MEMORANDUM OF UNDERSTANDING BETWEEN THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, ON BEHALF OF ITS BERKELEY CAMPUS AND THE COUNTY OF MONTEREY ON BEHALF OF MONTEREY COUNTY BEHAVIORAL HEALTH

This Memorandum of Understanding (the *"MOU"*) is entered into effective March 2nd, 2020, (*"Effective Date"*) by and between The Regents of the University of California, on behalf of its Berkeley campus ("UC BERKELEY") and the County of Monterey, on behalf of Monterey County Behavioral Health ("MCBH"), a Department of Monterey County Health Department (each a "Party" and collectively the "Parties"). The term of this MOU is four years and may be extended upon written mutual agreement.

Whereas, MCBH directly and through contractual agreements with community based providers, makes available mental health and alcohol/drug services to the most vulnerable Monterey County residents; and

Whereas, MCBH is working to improve the health and wellbeing of patients ("Consumers") receiving mental health and alcohol/drug services; and

Whereas, in September, 2019, UC BERKELEY was the recipient of a grant from the National Institute of Mental Health (NIMH), a division of the US Department of Health and Human Services Administration, to facilitate Behavioral Health Care Services providers to deliver therapeutic treatment to improve participant sleep outcomes to consumers with a mental illness or substance-related challenge; and

Whereas, it is the intent of UC BERKELEY to provide grant funded training services to enable MCBH providers to furnish therapeutic treatments to improve sleep outcomes as part of the mental health services serving Consumers with mental health or substance use disorders;

Whereas, it is the intent of UC BERKLEY to measure the effectiveness of the grant-funded services by conducting a research study entitled "Implementing and Sustaining a Transdiagnostic Sleep and Circadian Treatment to Improve Severe Mental Illness Outcomes in Community Mental Health" (the "Study"); and

Whereas, the Parties desire to articulate and clarify the roles, responsibilities and expectations in a framework of collaboration between MCBH and UC BERKELEY in the implementation of the services and the study of the outcomes of the treatment; and

Whereas, the intended outcome of the collaboration is to improve the physical and mental health of MCBH's consumers by helping them to improve their sleep, and to measure that improvement as part of a study conducted by UC BERKELEY researchers.

Now therefore it is agreed,

A GOALS AND OBJECTIVES

Goal 1. To provide opportunities for improvements in sleep and circadian functioning in MCBH patients.

In order to accomplish this goal. UC BERKELEY will work to achieve the following:

- Provide training in an evidence-based psychosocial approach to improving sleep health, materials, and on-call support and at MCBH's option, drop-in supervision to MCBH providers who volunteer to become sleep coaches; and Participate in ongoing project planning meetings with MCBH and provide responsive communication to requests (email or phone) from designated MCBH staff.

In order to accomplish this goal, MCBH will work to achieve the following:

- Contact and encourage providers who are interested to participate in the use of sleep therapy in their practice ("Project") ("Providers");

- Participate in ongoing project planning meetings with UC BERKELEY and provide responsive communication to requests (email or phone) from the UC BERKELEY team.

Goal 2. To evaluate the efficacy of a four (4) session therapeutic program over a four (4) year grant period. The study seeks to ascertain if there are improvements in sleep and circadian functioning in enrolled participants.

In order to accomplish this goal UC BERKELEY will work to achieve the following:

Approval of the Study Protocol from the Committee for the Protection of Human Subjects (CPHS) at the University of California, Berkeley. UC BERKLEY shall ensure that every aspect of the study, as well as the recruitment brochures, advertisements and flyers, are approved before commencement of the research. The UC BERKELEY team will make sure the annual reports to the CPHS and will submit any amendments in a timely manner. CPHS approval was granted on May 23, 2019. The Protocol ID is 2019-04-12091.

- Provide informed consent forms for participants and any amendments thereto, and follow protocols for ethical consenting of participants.

- Provide HIPAA authorization forms that identify UC BERKLEY as recipient of Study data.

- Notify MCBH of any proposed changes to the Protocol or Informed Consent. Follow safety and confidentiality protocols provided by MCBH.

- Provide facilitators, project coordinators, assessors, and data analysts as needed for the day-to-day conduct of the study, including assessments, follow-up assessments, data collection and data analysis activities, and provide weekly and on-call supervision for such staff. Provide all materials needed for the conduct of

the study, including workbooks that describe the treatment for the providers and Consumers

In order to accomplish this goal MCBH will work to achieve the following:

- Assist UC BERKELEY project staff to recruit approximately 7 individual providers by around April 2020, and approximately 5 more individual providers by April 2021 during the second year of the study (tentatively April 2021 - April 2022). (This means that UC BERKLEY will provide sleep coach training, support, and supervision to about 12 individual providers over a 2-year period. If more providers are interested in being trained, they will be welcome too.)

- Assist UC BERKELEY project staff to recruit approximately 2-3 Consumers per month during the first year of the study (tentatively April 2020 - April 2021), and 4-5 Consumers per month during the second year of the study (tentatively April 2021 - April 2022). This accounts for a goal of providing therapy services to about 78 consumers over a 2-year period.

- Provide the project team with technical assistance and information on how to reach study participants, especially for follow-up assessments. Assist in helping the Study adhere to the Project Timeline.

- Assist UC BERKELEY in maintaining the integrity of the research design by ensuring appropriate treatment for the Usual Care (control) group and the Sleep Treatment group in accordance with the Study Protocol: The funding for this research study is for an experimental design in which patients will be randomly allocated to The Sleep Treatment (n = 39) or 4-weeks of Usual Care followed by Delayed Treatment with The Sleep Treatment (n = 39)(UC- DT). The integrity of the research, and its value for the mental health field, depends on there being a meaningful difference between the two arms.

Table 1. Project Timeline, Key Events in Calendar Quarters (shading denotes tasks in progress)

	Year 1				*Year 2*				*Year 3*				*Year 4*			
Quarters	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Start-up																
Recruitment																
Treatment																
Follow-up Assessments																
Data entry																
Focus on sustainability/ dissemination																
Analyses, manuscripts																

B. MUTUAL AGREEMENTS AND RESPONSIBILITIES

To accomplish the goals and objectives described in this MOU, MCBH and UC BERKELEY agree to collaboratively:

1. Work collaboratively to achieve the health improvement outcomes for participants.

2. Staff of MCBH and UC BERKELEY will work cooperatively together. However, MCBH staff/employees shall take direction from and be supervised only by MCBH Supervisors/Managers and UC BERKELEY staff/employees shall take direction from and be supervised by UC BERKELEY Supervisors/Managers.

3. MCBH and UC BERKELEY representatives will meet and communicate regularly to support the achievement of the goals and the objectives of the Project. This communication will include discussing and assessing operational needs throughout the project period, reviewing the project budget and spending, and reviewing data.

4. Compliance with Applicable Laws:

4.1 Compliance: This MOU will be governed and construed by the laws of the State of California. The Parties will each abide by applicable laws, including, without limitation, the disclosing and handling of intellectual property, developed technologies, and Confidential Information (defined below), including PHI.

4.2 Confidentiality: In the course of the activities contemplated by this MOU, a Party may disclose Confidential Information to the other Party. Unless otherwise agreed in writing, "Confidential Information" includes any and all non-public information. Confidential Information will be clearly marked as such in writing. If information is orally disclosed which is deemed or desired to be confidential, such Confidential Information must be reduced to writing by the Disclosing Party within thirty (30) days of oral disclosure and provided to the Receiving Party. Protected health information (PHI) will be handled in accordance with applicable laws and regulations. Confidential Information does not include information that (a) is publicly known at the time of the disclosure, (b) is lawfully received by the Receiving Party from a third party which does not have confidentiality obligations to the Disclosing Party, or (c) the Receiving Party can demonstrate was in its possession or known prior to receipt from the Disclosing Party. Confidential Information shall be received and treated in confidence, and shall not be used except as necessary to perform the activities contemplated in this MOU and shall not be further disclosed without prior written consent of the Disclosing Party; provided that, if a Receiving Party is required by law to disclose Confidential Information, the Receiving Party shall notify the Disclosing Party and reasonably cooperate with the Disclosing Party's efforts to prevent disclosure or redact as allowed under law.

5. Data Sharing

5.1 The Parties agree that protected health information, as defined at 45 CFR 160.103 ("PHI"), of Provider's patients will be shared in connection with the Project, as follows:

A. MCBH will recruit patients and obtain their consent to refer them to the UC BERKELEY Study team for further information.

6. Intellectual Property: "Background Intellectual Property" means any intellectual property and a party's intellectual property rights therein, existing prior to the effective date or outside the scope of this MOU. All Background Intellectual Property belonging to one party is and shall remain the exclusive property of the party owning it. To the extent legally able, each party agrees to grant the other party a non-commercial, royalty-free, non-transferrable, non-exclusive, internal research license to use its Background Intellectual Property for the sole purpose of the performance of the work under this MOU.

MCBH shall own the entire right, title and interest, including all copyrights and other intellectual property rights, in and to all materials, inventions, works of authorship, software, information and data conceived or developed by MCBH in the performance of this project. In consideration of UC BERKELEY's support of this work, and to the extent that MCBH has the right to grant such a license, when publications or similar materials are developed from work supported in whole or in part by UC BERKELEY under this MOU, MCBH shall grant to UC BERKELEY a non-transferable, non-exclusive, irrevocable, worldwide, royalty-free license to use, reproduce, publish, or re-publish, or otherwise disseminate such copyrightable materials for non-commercial purposes. Further, MCBH grants UC BERKELEY the right to use data created in the performance of this MOU for the purposes described herein.

UC BERKELEY shall own the entire right, title and interest, including all copyrights and other intellectual property rights, in and to all materials, inventions, works of authorship, software, information and data conceived or developed by UC BERKELEY in the performance of this project. In consideration of MCBH's support of this work, and to the extent that UC BERKELEY has the right to grant such a license, when publications or similar materials are developed from work supported in whole or in part by MCBH under this MOU, UC BERKELEY shall grant MCBH a non-transferable, non-exclusive, irrevocable, worldwide, royalty-free license to use, reproduce, publish, or re-publish, or otherwise disseminate such copyrightable materials for non-commercial purposes. Further, UC BERKELEY grants MCBH the right to use data created in the performance of this MOU for the purposes described herein.

MCBH and UC BERKELEY shall jointly own the entire right, title and interest, including all copyrights and other intellectual property rights, in and to all materials, inventions, works of authorship, software, information and data conceived or developed jointly by MCBH and UC BERKELEY in the performance of this project.

7. Human Subjects: If research involving human subjects is performed pursuant to this MOU, Parties shall ensure that they comply with applicable statutes, regulations and policies concerning the protection of human research subjects. In particular, Parties shall be responsible for compliance with: (i) the requirements set forth by the Department of Health and Human Services, at 45 C.F.R. Part 46; and (ii) the Privacy Regulations in the Health Insurance Portability and Accountability Act of 1996 (45 C.F.R. Parts 160 and 164) for the use and

disclosure of protected health information. No team member will present or publish any data with identifying information without the written informed consent of the individual.

B . MCBH Responsibilities

1. Documentation and Data Management: MCBH will:

Share data on diagnosis, health improvements, hospitalization, and changes in contact information, and other information with the Informed Consent and HIPAA Authorization of project participants, if requested by UC BERKELEY researchers for the Study.

UC BERKELEY Responsibilities

1. Documentation and Data Management: UC BERKELEY will:

Provide MCBH clinicians with access to the data and behavioral health information collected during the Study, with the Informed Consent and HIPAA Authorization of project participants, if requested by MCBH, and maintain data confidentiality protocols consistent with the IRB.

UC BERKELEY will provide an iPod Touch to MCBP clinicians to audio tape their sleep coaching sessions with patients.

UC BERKELEY supervisors will provide feedback on the sleep coaching sessions to MCBH clinicians to promote skill development.

2. Supplies and Equipment: UC BERKELEY will purchase and provide supplies needed for the study.

3. UC BERKELEY will promptly report any life threatening issues or client emergencies to MCBH clinical staff/case managers or to emergency medical personnel.

C ADDITIONAL TERMS

1. Independence. The independence of MCBH and UC BERKELEY will be respected by all Parties, and no Party shall act in a manner that interferes with, is inconsistent with, or undermines the independence of either entity.

2. Books and Records. The Parties shall maintain their respective books and records as required by law, and that part of such books and records which are generally available to the public will be furnished by one Party to the other upon written request.

3. Data Management. UC BERKELEY will maintain and share its Study database of current Study Data on Study Participants and any other clinical data directly related to the evaluation of the health outcomes of the Study Participants under this MOU requested from MCBH by UC BERKELEY, in accordance with legal requirements.

4. Mutual Cooperation. MCBH and UC BERKELEY will cooperate with each other in good faith to further their mutual goals of improving the health of all Project Participants.

5. Reporting: The UC BERKELEY team will provide a written report on the progress of the study to MCBH on a 6-month basis across all four years of the study.

D General Terms

1. Term and Termination

1.1 Term. The term of this Agreement is for four years beginning on the Effective Date. If an extension is needed, at least three months prior to the 48th month, the Parties will begin to negotiate in good faith to determine whether this MOU should be extended or modified. If the Parties fail to reach agreement, then this MOU will expire on the 48th month anniversary of the Effective Date.

1.2 Termination without cause. MCBH and UC BERKELEY each may terminate this Agreement with or without cause by giving at least 60 days written notice of termination ("Termination Notice") to the other Party. The effective date of termination shall be referred to as the "Termination Date."

1.3 Termination with cause. With reasonable cause, if there is a violation of this MOU by any Party, after 30 days written notice and opportunity to correct the violation, if the violation is not cured the non-violating Party may terminate this MOU with 10 days written notice of termination to the other Party. The effective date of termination shall be referred to as the "Termination Date."

2. Review of MOU: The Parties will review this MOU on an annual basis in order to determine whether any changes in its terms should be made. Each Party will consider in good faith any modifications proposed by the other Party.

3. Written Amendments. Any amendments to this MOU must be in a written document signed by all Parties.

4. Authority. MCBH represents to UC BERKELEY that the execution, delivery, and performance of this MOU have been duly authorized and that the person signing on behalf of MCBH is authorized to do so. UC BERKELEY represents to MCBH that the execution, delivery, and performance of this MOU have been duly authorized and that the person signing on behalf of UC BERKELEY is authorized to do so.

5. Dispute Resolution: A complaint by either Party to this MOU against the other Party, claiming that the other Party has violated the MOU, shall be resolved as follows:

- The Party asserting a violation made by the other Party must send a letter to the other Party specifically detailing the basis for its assertion.

- The Parties shall cooperate in good faith to reach a mutually agreeable resolution within a reasonable time not to exceed thirty (30) days If the Party asserting the MOU violation is not satisfied with the steps taken to correct the violation, the Party may submit the matter to binding arbitration with one mutually agreed upon

neutral mediator/arbitrator and otherwise in accordance with the AAA commercial arbitration rules.

- The rights to terminate this agreement shall have precedent over this Section D.5.

6. Third Party Rights. Nothing express or implied in this MOU is intended to confer, nor shall anything herein confer, upon any person other than MCBH any rights, remedies, obligations or liabilities whatsoever.

7. Notice: Any notices to be given to either Party shall be made via email or U.S. Mail.

Monterey County Behavioral Health
1270 Natividad Road
Salinas CA 93906
Attn: Katy Eckert, MBA, Monterey County Behavioral Health Bureau Chief

The Regents of the University of California, on behalf of its Berkeley campus
Sponsored Projects Office1608 Fourth St., Suite 220
Berkeley, CA 94710-1749
Attn: Noam Pines, Associate Director
Email: spoawards@berkeley.edu

8. Separate Entities: No relationship of employer and employee is created by this MOU. It being understood and agreed that UC BERKELEY and MCBH are separate entities. MCBH and its employees and contractors are not agents or employees of UC BERKELEY in any capacity whatsoever. UC BERKELEY and its staff are not the agent or employee of MCBH in any capacity whatsoever. The staff of each Party shall have no claim under this Agreement or otherwise, for seniority, vacation time, vacation pay, sick leave, personal time off, overtime, health insurance medical care, hospital care, retirement benefits, social security, disability, Workers' Compensation, or unemployment insurance benefits, civil service protection, or employee benefits of any kind against the other Party. Each Party shall be obligated to pay directly all applicable payroll taxes (including federal and state income taxes) or contributions for unemployment insurance or old age pensions or annuities which are imposed by any governmental entity in connection with the labor used or which are measured by wages, salaries or other remuneration paid to its officers, agents or employees.

9. Insurance:

The Parties shall keep in full force and effect during the Term, at each Party's own expense, insurance or in the case of the University, self-insurance with coverage as follows ("Insurance"):

Commercial Form General Liability Insurance with minimum limits as follows:

Each Occurrence	$1,000,000
Products/Completed Operations Aggregate	$2,000,000
Personal and Advertising Injury	$1,000,000
General Aggregate	$2,000,000

Workers' Compensation as required by applicable law.

Business Automobile Insurance with insurance coverage amount of $1,000,000 per occurrence will be required.

If the Insurance is written on a claims-made form, it will continue for three (3) years following termination of this Agreement.

Upon execution of this Agreement, each Party will furnish the other Party with a Certificate of Insurance (**"Certificate of Insurance"**) evidencing compliance with the insurance provisions of this MOU. Each Insurance shall be primary to any insurance or self-insurance maintained by the other Party, and the Insurance shall not be called upon to contribute to a loss covered by each Party's insurance.

10. Indemnification:

UC BERKELEY shall defend, indemnify and hold County of Monterey, its officers, employees and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damage arising out of the performance of this MOU, but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of UC BERKELEY, its officers, agents or employees.

MCBH shall defend, indemnify and hold UC BERKELEY, its officers, employees and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damage arising out of the performance of this MOU, but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of County of Monterey, its officers, agents or employees.

11. Principal Contacts: The day-to-day operation of services pursuant to this MOU may be provided by Allison Harvey, Emma Agnew and Marlen Diaz; however, the principal contacts for MCBH will be Michael Lisman.

12. Survival. The following provisions will survive the termination of this Agreement: SectionsB.4.-5., C., D.10.-11.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement.

Monterey County Behavioral Health: **UC Berkeley:**

By:_____
Signature
, MCBH

By: Noam Pines 2021.06.16 11:11:27 -07'00'
Signature
Noam Pines, Associate Director, UC BERKELEY

Date:_____

Date: 6/16/21

EXHIBITS:

Exhibit A – **Client Main Consent**

Exhibit B – **Provider Main Consent – First Generation**

Exhibit C – **Provider Main Consent – Second Generation**

Exhibit D – **Client and Provider Audio Consent**

Exhibit A

Client Main Consent

UNIVERSITY OF CALIFORNIA, BERKELEY

DEPARTMENT OF PSYCHOLOGY
BERKELEY, CALIFORNIA 94720-1650
2121 Berkeley Way #3302
TEL: (510) 643-3797;
FAX: (510) 642-5293

Consent to Participate in Research

Implementing and Sustaining a Transdiagnostic Sleep and Circadian Treatment to Improve Severe Mental Illness Outcomes in Community Mental Health

Key Information

- You are being invited to participate in a research study. Participation in research is completely voluntary.
- The purpose of the study is to explore the barriers and facilitators of the implementation of a validated sleep treatment in a new setting.
- The study will take up to a total of 5.58 hours. You will receive a sleep treatment and you will also be asked to fill out some questionnaires.
- Risks and discomforts may include becoming upset due to talking about the difficulties you are experiencing relating to your mental health. Note that while there is a small chance that the confidentiality of the information collected could be compromised; we will take care to prevent this from happening.
- It is hoped that your participation in this treatment will help to improve your mental health and sleep symptoms. However, it is possible that you will not directly benefit from participating in this study.

My name is Professor Allison Harvey. I am a faculty member in the Department of Psychology, University of California, Berkeley. I would like to invite you to take part in the research that is underway. This study is a collaboration between your community mental health center and my group at the University of California, Berkeley. The aim of this study is to explore the barriers and facilitators of the implementation of a validated sleep treatment in a new setting. We are hoping that this research will help us learn how to best implement new treatments like the sleep treatment in your community mental health center and other community settings.

Description of the research study

If you agree to take part in this research, before you begin the main part of the study, you will need to have the following screening procedure to find out if you can be in the main part of the study:

We will invite you to complete an interview. The interview will be conducted either in a private room at your community mental health center or over the phone. During this interview, we will ask you questions about your medical and psychological history, as well as some sensitive and personal questions about some of your other behaviors. Additionally, we will ask you to fill out a number of questionnaires. You do not have to answer any questions you do not feel like answering. The interview will take approximately 45 to 60 minutes. You may take a break at any time during the interview.

With your permission, these assessments will be audio-recorded. If you are eligible for and choose to enroll in the study, the sleep coaching sessions will also be audio-recorded, with your permission. This is done so that we can ensure the assessments and sleep coaching sessions are completed to the highest standards, and so that we can ensure that the assessments are conducted in a standardized manner and that everyone receives the same level of support in sleep coaching sessions. The audio recordings are encrypted and stored on a password-protected computer, which means that no one can listen to them except for project staff.

If it appears that you might benefit from our treatment, you will be invited to participate in the study. During the main part of the study, if you agree to participate, you will be randomly assigned to one of two conditions. While both groups will receive the same scientifically validated psychological treatment (which does not involve a medication), the conditions differ in terms of the timing that the treatment is offered. One group begins the treatment immediately after the first interview. The other group will be asked to complete two more interviews at 4 weeks after the first interview, before beginning the treatment phase. The content of these interviews is similar to the first interview and will take approximately 45 to 60 minutes. You may take a break during the interview. The delayed treatment group plays an important role in the research. It is the comparison against which the sleep treatment is compared.

During the treatment phase, you will be attending a 20 minute session, once per week, for 4 weeks, in your usual care setting at your community mental health center. In each session, the sleep coach will work together with you to determine what is causing the sleep problems negatively affecting your mental health. Then, with your sleep coach, you will develop ways to change those things that are contributing to these problems. This study will not give you medication and all parts of the treatment involve talking and working with your sleep coach.

Once you complete the sleep coaching sessions, we will interview you again to see how you are doing after the treatment. We would like to do this on two occasions; 2 weeks after sleep coaching has finished and again 6 months after the treatment has finished. These interviews will involve the same activities as the first interview and will take approximately 45 to 60 minutes. You may take a break during the interview.

Summary of total time commitment

All participants will attend:

Pre-treatment interview: maximum of 45-60 minutes for interview

Treatment sessions: 4 sessions (20 minutes each)

2-weeks post-treatment interview: maximum of 45-60 minutes for interview

6 months post-treatment interview: maximum of 45-60 minutes for interview

Mid-treatment interview: 15 minutes

Some participants will attend 1 additional interview:

8 weeks after first interview: maximum of 45-60 minutes for interview

Total time commitment *without* additional interviews: 4.58 hours

Total time commitment *with* additional interviews: 5.58 hours

Risks

Occasionally a participant can find it upsetting to talk about the difficulties they are experiencing relating to their mental health. You may choose to not answer or skip any question you do not wish to answer, and you have the right to discontinue your involvement in the study at any time. Note that while there is a small chance that the confidentiality of the information collected could be compromised; we will take care to prevent this from happening.

Benefits

It is hoped that your participation in this treatment will help to improve your mental health and sleep symptoms. However, it is possible that you will not directly benefit from participating in this study. The research we are doing may help improve treatments for sleep and mental health symptoms in the future, and may help other individuals suffering from sleep and mental health symptoms.

Rights

If you are receiving other services within your community mental health center, whether or not you choose to take part in this research will have no bearing on your standing within the system. There will be no penalty, and you will not lose any benefits to which you would otherwise be entitled.

Compensation/Costs

In gratitude of your time and inconvenience and to cover any travel expenses you may have incurred, we would like to offer you:

At the post-sleep coaching interview:

- "Berkeley Sleep Team" t-shirt

For all interviews and sleep coaching sessions:

- Assistance with transportation to the center where your sleep coaching sessions and interviews are held

Confidentiality

All of the information that I obtain from you during the research will be kept as confidential as possible. Your information will be de-identified and stored in a secure Health Insurance Portability and Accountability Act (HIPAA) compliant server at all times. All data collected from you will be identified in study records by a code number and your individual identity that is linked with the code will be stored separately in a locked file and/or encrypted spreadsheet. I will store the audio recordings on a secure computer. I will not use your name or other identifying information in any reports of the research. After this research is completed, I may save the data, recordings and my notes for use in future research by myself and others in the research group. However, the same measures described above will apply to future storage and use of the materials. In addition, all identifiers will be removed from the identifiable private information. After de-identification of the study data in accordance with the Health Insurance Portability and Accountability Act, the information could be used for future research studies or distributed to other investigators for future research studies without additional informed consent from you. Note that while there is a small chance that the confidentiality of the information collected could be compromised; we will take care to prevent this from happening.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing certain information about you for legal or ethical reasons. For example, we will report information about child abuse, elder abuse, or intent to hurt yourself or others. If an insurer, employer, or other person obtains your written consent to receive research information, we cannot use the Certificate to withhold that information. In addition, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects or information needed by the FDA, e.g., for quality assurance or data analysis.

Rights and Other Information

Your participation in this research is voluntary. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. If you participate throughout this study, you may refuse to answer any question(s) that might make you feel uncomfortable.

I would like you to be aware that the sleep study has special criteria for selecting people to participate, so some people may be invited to participate, and it may be the case that some who are interviewed are not a good fit for the study. Whether or not you are invited to be a sleep study participant, we will be available for any questions you have about sleep. With your

permission, information about you will be kept because it will help us with the research, but identifiable information about participants is never given in publications.

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

Authorization for Release/Exchange of Mental Health and Medical Information

I authorize the Berkeley Sleep Team at the University of California, Berkeley and my community mental health center to release/exchange information pertaining to mental health diagnosis or treatment, information pertaining to drug and alcohol abuse diagnosis or treatment, and/or other medical information for the purpose of conducting research-related treatment (sleep coaching).

This Authorization to release mental health and medical information is voluntary and may be revoked at any time. The revocation must be in writing, signed by you or your client representative, and mailed to the Berkeley Sleep Team Office at 2121 Berkeley Way #3302 Berkeley, CA 94720. The revocation will take effect when the Berkeley Sleep Team office receives it, except to the extent the Berkeley Sleep Team or others have already relied on it.

Unless otherwise revoked, this Authorization expires 24 months after the date of you signing the form.

_____

Signature Date: Time

Questions

If you have any questions about the research, you may call me, Allison Harvey, at (510) 643-3797 or email: aharvey@berkeley.edu. If you agree to take part in the research, please sign the form below. Please keep the other copy of this agreement for future reference.

If you have any questions about your rights or treatment as a participant in this research project, please contact the University of California at Berkeley's Committee for Protection of Human Subjects at (510) 642-7461, or e-mail: subjects@berkeley.edu. The link to this study's page on clinicaltrials.gov is [INSERT LINK].

SIGNATURE OF RESEARCH SUBJECT

If you agree to take part in the research, please sign the form below. Please keep the other copy of this agreement for future reference.

_____

Name Date:

_____

Signature Date:

If you agree to allow the research group to keep your information for use in future research, please sign the form below. Please keep the other copy of this agreement for future reference.

_____

Name Date:

_____

Signature Date:

SIGNATURE OF INVESTIGATOR OR DESIGNEE

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____

Name Date:

_____

Signature Date:

Exhibit B

Provider Main Consent – First Generation

UNIVERSITY OF CALIFORNIA, BERKELEY

DEPARTMENT OF PSYCHOLOGY
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Key Information

- You are being invited to participate in a research study. Participation in research is completely voluntary.
- The purpose of the study is to explore the barriers and facilitators of the implementation of a validated sleep treatment in a new setting.
- The study will take up to a total of 25.17 hours and you will be asked to learn and implement a sleep treatment.
- Risks and discomforts may include difficulty working with a new treatment. Note that while there is a small chance that the confidentiality of the information collected could be compromised; we will take care to prevent this from happening. It is hoped that your participation in this study will help you develop skills in improving sleep for people who have been diagnosed with a mental illness. Also, the results from the study may help us best learn how to implement new treatments such as our sleep treatment within community clinic settings.

My name is Professor Allison Harvey. I am a faculty member in the Department of Psychology, University of California, Berkeley. I would like to invite you to take part in the research that is underway. This study is a collaboration between your community mental health center and my group at the University of California, Berkeley. The aim of this study is to explore the barriers and facilitators of the implementation of a validated sleep treatment in a new setting. We are hoping that this research will help us learn how to best implement new treatments like the sleep treatment in your community mental health center and other community settings.

Description of the research study

If you agree to take part in this research, you will begin by receiving training in the Adapted Transdiagnostic Sleep and Circadian Rhythm Intervention (Adapted TranS-C). The training is a workshop (4 hours) and will be provided either by myself (Dr. Allison Harvey) or another trained member of the UC Berkeley team. Prior to the training, we will ask you to read a treatment manual and patient workbook. At the beginning of the training you will complete a questionnaire about your basic demographics. The training will be audio and visually recorded and edited for training future generations of Adapted TranS-C providers. You will not be visually recorded as the camera will be focused on the UCB research member conducting the training.

Once you have been trained, you will be asked to refer consumers you believe to potentially benefit to our treatment program. Should a consumer meet the eligibility criteria for participation, we will let you know. Then, eligible consumers will be randomly assigned to one of two conditions: immediate or delayed treatment. We will notify both you and the consumer of their condition once it is assigned. Consumers in the immediate treatment condition will start Adapted TranS-C with you right away; those who are in the delayed treatment condition will partake in several assessments and, you will be asked to start Adapted TranS-C with them in eight months, once the immediate condition participants have completed their final follow up assessment. Half way through each patient's time in sleep coaching, you will administer a very brief set of questionnaires. Throughout your time as a provider, weekly 60-minute group supervision will be offered. Supervision may include symptom monitoring and reviewing audio tapes of sessions. At 6 months and 12 months after completing the study, you may be asked to complete an additional brief follow-up interview to see how you are feeling about the intervention.

In addition to providing treatment, you may be asked if you are interested in becoming a trainer yourself for the second phase of the study. If this is the case, and you wish to train others, you will lead a training where you will train other community mental health center providers to become Adapted TranS-C providers. Following this training, Dr. Harvey or another UC Berkeley team member will facilitate, review tapes and provide feedback.

If you grant permission, it is our hope that all sessions and trainings will be audio recorded.

Summary of total time commitment:

Human Subjects Training: 4 hours

Adapted TranS-C Training: 4 hours

Patient Screening: Maximum of 15 minutes

Treatment Sessions: Four 20-minute sessions with six clients (8 hours total)

Administer mid-treatment interview: Maximum of 15 minutes

Supervision: 1-hour weekly supervision meetings

Sustainment Phase 6-Month Follow-Up Interview: Maximum of 35 minutes (20% will be randomly selected to complete semi-structured interview, 30 minutes)

Sustainment Phase 12-Month Follow-Up Interview: Maximum of 35 minutes (20% will be randomly selected to complete semi-structured interview, 30 minutes)

Total time commitment *without* semi-structured interview: 24.17 hours

Total time commitment *with* semi-structured interview: 25.17 hours

Risks, benefits and costs

Occasionally a participant can find it difficult to work with a new treatment. You may always ask for help and assistance from the UC Berkeley team, and you have the right to discontinue your involvement in the study at any time. There is always a small chance that the confidentiality of the information collected could be compromised; however, we will take care to prevent this from happening.

It is possible that you will not directly benefit from participating in this study. It is hoped that your participation in this study will help us best learn how to implement new treatments such as our sleep treatment within community clinic settings.

Compensation/Costs

In gratitude of your time, we would like to offer you a UC Berkeley Sleep Team t-shirt.

Confidentiality

All of the information that I obtain from you during the research will be kept as confidential as possible. Your information will be de-identified and stored in a secure Health Insurance Portability and Accountability Act (HIPAA) compliant server at all times. All data collected from you will be identified in study records by a code number and your individual identity that is linked with the code will be stored separately in a locked file and/or encrypted spreadsheet. I will store the audio recordings on a secure computer. I will not use your name or other identifying information in any reports of the research. After this research is completed, I may save the data, recordings and my notes for use in future research by myself and others in the research group. However, the same measures described above will apply to future storage and use of the materials. In addition, all identifiers will be removed from the identifiable private information. After de-identification of the study data in accordance with the Health Insurance Portability and Accountability Act, the information could be used for future research studies or distributed to other investigators for future research studies without additional informed consent from you. Note that while there is a small chance that the confidentiality of the information collected could be compromised; we will take care to prevent this from happening.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or

local civil, criminal, administrative, legislative, or other proceedings. Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing certain information about you for legal or ethical reasons. For example, we will report information about child abuse, elder abuse, or intent to hurt yourself or others. If an insurer, employer, or other person obtains your written consent to receive research information, we cannot use the Certificate to withhold that information. In addition, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects or information needed by the FDA, e.g., for quality assurance or data analysis.

Other Information

Your participation in this research is voluntary. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. If you participate throughout this study, you may refuse to answer any question(s) that might make you feel uncomfortable.

If you have any questions about the research, you may call me, Allison Harvey, at (510) 643-3797 or email: sleepteamucb@gmail.com. If you agree to take part in the research, please sign the form below. Please keep the other copy of this agreement for future reference.

If you have any questions about your rights or treatment as a participant in this research project, please contact the University of California at Berkeley's Committee for Protection of Human Subjects at (510) 642-7461, or e-mail: subjects@berkeley.edu. The link to this study's page on clinicaltrials.gov is [INSERT LINK].

SIGNATURE OF RESEARCH SUBJECT

Please print and sign your name below to indicate that you have read this consent form and agree to take part in this research.

_____

Name Date:

_____

Signature Date:

SIGNATURE OF INVESTIGATOR OR DESIGNEE

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____

Name Date:

_____

Signature Date:

Exhibit C

Provider Main Consent – Second Generation

UNIVERSITY OF CALIFORNIA, BERKELEY

DEPARTMENT OF PSYCHOLOGY
BERKELEY, CALIFORNIA 94720-1650
2121 Berkeley Way #3302
TEL: (510) 643-3797;
FAX: (510) 642-5293

Consent to Participate in Research

Implementing and Sustaining a Transdiagnostic Sleep and Circadian Treatment to Improve Severe Mental Illness Outcomes in Community Mental Health

Key Information

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Once you have been trained, you will be asked to refer consumers you believe to potentially benefit to our treatment program. Should a consumer meet the eligibility criteria for participation, we will let you know. Then, eligible consumers will be randomly assigned to one of two conditions: immediate or delayed treatment. We will notify both you and the consumer of their condition once it is assigned. Consumers in the immediate treatment condition will start Adapted TranS-C with you right away; those who are in the delayed treatment condition will partake in several assessments and, you will be asked to start Adapted TranS-C with them in eight months, once the immediate condition participants have completed their final follow up assessment. Half way through each patient's time in sleep coaching, you will administer a very brief set of questionnaires. Throughout your time as a provider, weekly 60-minute group supervision will be offered. Supervision may include symptom monitoring and reviewing audio tapes of sessions. At 6 months and 12 months after completing the study, you may be asked to complete an additional brief follow-up interview to see how you are feeling about the intervention.

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Compensation/Costs

In gratitude of your time, we would like to offer you a UC Berkeley Sleep Team t-shirt.

Confidentiality

All of the information that I obtain from you during the research will be kept as confidential as possible. All data collected from you will be identified in study records by a code number and your individual identity that is linked with the code will be stored separately in a locked file and/or encrypted spreadsheet. I will store the audio recordings on a secure computer. I will not use your name or other identifying information in any reports of the research. After this research is completed, I may save the recordings and my notes for use in future research by myself and others in the research group. However, the same measures described above will apply to future storage and use of the materials. Identifiers might be removed from the identifiable private information. After such removal, the information could be used for future research studies or distributed to other investigators for future research studies without additional informed consent from you. Note that while there is a small chance that the confidentiality of the information collected could be compromised; we will take care to prevent this from happening.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing certain information about you for legal or ethical reasons. For example, we will report information about child abuse, elder abuse, or intent to hurt yourself or others. If an insurer, employer, or other person obtains your written consent to receive research information, we cannot use the Certificate to withhold that information. In addition, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects or information needed by the FDA, e.g., for quality assurance or data analysis.

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Your participation in this research is voluntary. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise

entitled. If you participate throughout this study, you may refuse to answer any question(s) that might make you feel uncomfortable.

If you have any questions about the research, you may call me, Allison Harvey, at (510) 643-3797 or email: sleepteamucb@gmail.com. If you agree to take part in the research, please sign the form below. Please keep the other copy of this agreement for future reference.

If you have any questions about your rights or treatment as a participant in this research project, please contact the University of California at Berkeley's Committee for Protection of Human Subjects at (510) 642-7461, or e-mail: subjects@berkeley.edu. The link to this study's page on clinicaltrials.gov is [INSERT LINK].

SIGNATURE OF RESEARCH SUBJECT

Please print and sign your name below to indicate that you have read this consent form and agree to take part in this research.

_____

Name Date:

_____

Signature Date:

SIGNATURE OF INVESTIGATOR OR DESIGNEE

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____

Name Date:

_____

Signature Date:

Exhibit D

Client and Provider Audio Consent

UNIVERSITY OF CALIFORNIA, BERKELEY

DEPARTMENT OF PSYCHOLOGY
BERKELEY, CALIFORNIA 94720-1650
2121 Berkeley Way #3302
TEL: (510) 643-3797;
FAX: (510) 642-5293

Audio Release Consent Form

Thank you for agreeing to participate in this study. As part of this project, we would like to make audio recordings of the sessions and supervision calls. Your name will not be identified, although it is possible that your voice could be recognized by those listening to the tapes. The audiotapes will be stored confidentially and will be only accessed by the research staff unless you consent otherwise. You may listen to any or all of your audiotapes before agreeing to let them be heard. You can also have any or all of your audiotapes erased. Consent to recordings is not mandatory for participation in the study but it is helpful for measuring treatment provider fidelity and ad hoc modifications made to the treatment, and will be used to provide supervision to the provider.

I consent to allow the researchers to audio record my treatment sessions and (for providers) supervision calls.

Audio _____ Initials

I consent to allow the researchers to use the recordings of the assessment and treatment sessions for research purposes. This includes the researchers rating the tapes for adherence to the protocol, and getting suggestions for improving the sessions from a supervisor. **Only researchers involved in this project** will hear these recordings, and my name will not be linked to this recording.

Audio _____ Initials

I understand that at no time will this audio recording be copied with the intention of distribution to individuals beyond those directly involved in the research project, and my name will not be linked to this recording.

I have read this consent form and agree to all actions I have initialed above.

_____
Name (please print)

_____
Signature Date: