PROJECT MIMIC

Maximizing Implementation of Motivational Incentives in Clinics (MIMIC) Study

Organization Participation Agreement

Version Date: December 12, 2018

Purpose

The purpose of this Organization Participation Agreement is to document in writing your opioid treatment center's agreement to participate in Project MIMIC (**M**aximizing **I**mplementation of **M**otivational **I**ncentives in **C**linics), a research study funded by the National Institute on Drug Abuse (NIDA). Project MIMIC tests two different strategies to train opioid treatment centers in contingency management, a treatment approach that provides patients with motivational incentives for complying with treatment. Project MIMIC will recruit 30 community-based opioid treatment clinics across New England. The study is being conducted by researchers at Brown University and RTI International, in partnership with the New England Addiction Technology Center.

What does participation in Project MIMIC entail for this opioid treatment center and its staff?

Because funds for this study are provided by NIDA, there will be no financial cost to the opioid treatment center for participating. If your center chooses to participate, your center will receive several forms of support at no cost to you: a) comprehensive state of the art training in CM provided by the New England ATTC, a SAMHSA-funded training center based at Brown University; b) two tablets for completing study assessments; c) supplies to provide CM reinforcement to patients; and d) monetary compensation paid to designated CM leaders and providers for completion of study assessments.

In exchange, your center must agree to recommend 2 center leaders and 2-5 center staff to participate in the study. Center leaders and center staff will receive informed consent forms describing the study and will have the choice of whether to participate. All participating center leaders will complete study measures. All participating center providers will submit audio recordings of CM sessions, receive performance feedback regarding the CM sessions, and complete study measures. Your center must also agree to have front-desk staff actively inform newly admitted patients about the study to support recruitment. Finally, your center must agree to be randomly assigned to one of the project's two conditions. All centers will receive the current state-of-the-art training and support package offered by the Addiction Technology Transfer Center (ATTC condition). In addition, half of the participating centers will be randomly assigned to receive a more intensive CM training and support package, which will include an *external facilitator* for the team of staff working on the project and *performance incentives* for the providers implementing CM with clients (Enhanced ATTC condition). We do not know whether the Enhanced ATTC condition is an effective use of time or financial resources, but Project MIMIC seeks to help address this question.

As part of Project MIMIC, randomization occurs at the center-level rather than staff-level. This means that each opioid treatment center will be randomly assigned to a condition using a process akin to flipping a coin. As a result, all opioid treatment center staff within your agency will be randomly assigned to the *same* condition. Below is a brief description of the two conditions and what the study would entail for your opioid treatment center and its staff.

1) ATTC Training Condition

All participating centers will have their designated staff receive comprehensive training from the New England Addiction Technology Transfer Center that consists of two active phases: Preparation and Implementation.

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During the 5-month Preparation phase, the two designated leaders at each opioid treatment center will be asked to create a definition of weekly CM compliance for clients and a target weekly CM benchmark for providers. Designated leaders will also be asked to complete an Organizational Background Form. Following completion of these steps, each center will be offered a full day of didactic training in CM. All OUD treatment providers and staff are welcome to attend this training at no cost and continuing education credits will be provided. A post-training CM Knowledge assessment will be administered to all providers attending the training. The designated treatment providers will be required to correctly answer 75% of the questions: if they do not, they will receive additional personalized support from the CM support team. Shortly after the training, the ATTC's CM training team will offer monthly condition-specific coaching calls for all center providers and leaders. These calls will continue throughout the Preparation and Implementation phases of Project MIMIC.

By the end of the Preparation phase, each of the particicpating treatment providers will be required to submit two role plays of themselves demonstrating CM skills. These CM role plays will be rated and performance feedback will be provided by the ATTC's CM training team. Center providers will be required to demonstrate the ability to proficiently deliver CM delivery before they can progress to the project's implementation phase. Participating center providers and leaders will also be asked to complete surveys about their opinions of the organization's support for CM implementation, their attitudes towards CM, as well as some basic socio-demographic questions. Participating center providers and leaders will receive $25 each for completing the first survey and $20 for completing the second survey.

During the project's 9-month implementation phase, front desk staff at the opioid treatment center must agree to actively inform newly admitted patients about the project. Each opioid treatment center must have sufficient patient flow to recruit about 1 new patient per week (25 patients over a 6-month period). In total, Project MIMIC will recruit 750 patients (30 centers * 25 patients each = 750 patients). Centers are encouraged to universally offer CM to all newly admitted patients regardless of whether or not they participate in the study.

Also during the project's 9-month Implementation phase, the participating center providers will begin offering CM to patients. Center providers must record their delivery of every CM session in the patient medical record using a Self-Report Data Extraction Form. Participating providers will also be asked to submit one audio recording of themselves delivering CM per month: these audio recordings will be submitted using Virtru encrypted email. Audio recordings will not identify patient's names and will be assigned numeric codes to protect patient's privacy. Recordings be reviewed by the project's research staff to assess how well each center provider is delivering CM. Each designated center provider will receive performance feedback on their submitted recordings from research staff. The recordings will be destroyed at the end of the project. By the end of the implementation phase, one of the designated opioid treatment center leaders will be asked to extract data from the patient medical records of the 25 recruited patients and enter the data into a Medical Record Data Extraction Form. Data entered into these forms will be de-identified. Participating center providers and leaders will be again asked to complete a brief survey about their opinions of the organization's support for CM implementation. Participating center providers and leaders will receive $10 each for completing this survey.

In order to assess the extent to which center providers continue to implement CM following the implementation phase of Project MIMIC, one of your center's designated CM leaders will be asked 12-months post-implementation to submit a Medical Record Data Extraction Form on 25 patient medical charts selected at random.

2) Enhanced ATTC Training Condition

Half of the centers will be randomly assigned to receive an Enhanced ATTC condition. We do not know if this condition is an effective use of time or financial resources, but Project MIMIC will help understand this issue. All the centers randomized to the enhanced ATTC condition will receive the services described above under "ATTC training condition." In addition, centers in this condition will receive external facilitation and participating center providers will have the opportunity to earn bonuses for achieving pre-defined performance criteria.

During the preparation phase, participating center leaders will be expected to participate in a full day planning meeting with the external facilitator. The external facilitator will also hold site-specific monthly facilitation calls for participating center providers and leaders.

During the implementation phase, the monthly site-specific facilitation calls will continue. In addition, the participating center providers will have the opportunity to earn bonuses based upon data entered in the medical record and the quality of CM delivery in the submitted audio recordings. Specifically, participating center providers will earn US $200 for each patient enrolled in the study that receives 10 or more CM sessions (i.e., CM Exposure), as verified by the data entered in the Medical Record Data Extraction Form. In addition, center providers will earn US $50 each month that they demonstrate skillful delivery of the submitted CM session (i.e., CM Skill), using an average score of 5.8 or higher on a well-validated Contingency Management Competence Scale that scores sessions from 1-7 on CM skills. These benchmarks are based on levels of CM exposure and skill that were found to be attainable in randomized clinical trials. The monetary payments are based on levels found effective in prior studies of provider performance incentives. ***It is not expected that providers will attain bonuses for every patient or every submitted audio recording.***

The maximum amount earned by participating center providers will vary as a function of caseload and quality of CM delivery, defined as a combination of CM Exposure and CM Skill. As an example, if a participating center provider works with the maximum caseload of 13 patients over a 9-month period, the maximum level of performance incentives for the highest quality CM delivery would be $2600 for CM Exposure ($200 * 13 patients = $2600) and $450 for CM Skill ($50 * 9 months = $450); in total, a participating center provider with a caseload of 13 patients who demonstrates the highest quality CM delivery could earn a maximum of $3,050 in performance bonuses. Alternately, if a participating center provider works with 5 recruited patients over a 9-month period, the maximum level of performance incentives for the highest quality CM delivery would be $1000 for CM Exposure ($200 * 5 patients = $1000) and $450 for CM skill ($50 * 9 months = $450); in total, a participating center provider with a caseload of 5 patients and the highest quality CM delivery could earn a maximum of $1,450 in performance bonuses. Providers may choose whether they prefer to receive these payments via cash, check, or Clincard, a rechargeable debit card that functions akin to a Mastercard.

Near the end of the implementation phase, leaders will again have a full-day meeting with the external facilitator focused on development of a plan to sustain CM after the removal of project support.

How long will the MIMIC study last?

This study is funded through August of 2023. Each participating center will receive active project support for 14 months, beginning from the time that the Organization Participation Agreement is signed.

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How do we participate in the MIMIC study?

We ask that the appropriate decision makers at each opioid treatment center review this Organization Participation Agreement and direct questions to the Brown University Principal Investigator. Once all your questions have been addressed, we hope that you will agree to participate by signing the Organization Participation Agreement and returning it to:

Dr. Sara J. Becker
MIMIC Study, Multiple Principal Investigator
Center for Alcohol and Addictions Studies
121 South Main Street
Providence, RI 02912
E-mail: sara_becker@brown.edu
Phone: (401) 863-6604

If you sign this Organization Participation Agreement, we ask that you work with your front desk staff to ensure that newly admitted patients are actively administered Consent to Contact forms in order to support study recruitment. The goal is to recruit about 1 patient per week (25 patients over a 6-month period). We also ask that you designate the two CM leaders and 2-5 center providers that you want to complete the activities outlined in this agreement. Please enter the information about the designated staff below.

ORGANIZATION STAFF ANTICIPATED TO PARTICIPATE IN THE MIMIC PROJECT

Staff Name	**Staff Contact Information**	**Staff Role (CM Provider, Leader)**
	Email: Phone:	
	Email: Phone:	
	Email: Phone:	
	Email: Phone:	
	Email: Phone:	
	Email: Phone:	
	Email: Phone:	

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ACKNOWLEDGEMENT OF PROJECT UNDERSTANDING AND AGREEMENT

The organization listed below understands what key activities are to be completed as part of project participation and agrees to participate in Project MIMIC.

Opioid Treatment Center Name:	
Opioid Treatment Center Address:	
Opioid Treatment Center Signing Official (Name):	
Opioid Treatment Center Signing Official (Signature):	
Date:	

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CONSENT FOR RESEARCH PARTICIPATION
Patient Consent

Implementing Contingency Management in Opioid Treatment Centers across New England: A Hybrid Type 3 Trial
Version Date: December 12, 2018

KEY INFORMATION:

You are invited to take part in a research study conducted by Brown University, in partnership with RTI International and the New England Addiction Technology Transfer Center. Your participation is voluntary.

- PURPOSE: This study is comparing two different ways to train staff at opioid treatment centers in contingency management (CM). CM is a treatment approach that provides patients with prizes for complying with treatment. The goal is to see if the type of training offered to opioid treatment centers can improve the delivery of CM and the outcomes of patients.
- PROCEDURES: You will be asked to answer questions about yourself at three different timepoints. Today, you will answer questions about your substance use over the past 90 days, problems you've experienced related to your substance use, your mental health, and your socio-demographics. You will then receive 12 weeks of CM treatment. In order to see how well staff are delivering CM, we ask your permission to audio record your sessions. At two additional times, you will again answer questions about your substance use and problems related to your substance use.
- TIME INVOLVED: The study will take you about 6 hours. You will complete an assessment today for about 1 hour, and two brief follow-up assessments for about 30 minutes each. You will also receive up to 12 CM sessions that will last 15-20 minutes each.
- COMPENSATION: You will receive up to $65 for completing assessments. You will also have the opportunity to earn prize draws in CM sessions. A patient who attends all 12 CM sessions and fully complies with treatment will earn 78 prize draws. On average, each draw is worth about $2 in prizes.
- RISKS: It is possible that you may experience emotional distress when answering questions about your substance use, mental health, or substance-related problems. There is a risk of loss of privacy that could lead to legal consequences if disclosed.
- BENEFITS: This study may not benefit you directly. This study might improve the outcomes of future patients in opioid treatment clinics by improving the delivery of CM.
- ALTERNATIVES TO PARTICIPATION All patients will receive standard medication-assisted treatment at the opioid treatment center. In addition, all patients will be offered CM, regardless of participation in the study. If you do not want CM sessions, you can request to receive medication-assisted treatment without prize draws.

1. Researcher(s):

PRINCIPAL INVESTIGATOR: Sara Becker, Ph.D. **Phone:** (401) 863-6604

2. What is this study about?

The purpose of this study is to compare two different ways to train opioid treatment centers in

contingency management (CM). CM is a treatment approach that has been shown to work in multiple research studies. It provides patients motivational incentives (or prizes) for complying with treatment. You are being asked to participate in this study because you were recently admitted to a participating opioid treatment center.

All participating opioid treatment centers receive state-of-the-art training in CM. We will enroll 30 opioid treatment centers and each opioid treatment center will enroll 25 patients (30 * 25 = 750 patients). This study is sponsored by the National Institute on Drug Abuse.

3. What will I be asked to do?

Today, you will be asked to complete questionnaires about your substance use over the past 90 days, any substance-related problems you have experienced, and your mental health. You will also be asked some basic demographic questions about yourself. Completing these questionnaires will take about an hour.

Three months and six months from today, you will complete brief questionnaires about your substance use and any substance-related problems over the phone. You will also be asked to provide a urine screen. You may choose whether you prefer to provide the urine screen at the participating opioid treatment center or at the Brown University research lab. In total, these sessions should take about 30 minutes each.

If you enroll in this study, you will receive the standard medication-assisted treatment offered at the opioid treatment center. In addition, you will receive CM sessions weekly for 12 weeks. Each CM session will last about 15-20 minutes and will consist of three elements: a) you will receive feedback on your compliance with treatment; b) you will learn whether your compliance was high enough to earn a prize draw; and c) you will either receive the prize draw immediately or will learn what you need to do to earn a draw at the next session. If you earn a prize draw, your odds of winning a prize are 1 in 2. Prizes range in value with small prizes worth $1 (odds of winning are 2 in 5), medium prizes worth $20 (odds of winning are 4 in 50), and a large prize worth $100 (odds of winning are 1 in 500). A typical draw is worth $2 in prizes. You will pick your prize from a cabinet. Each week that you attend your CM session and meet the compliance goal, you will earn an extra draw. Each week that you miss your session or miss the compliance goal, the number of draws gets reset to 0. If you attend all 12 sessions and fully comply with treatment, you will earn a maximum of 78 prize draws. On average, this would result in $156 worth of prizes.

Your provider will occasionally ask permission to audio record your CM sessions. The reason for audio recording is so that research staff can evaluate how well your provider delivers CM. The audio tape will be sent to research staff using encrypted email and stored on a secure server at Brown University. The tape will be erased at the end of the project. You may refuse to audio record your sessions at any time.

4. Will I be paid?

If you choose to enroll, you will receive $20 after completing today's questionnaires. You will receive another $20 for completing questionnaires 3 months from now and another $25 for completing questionnaires 6 months from now. In total, you can earn up to $65 for completing the study assessments. All payments for study assessments will be made via a rechargeable gift card. If you leave the study early, or if we have to take you out of the study, you will be paid for only those assessments you completed.

You will also have the ability to earn up to 78 prize draws as part of your CM sessions. On average, each prize draw is worth about $2 in prizes. If you leave the study early, or if we have to take you out

of the study, you will be paid for only those assessments you completed. You will also only earn CM prize draws when you attend sessions and meet the compliance goal.

Most of the clinical services that you will receive during this research study are considered "routine clinical services" that you would have received even if you were not in the research study. Examples include your medication and any counseling sessions that you receive at the opioid treatment center. These services will be billed to your health insurance. You will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

5. What are the risks?

In this study we will be asking you about your substance use, problems related to your substance use, and your mental health. Some of these questions may make you uncomfortable, or bring up unpleasant feelings or memories.

You should also be aware that all opioid treatment centers participating in this study will receive financial support to cover the costs of the CM prize draws. All centers will also receive intensive training in CM free of charge. In addition, providers at half the centers will have the chance to earn performance bonuses based on how well they deliver CM. The amount providers can earn will depend on their caseload and skill in CM delivery. A provider with the maximum caseload of 13 patients who consistently delivers CM with the highest level of skill can earn a maximum of $3,050. Providers can earn incentives whether or not you comply with treatment, so you should not feel pressured to change your behavior in any way.

You may choose not to answer any questions and you may stop your participation in the study at any time. You may also request to speak with the Principal Investigator, Sara Becker, Ph.D., a licensed clinical psychologist, at any time if you become upset or experience emotional distress. There is also a risk of loss of privacy or confidentiality of these sensitive data, which could potential lead to adverse legal consequences if disclosed. We take this risk very seriously, and we will take steps to protect your information. We describe the steps we will take in Section 7 “How will my information be protected”.

6. What are the benefits?

This study may not benefit you personally. The data collected in this study could help to inform how opioid treatment centers are trained in CM. This could potentially help other patients in the future by improving how well CM is delivered.

7. How will my information be protected?

All of your records from this study will be treated as private records. The records will be protected according to the rules of Brown University. Your name will not be on any of the questionnaires. All information will be identified only by a code number, not your name. Information collected during the assessments are treated as confidential and will not be shared. All data collected electronically will be stored on a secure server. Only researchers working on this study will have access to the information provided by you.

Your provider will occasionally ask your permission to audio record sessions. We will use a digital recorder and will store the audio recordings on a secure server. We will keep this information confidential. Recordings will be destroyed at the end of the project.

Your records from this study (research records) will be maintained separately from your medical records. A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose research information that may identify you, even by court subpoena, in any federal, state, or local, civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any compulsory legal demands for research information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself, or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive such information, then the researchers may not use the Certificate to withhold that information. This means that you must actively protect your own privacy by not sharing information about your participation.

There are times when the law might require Brown University to release your information without your permission. To give you some examples, if you disclose information that makes us suspect abuse or neglect of your children, State Law requires that we report that information to the Department of Children, Youth, & Families (DCYF). If you disclose information that makes us concerned that you are a harm to yourself/themselves or others, we will be required to share that information with a licensed clinician.

Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

This study is a cluster randomized clinical trial in which organizations are randomly assigned to one or more different training strategies. A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

8. Are there any alternatives to this study?

All patients will receive the standard medication-assisted treatment offered at the opioid treatment center. In addition, the opioid treatment center has agreed to offer all new patients CM prize draws. You will be offered the CM prize draws whether or not you choose to participate in this study. You may choose not to receive CM and may opt out of the CM prize draws at any time. Whether or not you participate in the study, you will receive the standard of care at the opioid treatment center, which may or may not receive CM.

9. What if I want to stop?

Taking part in research is voluntary. You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with the opioid treatment center will not be affected.

10. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call the Principal Investigator

of the program, Dr. Sara Becker at (401) 863-6604.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

12. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Clicking the box below confirms that you have read and understood the information in this document and you agree to volunteer as a research participant for this study.

Consent

- ☐ Yes, I have read and understood the information in this document and would like to volunteer as a research participant in the study.
- ☐ No, I do not wish to participate.

[If YES is selected to the consent item above, participant will be routed to a separate survey, where identifying data will be kept separate the consent form, so that if names were ever discovered, there would be no linkage to study content.]

Please enter your electronic signature in the line below:

_____

Please select one box below to indicate how you would prefer to receive a copy of this consent form.

- ☐ I would prefer to receive an electronic copy by email. My email address is _____
- ☐ I would prefer to receive a paper copy by mail. My home address is _____

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CONSENT FOR RESEARCH PARTICIPATION
ATTC Condition: Center Providers and Leadership Consent

Implementing Contingency Management in Opioid Treatment Centers across New England: A Hybrid Type 3 Trial
Version Date: December 10, 2018

KEY INFORMATION:

You are invited to take part in a research study conducted by Brown University, in partnership with RTI International and the New England Addiction Technology Transfer Center. Your participation is voluntary.

- PURPOSE: To compare two different ways to train providers and leaders at opioid treatment centers in contingency management (CM).
- PROCEDURES: Center providers and leaders will be asked to complete 1) a survey about their opinions of the organization's support for CM implementation, their attitudes towards CM, as well as some basic demographic questions, at two time points, 2) a full-day CM workshop, and 3) monthly coaching calls. Additionally, center providers will be asked to record and send "practice" CM sessions and actual CM sessions (with patients who have provided consent to participate) for performance feedback. They will be asked to completed CM self-report forms. Center leaders will be asked to work with a CM trainer to develop a CM compliance definition and benchmark and to complete Medical Record Data Extraction forms.
- TIME INVOLVED: The study will take about 30 hours for center providers and 40 hours for center leadership. Most activities will occur during two study phases over 14-months.
- COMPENSATION: You will receive $25 for the first and $20 for the second survey.
- RISKS: You may be uncomfortable providing details about yourself or your organization. You do not have to answer any questions that make you uncomfortable.
- BENEFITS: You will receive free comprehensive training and coaching in CM. This study may improve the outcomes of patients in opioid treatment clinics by improving the delivery of CM.
- ALTERNATIVES TO PARTICIPATION: If you decide not to participate, you will still be eligible to attend the CM workshop at no cost to you.

1. Researcher(s):

PRINCIPAL INVESTIGATOR: Sara Becker, Ph.D. **Phone:** (401) 863-6604

2. What is this study about?

The purpose of this study is to compare two different ways to train opioid treatment centers in contingency management (CM). CM is a treatment approach that has been shown to work in multiple research studies. It provides patients motivational incentives (or prizes) for complying with treatment.

You are being asked to participate because you are a treatment provider or leader at an opioid treatment center that has agreed to participate in this study.

All participating opioid treatment centers receive state-of-the-art training in CM. We will enroll 30 opioid treatment centers and each opioid treatment center will enroll 25 patients (30 * 25 = 750 patients). This study is sponsored by the National Institute on Drug Abuse.

3. What will I be asked to do?

This study has two main phases. In the *Preparation Phase*, center leaders will have a 1-hour kick-off meeting with research staff. During this meeting, leaders will complete a brief Organizational Background form that reports on organization characteristics (e.g., number of patients served annually, types of pharmacotherapy offered, etc.) and will develop a CM compliance definition and benchmark.

Participating center providers and leadership will also be asked to attend a full-day (8 hour) CM workshop. The workshop will cover principles of CM and will provide the opportunity to role play CM delivery with CM staff and leaders from other opioid treatment centers. Continuing education credits will be provided. At the end of the workshop, center providers and leaders will complete a CM knowledge test. Any CM providers or leaders that do not score over 75% on the practice test will receive extra coaching support from the trainer. Center providers will complete at least two role plays using CM with other providers or supervisors (i.e., "practice cases") to demonstrate the ability to proficiently deliver CM delivery. Practice sessions will be audio recorded and sent via Virtru encrypted email (1.5 hours total) to the CM training team who will provide performance feedback.

In the *Implementation Phase* of the study, center providers and leaders will participate in monthly coaching calls (1 hour/each during the 9-month implementation phase). They will again be asked to complete a brief survey about their opinions of the organization's support for CM implementation (20-30 minutes).

Center providers will submit an audio recording of at least 1 CM session per month (with patients who have provided consent to participate), which will be submitted via Virtru encrypted email (1 hour/month). They will receive ongoing performance feedback on their CM competence from a CM trainer. After each CM session, providers will complete a brief self-report data form about the components of the session (5 minutes/session).

Center leadership, at the end of the implementation phase, will be asked to designate someone to extract de-identified data from the patient medical records of the 25 recruited patients and enter the data into a Medical Record Data Extraction Form. Each data form will take 15-20 minutes to complete. About 12 months after the Implementation Phase, CM leadership will be asked to submit a Medical Record Data Extraction Form on an additional 25 patient medical charts selected at random.

Center providers are expected to spend about 30 hours on study activities, while center leaders are expected to spend about 40 hours on study activities.

4. Will I be paid?

If you enroll will receive $25 for completing the first survey and $20 for completing the second survey. In total, you can earn up to $45 for completing the study assessments. You may choose whether you prefer to receive these payments via cash, check, or ClinCard, a rechargeable debit card that functions akin to a Mastercard.

5. What are the risks?

In this study we will be asking you about you opinions of the organization's support for CM

implementation and your attitudes towards CM. While we are not asking anything sensitive, some individuals may be uncomfortable providing this information. The likelihood of this is low and you do not have to answer any questions that make you uncomfortable.

You may choose not to answer any questions and you may stop your participation in the study at any time. You may also request to speak with the Principal Investigator, Sara Becker, Ph.D., a licensed clinical psychologist, at any time if you become upset or experience emotional distress.

6. What are the benefits?

You will receive free CM training consisting of a didactic workshop, performance feedback, and monthly coaching calls. The full day didactic workshop will provide continuing education credits at no cost to you. You will also get access to performance feedback and peer consultation with an expert CM trainer. The data collected in this study could help to inform how opioid treatment centers are trained in CM. This could potentially help patients in the future by improving how well CM is delivered.

7. How will my information be protected?

All of your records from this study will be treated as private records. The records will be protected according to the rules of Brown University. Your name will not be on any of the questionnaires. All information will be identified only by a code number, not your name. Information collected during the assessments are treated as confidential and will not be shared. All data collected electronically will be stored on a secure server. Only researchers working on this study will have access to the information provided by you.

Center providers will be asked to audio record 1 session per month. Recordings will be submitted to research staff via Virtru encrypted email. Research staff will keep this information confidential. Recordings will be destroyed at the end of the project.

Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

This study is a cluster randomized clinical trial in which organizations are randomly assigned to one or more different training strategies. A description of this clinical trial will be available on http://www.Clinical Trials.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.

8. Are there any alternatives to this study?

If you decide not to participate, you will still be eligible to attend the CM workshop at no cost to you. Your decision to participate will not affect your employment in any way.

9. What if I want to stop?

Taking part in research is voluntary. You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with the opioid treatment center in which you work and your job status will not be affected.

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10. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call the Principal Investigator of the program, Dr. Sara Becker at (401) 863-6604.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

12. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Clicking the box below confirms that you have read and understood the information in this document and you agree to volunteer as a research participant for this study.

Consent

- ☐ Yes, I have read and understood the information in this document and would like to volunteer as a research participant in the study.
- ☐ No, I do not wish to participate.

[If YES is selected to the consent item above, participant will be routed to a separate survey, where identifying data will be kept separate the consent form, so that if names were ever discovered, there would be no linkage to study content.]

Please enter your electronic signature in the line below:

_____

Please select one box below to indicate how you would prefer to receive a copy of this consent form.

- ☐ I would prefer to receive an electronic copy by email. My email address is _____
- ☐ I would prefer to receive a paper copy by mail. My home address is _____

Contact for Future Research

Brown University researchers may contact me in the future to ask me to take part in other research studies.

- ☐ Yes
- ☐ No

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CONSENT FOR RESEARCH PARTICIPATION
Enhanced ATTC Condition: Center Providers and Leadership Consent

Implementing Contingency Management in Opioid Treatment Centers across New England: A Hybrid Type 3 Trial
Version Date: December 10, 2018

KEY INFORMATION:

You are invited to take part in a research study conducted by Brown University, in partnership with RTI International and the New England Addiction Technology Transfer Center. Your participation is voluntary.

- PURPOSE: To compare two different ways to train providers and leaders at opioid treatment centers in contingency management (CM).
- PROCEDURES: Center providers and leaders will be asked to complete 1) a survey about their opinions of the organization's support for CM implementation, their attitudes towards CM, as well as some basic demographic questions, at two time points, 2) a full-day CM workshop, and 3) monthly coaching calls. Additionally, center providers will be asked to complete self-report forms and submit CM sessions for performance feedback. Providers will have the opportunity to earn performance bonuses for the quality of CM delivery. Center leaders will participate in monthly leadership coaching calls, and will receive two site visits from an expert leadership coach. Center leaders will also be asked to work with a CM trainer to develop a CM compliance definition and benchmark and to complete Medical Record Data Extraction forms.
- TIME INVOLVED: The study will take about 30 hours for center providers and 40 hours for center leadership. Most activities will occur during two study phases over 14-months.
- COMPENSATION: Center providers and leaders will receive $25 for the first and $20 for the second survey. Center providers can earn up to performance bonuses for CM delivery.
- RISKS: You may be uncomfortable providing details about yourself or your organization. You do not have to answer any questions that make you uncomfortable.
- BENEFITS: Center staff and leaders will receive free comprehensive training and coaching in CM. Center providers will have the opportunity to earn performance bonuses. This study may improve the outcomes of patients in opioid treatment clinics by improving the delivery of CM.
- ALTERNATIVES TO PARTICIPATION: If you decide not to participate, you will still be eligible to attend the CM workshop at no cost to you.

1. Researcher(s):

PRINCIPAL INVESTIGATOR: Sara Becker, Ph.D. **Phone:** (401) 863-6604

2. What is this study about?

The purpose of this study is to compare two different ways to train opioid treatment centers in contingency management (CM). CM is a treatment approach that has been shown to work in multiple research studies. It provides patients motivational incentives (or prizes) for complying with treatment.

You are being asked to participate because you are a treatment provider or leader at an opioid treatment center that has agreed to participate in this study.

All participating opioid treatment centers receive state-of-the-art training in CM. We will enroll 30 opioid treatment centers and each opioid treatment center will enroll 25 patients (30 * 25 = 750 patients). This study is sponsored by the National Institute on Drug Abuse.

3. What will I be asked to do?

This study has two main phases that last up to 14 months. In the *Preparation Phase* (up to 5 months), center leaders will have a 1 hour kick-off meeting with research staff. During this meeting, leaders will complete a brief Organizational Background form that reports on organization characteristics (e.g., number of patients served annually, types of pharmacotherapy offered, etc.) and will develop a CM compliance definition and benchmark.

Participating center providers and leadership will also be asked to attend a full-day (8 hour) CM workshop. The workshop will cover principles of CM and will provide the opportunity to role play CM delivery with CM staff and leaders from other opioid treatment centers. Continuing education credits will be provided. At the end of the workshop, center providers and leaders will complete a CM knowledge test. Any CM staff or leaders that do not score over 75% on the practice test will receive extra coaching support from the trainer. Center providers will complete at least two role plays using CM with other staff or supervisors (i.e., "practice cases") to demonstrate the ability to proficiently deliver CM delivery. Practice sessions will be audio recorded and sent via Virtru encrypted email (1.5 hours total) to the CM training team who will provide performance feedback. Near the end of this phase, center leaders will have a full-day meeting with an external leadership coach to make a detailed implementation plan.

In the *Implementation Phase* of the study, center providers and leaders will participate in monthly group coaching calls (1 hour/each during the 9-month implementation phase). They will again be asked to complete a brief survey about their opinions of the organization's support for CM implementation (20-30 minutes).

Center providers will submit an audio recording of at least 1 CM session per month (with patients who have provided consent to participate), which will be submitted via Virtru encrypted email. Providers will receive ongoing performance feedback on their CM competence from a CM trainer. After each CM session, providers will complete a brief self-report data form about the components of the session (5 minutes/session). Center providers will also have the opportunity to earn performance bonuses based on the quality of CM delivery. For every patient who receives at least 10 CM sessions [CM Exposure target], the provider will receive a $200 bonus. In addition, the provider will have the chance to earn a bonus for every audio-recording. The recordings will be reviewed by research staff and rated using a well-established scale: a score indicating advanced skill will earn a $50 bonus [CM Skill target]. These targets are based on benchmarks in prior studies showing what CM providers are able to achieve.

Center leadership will participate in monthly leadership calls with the external facilitator. At the end of the implementation phase, center leadership will participate in a full-day sustainment planning retreat. Leaders will also be asked to designate someone to extract de-identified data from the patient medical records of the 25 recruited patients and enter the data into a Medical Record Data Extraction Form. Each data form will take 15-20 minutes to complete. About 12 months after the Implementation Phase, CM leadership will be asked to submit a Medical Record Data Extraction Form on an additional 25 patient medical charts selected at random.

Center providers are expected to spend about 30 hours on study activities, while center leaders are expected to spend about 50 hours on study activities.

4. Will I be paid?

If you enroll will receive $25 for completing the first survey and $20 for completing the second survey. In total, you can earn up to $45 for completing the study assessments.

Center providers will also have the opportunity to earn performance bonuses for the quality of CM delivery. The amount center staff can earn will depend on their caseload and quality of CM delivery. For example, a provider with the maximum caseload of 13 patients who consistently delivers CM with the highest level of quality can earn $2,600 for CM Exposure [13 patients * $200/patient] and $450 for CM Skill [9 months * $50/audio recording], for a total of $3,050. Alternately, a provider with a caseload of 5 patients who consistently delivers CM with the highest level of quality can earn $1,000 for CM Exposure [5 patients * $200/patient] and $450 for CM Skill [9 months * $50/audio recording], for a total of $1,450. Center providers can earn incentives whether or not the patient complies with treatment, so patients should not be pressured to change their behavior in any way.

Center providers and leaders may choose whether they prefer to receive these payments via cash, check, or ClinCard, a rechargeable debit card that functions akin to a Mastercard.

5. What are the risks?

In this study we will be asking you about you opinions of the organization's support for CM implementation and your attitudes towards CM. While we are not asking anything sensitive, some individuals may be uncomfortable providing this information. The likelihood of this is low and you do not have to answer any questions that make you uncomfortable.

You may choose not to answer any questions and you may stop your participation in the study at any time. You may also request to speak with the Principal Investigator, Sara Becker, Ph.D., a licensed clinical psychologist, at any time if you become upset or experience emotional distress.

6. What are the benefits?

Both staff and leadership will receive free CM training consisting of a didactic workshop, performance feedback, and monthly coaching calls. The full day didactic workshop will provide continuing education credits at no cost to you. Center staff will get access to performance feedback and peer consultation with an expert CM trainer. Additionally, center staff will have the opportunity to earn performance bonuses for quality CM delivery. Meanwhile, center leaders will receive monthly calls from an expert facilitator. The data collected in this study could help to inform how opioid treatment centers are trained in CM. This could potentially help patients in the future by improving how well CM is delivered.

7. How will my information be protected?

All of your records from this study will be treated as private records. The records will be protected according to the rules of Brown University. Your name will not be on any of the questionnaires. All information will be identified only by a code number, not your name. Information collected during the assessments are treated as confidential and will not be shared. All data collected electronically will be stored on a secure server. Only researchers working on this study will have access to the information

provided by you.

Center staff will be asked to audio record 1 session per month. Recordings will be submitted to research staff via Virtru encrypted email. Research staff will keep this information confidential. Recordings will be destroyed at the end of the project.

Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

This study is a cluster randomized clinical trial in which organizations are randomly assigned to one or more different training strategies. A description of this clinical trial will be available on http://www.Clinical Trials.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.

8. Are there any alternatives to this study?

If you decide not to participate, you will still be eligible to attend the CM workshop at no cost to you. Your decision to participate will not affect your employment in any way.

9. What if I want to stop?

Taking part in research is voluntary. You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with the opioid treatment center in which you work and your job status will not be affected.

10. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call the Principal Investigator of the program, Dr. Sara Becker at (401) 863-6604.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

12. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Clicking the box below confirms that you have read and understood the information in this document and you agree to volunteer as a research participant for this study.

Consent

☐ Yes, I have read and understood the information in this document and would like to volunteer as a research participant in the study.

⎦ No, I do not wish to participate.

[If YES is selected to the consent item above, participant will be routed to a separate survey, where identifying data will be kept separate the consent form, so that if names were ever discovered, there would be no linkage to study content.]

Please enter your electronic signature in the line below:

_____

Please select one box below to indicate how you would prefer to receive a copy of this consent form.

⎦ I would prefer to receive an electronic copy by email. My email address is _____
⎦ I would prefer to receive a paper copy by mail. My home address is _____

Contact for Future Research

Brown University researchers may contact me in the future to ask me to take part in other research studies.

⎦ Yes
⎦ No