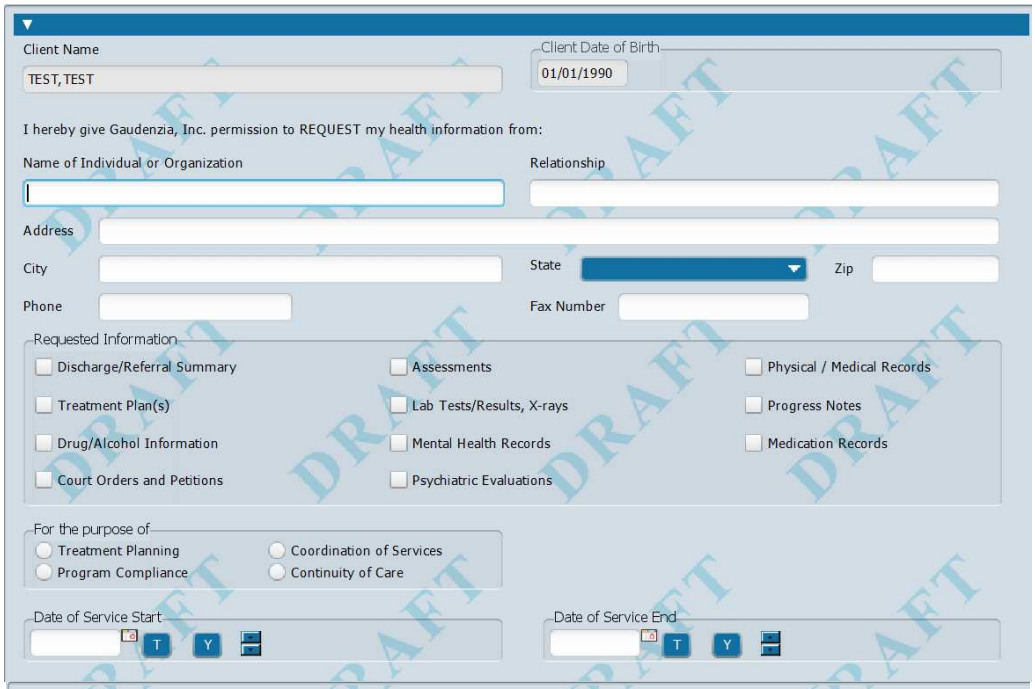
Date

Power of Attorney Guardianship Order
(attach a copy of stated authority)

Staff Signature

Get Signature

Date



This information has been disclosed to you from records protected by state and federal confidentiality rules (42CFR Part 2 and 45 CFR Part 160 and 164). The federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42CFR Part 2. A general authorization for the release of medical or other information is not sufficient for this purpose. The federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse client. I further understand that the information specified above will be disclosed pursuant to this authorization, and that the recipient of the information may re-disclose the information and it may no longer be protected by the HIPAA privacy law. Federal Law for Drug and Alcohol Confidentiality prohibits the re-release of information. This consent is effective from the date of the client's signature for one year.

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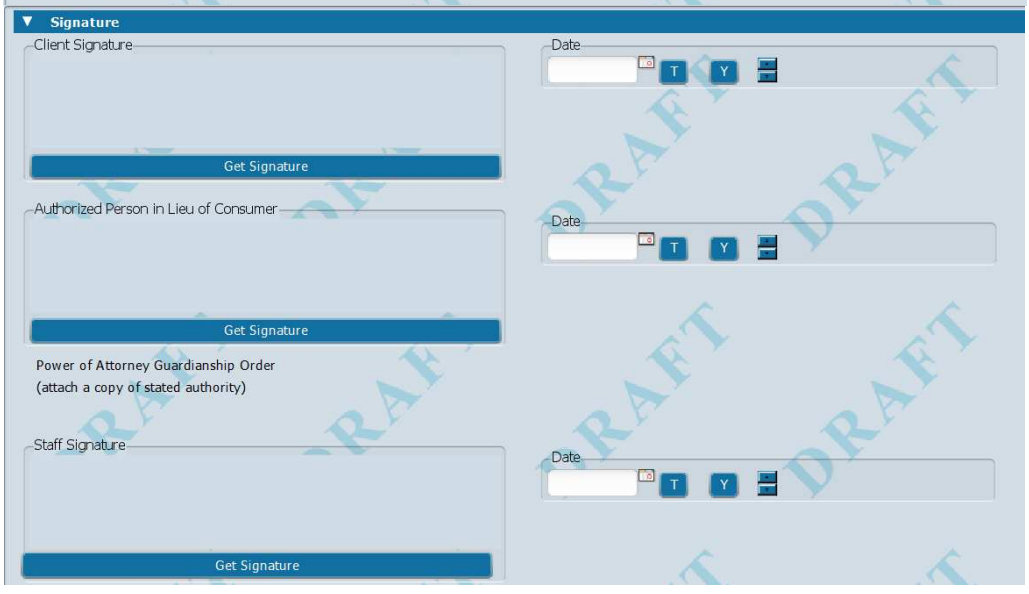

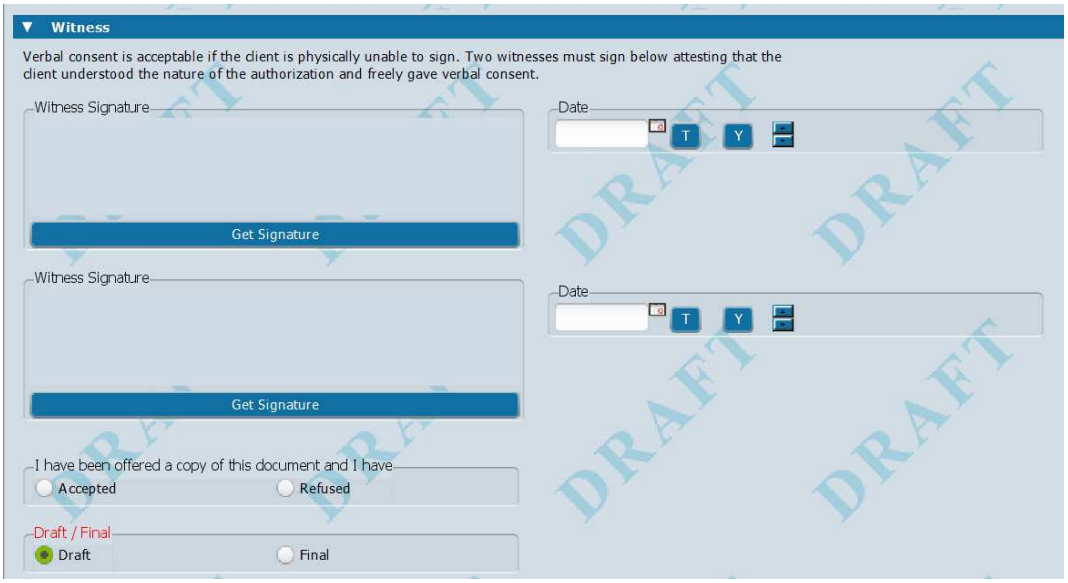
Witness
Verbal consent is acceptable if the client is physically unable to sign. Two witnesses must sign below attesting that the client understood the nature of the authorization and freely gave verbal consent.
Witness Signature
Get Signature
Date
T
Y
Witness Signature
Get Signature
Date
T
Y
I have been offered a copy of this document and I have
Accepted
Refused
Draft / Final
Draft
Final

Summary of Protocol Amendments

The following amendments were made during the trial to optimize data collection and to further enhance participant safety. Modifications were reviewed and approved by both the PI's IRB and the affiliated DSMB prior to implementation. Modifications that the PI believed would constitute 'significant' modification were discussed with and approved by NIDA Program Officer (Sarah Duffy, Ph.D.) prior to being addressed. Generally, all amendments were considered to be non-substantial in nature. See below for summary.

MODIFICATION: 7-23-21

This proposal was initially approved by the IRB using the old review/approval systems (i.e., emailed copies of all documents to IRB@wcupa.edu). To expedite future modification needs, the previously approved protocol was updated to Cayuse (online IRB portal) and subsequently approved.

However, the most recently uploaded proposal/protocol did not include all components of the previously approved IRB proposal/protocol. Prior to making future amendments, this PI is submitting changes to the present protocol to be 100% consistent with the previously approved research protocol (per the guidance of Nicky Cattano; correspondence on 7/15/21). All content (i.e., changes) included in the present IRB protocol reflect an IRB proposal/protocol that was previously approved by the IRB.

MODIFICATION: 7-28-21

- Modified DSMP. Per standard procedure, following WCU approval, secondary approval will be sought through submission of the updated IRB and DSMP to the University of Pennsylvania DSMB. In the event that the UPenn DSMB requires modifications to the DSMP, a new modification will be submitted to the WCU IRB. This study will not start until approvals have been secured from both WCU and UPenn-DSMB.
- Inclusion of compensation to study participants (i.e., receipt of MP3 Player used in treatment protocol)
- Modification to Data collection methodology for follow-up assessment procedures: Inclusion of protocol-driven procedures outlining how to address potential adverse/serious adverse events experienced by patient-participants during post-discharge follow-up procedures.
- Modification to Informed Consent to include reference to consent for follow-up contact during post-discharge assessment periods, and notation on potential need to communicate with treatment provider regarding potential Adverse Event/Serious Adverse Event incurred by participant.
- Modified Procedures for follow-up assessment data collection (i.e., using MeU CARE to enable connection to an anonymous online Qualtrics data collection portal).

MODIFICATION: 8-5-21

- Inclusion of two graduate student clinical research assistants to the study protocol.

MODIFICATION: 10-27-21

Study modifications reflect the recent receipt of a NIH supplemental grant (Award Number: 3-R15-DA050102-01A1S1; *Supplements to Support Research on Health Equity*). The supplemental award will enhance the ability to evaluate how race-related variables influence outcomes related to parent-grant. Study modifications include minimal changes to study procedures and include the following:

- Minor modification to the Informed Consent to reflect the inclusion of additional questionnaires to be completed by prospective underrepresented minority (URM) participants.
- Inclusion of two additional self-report questionnaires (Perceived Ethnic Discrimination Questionnaire, PEDQ; Trauma Symptoms of Discrimination Scale, TSDS).
- Inclusion of additional research team members: Co-Investigators: Ebony White, Ph.D. and Stevie Grassetti, Ph.D.; Graduate Student Research Assistant. Modified DSMB (to reflect all aforementioned changes); Modified Study Assessments (to reflect all aforementioned changes)

MODIFICATION: 2-24-22

Informed Consent Change

- The currently approved informed consent provides no indication that information shared with the study team may be shared with the treatment staff within the research study-site (Gaudenzia West Chester House; GWCH). However, while meeting with prospective participants during study eligibility screening, information may be revealed to study staff that would need to be communicated to the GWCH treatment staff to provide more appropriate levels of treatment services. (e.g., if prospective participant endorses suicidal ideation, it would be incumbent upon the study PI to communicate such information to the study staff to ensure that prospective participant receives appropriate treatment resources).
- Language has been included in the informed consent under the "What will you do with my identifiable information?" section to explicitly enable the study PI's permission to communicate relevant information to GWCH treatment staff.
- The study PI is a licensed clinical psychologist and will use clinical discretion when making the determination as to whether to communicate information prospective participants share to GWCH study staff. The PI will also communicate to the prospective participant his intention to share such information prior to sharing information with study staff.

Informed Consent Change

- All participants complete signed informed consent procedures prior to completing baseline eligibility screening assessments. However, it is not explicitly stated that participants data may be used if they are not included in treatment randomization assignment.
- An additional section has been included under the "What is the Purpose of this Research Study?" section to explicitly state that eligibility assessment data will be used – even if participants are not assigned to a treatment condition.

Assessment Questionnaire Changes

- The *Posttraumatic Stress Checklist for DSM-5 (PCL-5)* is routinely collected from all prospective participants during admission procedures into the GWCH treatment facility and is collected, through electronic health record (EHR) review, as part of the approved study procedures. Approval is requested for study modifications to collect this measure again during post-treatment/pre-discharge assessment procedures and at follow-up assessments.
- Due to emerging research indicating the salience of drug-abstinence efficacy, approval is requested for study modifications to administer the *Drug-Taking Confidence Questionnaire (DTCQ-8)* during baseline eligibility assessment and during post-treatment/pre-discharge assessment procedures and during each of the 3 follow-up assessment periods.

Changes to Study Team

- Graduate research assistants to be removed from study protocol or added based on contributions to the project

MODIFICATION: 6-7-22

Participant recruitment for this study has been more challenging due, in part, to the inclusion criterion (i.e., stipulation that participants be prescribed and adhering to medication assisted treatment (MAT) for opioid use disorder (OUD)). This has impacted the study and clinical implementation of treatment procedures in the following ways: (1) Reduced overall sample size due to smaller population to recruit from, (2) Reduced size of Mindfulness-Based Relapse Prevention (MBRP) groups [Group didactics and discussions function more effectively when there are more participants attending MBRP sessions].

- To optimize the study recruitment process and to enhance the delivery of a clinical service for a population in high need of treatment resources, study procedures will be modified to omit the requirement for participants to be prescribed MAT to be eligible for study inclusion.
- Participants diagnosed with OUD and prescribed MAT will be prioritized for study enrollment (i.e., screened prior to OUD participants without MAT). However, to increase participant recruitment and to increase the MBRP group size, OUD participants without MAT will also be targeted for recruitment and study inclusion.

DETAILED CHANGES TO PROCEDURES/STUDY DOCUMENTATION:

Informed Consent Change – Modification 1

- Within the *"Who is eligible to participate in this study?"* section of the informed consent, language has been modified to indicate that study participants do not need to be prescribed MAT to be eligible for student enrollment.
- Within the *"What do I have to do if I participate in this study?"* section language was added to account for the potential of none-MAT prescribed participants (i.e., "if applicable to you").
- Within the *"What is the purpose of this study?"* section language was modified to account for prospective participants not prescribed MAT.

Cayuse Submission Portal – Section 4: Study Selection

- Within the ***"Total Study Enrollment"*** section, language was modified to include eligibility and recruitment of OUD participants regardless of whether they are receiving MAT services.
- Within the ***"Special Arrangements"*** section, language was modified to account for non-MAT participants being eligible for study enrollment.

Cayuse Submission Portal – Section 5: Study Design

- Within the ***"Research Design"*** section, language was modified to reference prospective individuals participating in the study that are not prescribed MAT.
- Within the ***"Inclusion Criteria"*** section, language was modified to account for non-MAT participants being eligible for study enrollment.

Cayuse Submission Portal – Section 6: Study Procedures

- The attached promotional flyer has been modified to omit language referencing the need for MAT prescription to be eligible for study enrollment. See attachment for changes in language omission.
- The Informed Consent document has been modified to reflect changes to eligibility to includes OUD participants not prescribed MAT (see attached document with all changes denoted with yellow highlight).

Cayuse Submission Portal – Section 7: Risks & Benefits

- **Potential Risks Section:** Language was included to reference non-MAT OUD participants' potential study inclusion and the intention to monitor potential changes in their MAT status following discharge (using standard procedures presently in place).
- **Participant Benefits Section:** Brief statement was included to reference the potential benefit of participating in MBRP regardless of MAT adherence.
- **Informed Consent Section:** Brief statement was included to reference the potential benefit of participating in MBRP regardless of MAT adherence.
- **Informed Consent Documents:** The DSMP was modified slightly to reflect the omission of participant inclusion criteria requiring MAT prescription.

MODIFICATION: 7-27-22

Participant retention during the follow-up phase (i.e., monthly assessments completed by phone/email/qualtrics) has been difficult. Specifically, numerous participants are not completing assessment measures after they discharge from the residential treatment facility (site of the in-person study procedures). To increase participant retention throughout the follow-up phase a change will be made to follow-up procedures: Participants will be provided with financial compensation via VISA gift cards for each of the follow-up assessments completed: Month-1 completion = $10; Month-2 completion = $10; Month-3 completion = $20. As completion of the follow-up assessments requires time/effort on the part of the participant, it is anticipated that adequately compensating them will increase retention of participants during a critically important phase of the study. The compensation procedures are consistent with other clinical trials that the PI has worked on and reflect adequate compensation (not incentivizing) for study procedures.

- Informed Consent: The section titled "Do I get paid to take part in this study?" has been modified to indicate the compensation scheme.
- SECTION 5. Study Design - Source of Participants: Gaudenzia, Inc. administrative policy to stipulates that participants in research study not be able to be compensated for research participation while actively engaged in residential treatment within their facilities. However, upon further correspondence with Gaudenzia administrators, it has become clear and confirmed that participants can be compensated for participation in research activities following their discharge from residential treatment. Modifications have been made to the language in this section to detail the change to this component of the study (i.e., paying participants with VISA gift cards for their completion of post-discharge follow-up assessments).

MODIFICATION: 9-2-22

- Inclusion of additional graduate research assistant on study protocol.

MODIFICATION: 4-6-23

- Omitting graduate research assistants from protocol no longer working on study and inclusion of new graduate research assistants on protocol.

MODIFICATION: 5-5-23

This justification outlines relatively minor changes to be implemented to optimize data collection to promote greater quality assurance with data. These changes are reflected in the attached documents (Questionnaires; Data Satefy Monitoring Plan; Data Collection Method) and the IRB portal sub-section, Confidentiality. These changes include the following:

- Changing self-report data collection methods to rely primarily on participant direct data entry/completion of self-report questionnaires into a qulatrics survey portal:
- BASELINE/PRE-DISCHARGE: Participants will not complete self-report questionnaires in the electronic medical record - Rather, they will enter responses directly into a Qualtrics survey portal (using a laptop computer located within the study-site research office). Participants will also enter their demographic information directly into qualtrics survey portals (rather than research assistants reviewing and recording this information from the participant medical record). Paper-pencil methods will still be employed for participant contact information (i.e., information containing name and phone number for participant will not be recorded electronically or transferred to any location outside the study site facility).
- FOLLOW-UP ASSESSMENTS (1-2-3 Months Following Residential Discharge): Follow-up assessments will continue to be completed by participants via electronic data entry (i.e., qualtrics web-link). However, the MeUCARES data collection portal will no longer be used (i.e., data collection method for assessing adverse events). Participants infrequently completed the adverse events questionnaire using the MeUCARES portal - As such, this brief questionnaire has been incorporated into the pre-existing Qualtrics survey portal that is emailed to participants during their follow-up assessment.

MODIFICATION: 6-8-23

This study requires the objective rating of audio-recorded MBRP sessions to determine adherence and competence (A/C) of treatment delivered (see procedures). Presently, only one rater has is included on the IRB (i.e., Ryan Shorey). The current requested changes reflect the addition of a second A/C rater (Dr. Elena Stein). Dr. Stein holds expertise in MBRP and will serve in the role of the second A/C rater - serving in the exact same function as described within the methods section. The appropriate content sections have been modified to include Dr. Stein and her CITI training certificates of completion have been included. Two student research assistants that are no longer working on the study have been removed from the protocol.

MODIFICATION: 7-6-23

- A new graduate student research assistant is being included on the study team.

MODIFICATION: 9-5-24

- No methodological procedures are changing for this project.
- Recruitment efforts for this project have concluded (i.e., no new participants are being included in the study).
- The composition of the research study team has been modified to reflect only those individuals that are actively working with study data.

Institutional Review Board (IRB) – Approval and Annual Review Documentation

Office of Research and Sponsored Programs | West Chester University | Wayne Hall
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Protocol ID # 20190703B-R2

TO: Michael Gawrysiak
FROM: Nicole M. Cattano, Ph.D.
Co-Chair, WCU Institutional Review Board (IRB)
DATE: 4/22/2021

Project Title: Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)
Date of Approval for Revision: 4/22/2021**

☒**Full Board Review Approval**

Approximately two months prior to the original approved application's end date, you will receive a Continuing Review of Research form. Per Federal regulations, this form must then be completed as soon as possible and returned to the IRB at irb@wcupa.edu , even if the project has been completed or discontinued. Any revisions to this protocol that are needed before that time will require approval by the WCU IRB. Please see www.wcupa.edu/research/irb.aspx for more information.

Any adverse reaction by a research subject is to be reported immediately through the Office of Research and Sponsored Programs via email at irb@wcupa.edu.

Signature:

Co-Chair of WCU IRB

WCU Institutional Review Board (IRB)
IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

WCU
WEST CHESTER UNIVERSITY

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex 111
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

TO: **Sarah Duffy, Ph.D., NIDA Program Officer**
Carol Alderson, NIDA Grants Management Specialist
RE: **R15-AWARD: 1-R15-DA050102-01A1**
Date: **May 6, 2021**

To Whom It May Concern:

My name is Dr. Nicole Bennett and I serve as the Vice Provost for Research and Creative Activity at West Chester University of Pennsylvania (WCU). In my role at WCU, I serve as the designated Authorized Organizational Official that will sign off on and approve Dr. Gawrysiak's NIH-NIDA award "entitled ***'Mindful MAT Adherence: MBRP to improve naltrexone (XR-NTX) adherence and outcomes for opioid use disorder (OUD)'*** (NIDA 1-R15-DA050102-01A1).

Dr. Gawrysiak has effectively addressed all issues relevant to the initiation of his study, which includes:

- Securing institutional IRB approval for updates to his research methodology (Updated IRB approval: 04-22-2021; please see attached).
- Securing approval from the University of Pennsylvania (UPenn) Data Safety Monitoring Board (DSMB) for his Data Safety Monitoring Plan (DSMP; UPenn-DSMB approval: 05-05-2021).

Our institution has received Dr. Gawrysiak's DSMP and DSMB approval letter and will address all research related issues (e.g., IRB approvals) with complementary assistance from the UPenn-DSMB. Dr. Gawrysiak will update his research documentation in ASSIST to reflect all updates to his study methodology and DSMP. We are enthusiastic about Dr. Gawrysiak's continued program of research supported by the NIDA and look forward continuing to support his efforts in whatever way we can. Please feel free to contact us with any additional questions or requests for additional documentation.

Sincerely,

Nicole S. Bennett, Ph.D.
Vice Provost for Research and Creative Activity
Vice Provost for Faculty Development
West Chester University of Pennsylvania

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Jul 9, 2021 4:19:52 PM EDT

To: Michael Gawrysiak
Psychology

Re: Initial - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted application to the WCUPA Institutional Review Board. We have had the opportunity to complete the review of your initial application submission for Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD).

Decision: Approved

Once the research study is approved - it will be approved through June 1, 2022 and would require a Continuing Review to be filed prior to that time.

Findings: This is a transition approval of a previously approved FULL Board IRB study via the older "email" system so that this project can be in the New Electronic Cayuse system.

If there are any questions, please don't hesitate to reach out to irb@wcupa.edu

Sincerely,
WCUPA Institutional Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Apr 15, 2022 12:34:29 PM EDT

Michael Gawrysiak
Psychology

Re: Renewal - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Dr. Michael Gawrysiak:
WCUPA Institutional Review Board has rendered the decision below for Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD).

Decision: Approved

Sincerely,
WCUPA Institutional Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Mar 15, 2023 9:35:22 AM EDT

Michael Gawrysiak
Psychology

Re: Renewal - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Dr. Michael Gawrysiak:
West Chester University Institutional Review Board has rendered the decision below for Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD).

Decision: Approved

Sincerely,
West Chester University Institutional Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Feb 19, 2024 11:37:40 AM EST

Michael Gawrysiak
Psychology

Re: Renewal - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Dr. Michael Gawrysiak:
West Chester University Institutional Review Board has rendered the decision below for Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD).

Decision: Approved

Sincerely,
West Chester University Institutional Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Institutional Review Board (IRB) – Amendment Approval Documentation

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Jul 23, 2021 12:23:32 PM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your WCUPA Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective July 23, 2021.

Decision: Approved

Findings: Approved and transitioned to Cayuse Online as previously approved.

Sincerely,
WCUPA Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Jul 28, 2021 8:17:00 AM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your WCUPA Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective July 28, 2021.

Decision: Approved

Sincerely,
WCUPA Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Aug 5, 2021 8:07:44 AM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your WCUPA Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective August 5, 2021.

Decision: Approved

Sincerely,
WCUPA Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

WCU
WEST CHESTER UNIVERSITY
Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Oct 27, 2021 10:56:33 AM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your WCUPA Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective October 27, 2021.

Decision: Approved

Sincerely,
WCUPA Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Feb 25, 2022 8:21:54 AM EST

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your WCUPA Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective February 25, 2022.

Decision: Approved

Sincerely,
WCUPA Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Jun 7, 2022 12:25:00 PM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your WCUPA Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective June 7, 2022.

Decision: Approved

Sincerely,
WCUPA Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Jul 27, 2022 11:05:12 AM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your WCUPA Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective July 27, 2022.

Decision: Approved

Findings: Modification to approved study.

Sincerely,
WCUPA Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Sep 2, 2022 8:44:52 AM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your WCUPA Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective September 2, 2022.

Decision: Approved

Sincerely,
WCUPA Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Apr 6, 2023 2:28:22 PM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your West Chester University Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective April 6, 2023.

Decision: Approved

Sincerely,
West Chester University Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

May 5, 2023 12:15:47 PM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your West Chester University Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective May 5, 2023.

Decision: Approved

Findings: Full board modification approved

Sincerely,
West Chester University Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

WCU
WEST CHESTER
UNIVERSITY

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Jun 8, 2023 3:27:23 PM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your West Chester University Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective June 8, 2023.

Decision: Approved

Findings: Full board modification approved.

Sincerely,
West Chester University Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

WCU
WEST CHESTER
UNIVERSITY
Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Jul 6, 2023 2:05:15 PM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your West Chester University Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective July 6, 2023.

Decision: Approved

Sincerely,
West Chester University Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Sep 5, 2024 3:24:27 PM EDT

To: Michael Gawrysiak
Psychology

Re: Modification - IRB-FY2022-2 Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD)

Dear Michael Gawrysiak:

Thank you for your submitted modification to your West Chester University Institutional Review Board approved project Mindful MAT Adherence: Mindfulness-Based Relapse Prevention (MBRP) to improve extended-release naltrexone (XR-NTX) adherence and drug-use outcomes for opioid use disorder (OUD). We have had the opportunity to review your modification and have rendered the decision below effective September 5, 2024.

Decision: Approved

Sincerely,
West Chester University Human Subjects Review Board

IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

Data Safety Monitoring Board – Annual Reviews & Approvals

Perelman School of Medicine
University of Pennsylvania

Department of Psychiatry
Center for Studies of Addiction

May 5, 2021

Michael Gawrysiak, PhD
Principal Investigator
West Chester University of Pennsylvania
124 W. Rosedale Avenue, West Chester, PA 19382

RE: DSMB Initial review of "Mindful MAT Adherence: Mindfulness-Based Relapse Prevention(MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD)."

Dear Dr. Gawrysiak:

The Data and Safety Monitoring Board reviewed the following study, "Mindful MAT Adherence: Mindfulness-Based Relapse Prevention(MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD)."

The board reviewed the full study protocol, informed consent form, and subject safety information. The board grants approval to initiate the study at this time.

If you have any questions concerning the information in this letter please don't hesitate to contact me.

Thank you for your cooperation with the Data and Safety Monitoring Board.

Sincerely,

James R. McKay

Jim McKay, Ph.D.
DSMB Chair

Perelman School of Medicine
University of Pennsylvania

Department of Psychiatry
Center for Studies of Addiction

April 8, 2022

Michael Gawrysiak, PhD
Principal Investigator
West Chester University of Pennsylvania
124 W. Rosedale Avenue, West Chester, PA 19382

RE: DSMB review of "Mindful MAT Adherence: Mindfulness-Based Relapse Prevention(MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD)."

Dear Dr. Gawrysiak:

The Data and Safety Monitoring Board reviewed the following study, "Mindful MAT Adherence: Mindfulness-Based Relapse Prevention(MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD)."

The board reviewed the DSMB report and subject safety information. The board grants approval to continue the study and would like to review it again in 12 months at the March 2023 board meeting. Please make appropriate changes to your protocol indicating this review schedule.

If you have any questions concerning the information in this letter please don't hesitate to contact me.

Thank you for your cooperation with the Data and Safety Monitoring Board.

Sincerely,

James McKay

Jim McKay, Ph.D.
DSMB Chair

Perelman School of Medicine
University of Pennsylvania

Department of Psychiatry
Center for Studies of Addiction

March 9, 2023

Michael Gawrysiak, PhD
Principal Investigator
West Chester University of Pennsylvania
124 W. Rosedale Avenue, West Chester, PA 19382

RE: DSMB continued review of "Mindful MAT Adherence: Mindfulness-Based Relapse Prevention(MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD)."

Dear Dr. Gawrysiak:

The Data and Safety Monitoring Board reviewed the following study, "Mindful MAT Adherence: Mindfulness-Based Relapse Prevention(MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD)."

The board reviewed the DSMB report and subject safety information. The board grants approval to continue the study and would like to review it again in 12 months at the March 2024 board meeting. The DSMB member who reviewed your study recognizes that your enrollment has picked up but that given the amount of time remaining on the grant you are unlikely to reach your goal. They recommended you develop a plan for a smaller sample size.

If you have any questions concerning the information in this letter, please don't hesitate to contact me.

Thank you for your cooperation with the Data and Safety Monitoring Board.

Sincerely,

Jim McKay, Ph.D.
DSMB Chair

Perelman School of Medicine
University of Pennsylvania

Department of Psychiatry
Center for Studies of Addiction

March 29, 2024

Michael Gawrysiak, PhD
Principal Investigator
West Chester University of Pennsylvania
124 W. Rosedale Avenue, West Chester, PA 19382

RE: DSMB continued review of "Mindful MAT Adherence: Mindfulness-Based Relapse Prevention(MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD)."

Dear Dr. Gawrysiak:

The Data and Safety Monitoring Board reviewed the following study, "Mindful MAT Adherence: Mindfulness-Based Relapse Prevention(MBRP) to improve Medication Assisted Treatment (MAT) adherence and drug-use outcomes for opioid use disorder (OUD)."

The board reviewed the DSMB report and subject safety information. The board grants approval to continue the study and, unless the study closes before that time, would like to review it again at the March 2025 board meeting.

If you have any questions concerning the information in this letter, please do not hesitate to contact me.

Thank you for your cooperation with the Data and Safety Monitoring Board.

Sincerely,

Reagan Wetherill, Ph.D.
DSMB Chair