PROJECT TITLE:	Project MIMIC (Maximizing Implementation of Motivational Incentives in Clinics)
PRINCIPAL INVESTIGATORS:	Sara Becker, PhD
	Bryan Garner, PhD
CLINICALTIALS.GOV IDENTIFIER:	NCT03931174
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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 12, 2019

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 three 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 complete Weekly CM Update forms. Center leaders will be asked to work with a CM trainer to develop a CM compliance definition and benchmark and to verify data in the Weekly CM Update 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 15 -months.
≠ COMPENSATION: You will receive $25 for the first and $20 each for the second and third surveys.
≠ 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. Center providers and leaders will be asked to complete a survey about their opinions of the organization's support for CM implementation, their attitudes towards CM, as well as some basic demographic questions.

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. 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 10-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) at two different time points: once about 5 months into the *Implementation Phase* and another 5 months later.

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 called the Weekly Update Form about the components of the session (5 minutes/session).

Center leadership, at the end of the implementation phase, will be asked to verify the data entered into the Weekly Update Form. Verification of each patient will take 15-20 minutes. About 12 months after the Implementation Phase, CM leadership will be asked to extract data on CM session attendance from 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, you will receive $25 for completing the first survey and $20 each for completing the second and third survey. In total, you can earn up to $65 for completing the study assessments. Center providers and leaders will receive payment via Amazon or Visa gift card.

5. What are the risks?

In this study we will be asking you about you opinions of your 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.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.

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

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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 12, 2019

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 three time points, 2) a full-day CM workshop, and 3) monthly coaching calls. Additionally, center providers will be asked to complete Weekly CM Update 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 verify data in the Weekly CM Update 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 15-months.
- COMPENSATION: Center providers and leaders will receive $25 for the first and $20 each for the second and third surveys. Center providers can earn 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. 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. Center providers and leaders will be asked to complete a survey about their opinions of the organization's support for CM implementation, their attitudes towards CM, as well as some basic demographic questions.

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. 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 10-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) at two different time points: once about 5 months into the *Implementation Phase* and another 5 months later.

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 called the Weekly Update 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 in the targeted timeframe [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 verify the data entered into the Weekly Update forms. Verification of each patient will take 15-20 minutes to complete. About 12 months after the Implementation Phase, CM

leadership will be asked to extract data on CM session attendance from 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, you will receive $25 for completing the first survey and $20 each for completing the second and third surveys. In total, you can earn up to $65 for completing the study assessments. Center providers and leaders will receive payment for survey completion via Amazon or Visa gift card.

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 a 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 $5-0 for CM Skill [10 months * $50/audio recording], for a total of $3,100. 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 $500 for CM Skill [10 months * $50/audio recording], for a total of $1,500. 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 will receive performance bonuses in the form of check.

5. What are the risks?

In this study we will be asking you about your opinions of your 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. 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.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.

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

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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 5: May 12, 2021

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 meeting attendance goals. 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, your level of pain, and your socio-demographics. You may then be offered 12 weeks of CM treatment. In order to see how well staff are delivering CM, your counselor may ask your permission to audio record your sessions. At two additional times, you will again answer questions about your substance use, your level of pain, and problems related to your substance use.
- TIME INVOLVED: The study will take you, at most, 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 may 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 may also have the opportunity to earn prize draws in CM sessions. A patient who attends all 12 CM sessions and fully complies with treatment can earn up to 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, pain, 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 may be offered CM, 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 meeting attendance targets. 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 adult 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, your mental health, and your level of pain. You will also be asked some basic demographic questions about yourself. Completing these questionnaires will take about an hour. You may refuse to answer or skip any question asked of you.

Three months and six months from today, you will complete brief questionnaires about your substance use, your level of pain, and any substance-related problems over the phone. 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 may be offered CM sessions weekly for 12 weeks. CM sessions last about 5-10 minutes and consist of three elements: a) feedback on compliance with treatment; b) feedback on whether compliance was high enough to earn a prize draw; and c) receipt of a prize draw or feedback on what is required 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. If you are offered CM, each week that you meet the attendance target, you will earn an extra draw. Each week that you miss your session or miss the attendance target, the number of draws will get reset to 0. If you attend all 12 sessions and meet all of your attendance goals, you will earn a maximum of 78 prize draws. On average, this would result in $156 worth of prizes.

If you are offered CM, your provider will complete a brief form after each session documenting components of the session including your attendance goal, your actual attendance, and the number of prize draws received. Your provider may 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. You may complete your study assessments even if you are no longer receiving treatment at the opioid treatment program. If you choose to remove yourself from the study entirely, or if we have to take you out of

the study, you will be paid for only those assessments you completed.

If you are offered CM, you will also have the ability to earn up to 78 prize draws. On average, each prize draw is worth about $2 in prizes. 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, your level of pain, 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 a 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 may 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 may offer new patients CM prize draws. You may 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 include 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 contact the Principal Investigator of the program, Dr. Sara Becker at (401) 863-6604 or sara_becker@brown.edu.

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

[If obtaining verbal consent from the participant:]

Do you understand what you are being asked to do and do you agree to participate?

If you answer "Yes", you are confirming that you understand the information in this document as it has been read to you and you agree to volunteer as a research participant for this study.

Consent

___ Yes, I have understood the information in this document that has been read to me and would like to provide verbal consent to volunteer as a research participant for this study.

___ No, I do not wish to participate.

[If obtaining electronic consent from the participant:]

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

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:

_____

[All participants:]

Please indicate whether you would prefer to receive a copy of this consent form by email or mail.

__ 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_____