

Improving Retention across the OUD Service Cascade upon Reentry from Jail using Recovery Management Checkups (RMC-A) Experiment

NCT 1135-0519

July 12, 2024

Informed Consent for Participation in Research

Project Title: *Improving Retention across the OUD Service Cascade upon Reentry from Jail using Recovery Management Checkups (RMC-A) Experiment* (NIDA Grant no. 1UG1 DA050065)

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Why is Lighthouse Institute doing this study? To see if we can help people coming out of jails with a heroin or opioid problem get into treatment. We also want to see if that helps make their lives better.

What will happen? You will be interviewed when you enroll in the study for about 1-2 hours. After that, interviews will take place at 1, 2, and 3 months and then every 3 months afterwards. The total number of interviews you complete depends on the date when you enter the study; all participants will have a minimum of 12 months of study participation, however, the number of follow-up interviews depends on the amount of time remaining in the study.

Interviews will be in person at our office in Chicago (transportation will be provided) or by phone or Zoom, depending on your circumstances. You can say no if you do not want to answer any question. You will be asked to give us phone numbers and addresses so we can stay in touch with you. You will receive a \$35 gift card for each of the interviews you complete and \$15 for each urine sample that you provide at the time of the interview.. If you are incarcerated at the time of the follow-up interview, we will attempt to conduct the interview by phone.

Based on the current date, you will have [completed by interviewer] interviews possible through December 2025, for a total amount of [completed by interviewer] if you complete all interviews and provide a urine sample for each.

How is the study organized? In addition to these interviews, you will be placed into 1 of 3 groups. One group will be provided with referral to local treatment services at the time of study admission and at each of the quarterly follow-up meetings. The second group will get quarterly recovery management checkups (RMC) to see if we can help people get into and stay in treatment. The third group will also get all of the above and RMC, but the frequency of the checkups will vary by how well they are doing. The number of RMC check-ups depends on the amount of time remaining in the study, with a minimum of 12 months. No matter which group you are in, you can always go to treatment and community-based recovery support services as usual.

How will information about me be shared with others? Your name and other information about you, like your date of birth, will be taken out of your interview file before it is given to anyone else. Your personal information will not be made public in any way. Your answers to interview questions will only have an ID number attached and not your name. Any information that can identify you will be kept separate from the data files. Only the Project Director and study interviewers who need to contact you will have access to your name and locator information. This information will be kept in a secure file.

This research is funded by the National Institutes of Health. Your answers to the interview questions may be shared with other researchers in a datafile. They will not see your name or any other information that can identify you. Funders may look at our records as part of an audit

or evaluation. Any written reports about the project will only talk about groups of people and not individuals. Your information will only be used for research, monitoring, and safety purposes.

We have a **Certificate of Confidentiality** from the National Institutes of Health. It means we cannot be “forced” to give out any information to anyone that tells them you are in this study. We would share information about you if you tell us you are going to hurt yourself or others. We also would share with the appropriate authorities your information if you tell us about a time when you hurt an older person or if you hurt or left a child uncared for.

Consent to Be Recorded. If you participate in the project, the linkage meetings and interviews will be recorded so that members of the research team can review how well the staff are doing their job. These recordings will be reviewed to rate how closely staff followed the instructions given to them, to give staff feedback, and to train staff how to do a better job in the future. If you have something very private to say, you have the right to tell the staff to turn off the recorder. If you refuse to be recorded, you can still participate in the project. To further protect you, the recordings will only have your research ID number associated with them and they will be destroyed 3 years after the project has been completed.

What risks am I taking? There is a chance that some information about you could be found out. This is not usually a problem. Staff people who work on these studies have to follow federal laws, which protect your information. The people who interview you know how to protect your information. They must follow the rules in the **Certificate of Confidentiality**.

What if I want to quit the study? You may take yourself out of the study at any time by contacting Dr. Dennis or Dr. Grella at the numbers below. You will still be able to go to your usual treatment or recovery services. When you stay in this study and take part in the interviews, you are helping us better understand people with drug problems, obstacles they often face, and ways to help them.

Participation in this research will have no effect on the disposition of your case, including your probation/parole eligibility or release date. There will be no penalty or prejudice of any kind for not participating in or withdrawing from this study.

I agree to take part in the study: The study has been explained to me. I had a chance to ask questions. I understand that I can choose not to answer any question and that I can take myself out of this study at any time. I can continue with my usual treatment even if I am not in the study. No one has made any promises about how the study will turn out. My personal information related to the study will be protected and kept private according to federal law. When my information is looked at for a required review or to protect my safety, my records will be protected by federal laws.

I hereby ___ agree / ___ do not agree (check one) to take part in the study that is described in this consent form. I have been given a copy of the consent form. I understand that if I have questions or concerns, I can contact the main person in charge of the study. The people in charge are Dr. Michael Dennis (Phone: 309-451-7801, Fax: 309-451-7761, e-mail: mdennis@chestnut.org) and Dr. Christine Grella (Phone: 309-451-7809, Fax: 309-451-7761, e-mail: cegrella@chestnut.org). If I have questions about my rights as a person in this research study, I can contact the person in charge of protecting my rights, Dr. Ralph Weisheit, at 309-451-7855.

_____	_____	_____
Participant (please print)	Participant (signature)	Date
_____	_____	
Witness (signature)	Date	
___ Ineligible ___ Refused (Reason: _____)		