Your rights as a research participant - check it out!

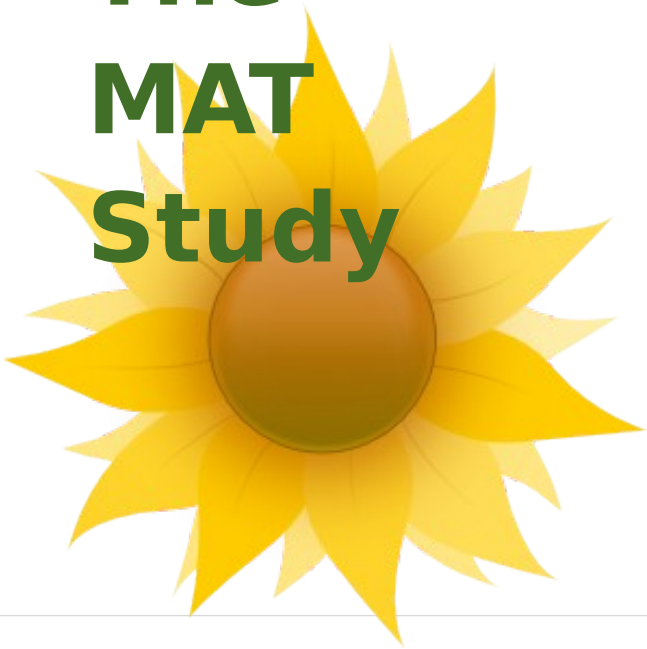
- You are important to the success of this study, and we will always answer any questions you have.
- Your participation is always voluntary. You may decide to skip any survey question or withdraw from the study at any time.
- Your information is always confidential and will not be linked to your name or identity. All data will be reported as a group, so no one will see your individual responses.
- Your rights as a research subject are always protected. The MAT Study was reviewed and

The RTI Team

Awaiting picture

Dr. Laura Dunlap (RTI), Dr. Mark Edlund (RTI), Victoria Albright (RTI), Donovan Newton (CDC), Marci Hertz (CDC)

The MAT Study



How do I learn more?

We will give you more details when we talk to you one-on-one about being in the study. We encourage you to ask us any questions you have. We are excited about what we are doing and hope you are too! We believe our research will help make better lives.

Learning how to make a difference

Contact Information

Dr. Laura Dunlap
RTI International
3040 E. Cornwallis Road
Research Triangle Park
Durham, NC 27709
Toll Free: 1-888-834-7088
Email: ljd@rti.org

"…It's about giving back to everyone working to regain control of their lives."

- Dr. Laura Dunlap

What Is This About?

We are studying the everyday lives of people who have sought and received treatment or help with their addiction. The MAT Study seeks to understand how your life goes once you enter treatment and after you leave treatment.

Why me?
This study is reaching out to individuals who have just started a treatment or care program for their substance use. We are surveying about 3,000 people like yourself across the United States.

What will I have to do?
We will ask you to take five surveys: one in a few days, one in 3 months, 6 months, 12 months, and 24 months. Each survey lasts about 50 minutes depending on your answers. You will take the survey in private. You will read the questions on a laptop screen and answer them using a mouse.

What will you ask me about?
We will ask about your employment status, physical and emotional health, use of drugs, overdoses, medical care, trips to the ED or hospital, relationships with friends and family, any legal problems, and overall well-being.

What do I get for being in the study?
You will receive up to $180 for completing all five online surveys over the 24-month period.

What will you do with the study results?
The study results will help us identify things that happen in everyday life that may affect relapse and remission. These findings may help people like yourself by aiding in the development of new treatment strategies for the future and increasing our knowledge about what opioid use treatments are most effective.

Who is conducting this study?
RTI International (RTI) is working in partnership with the CDC and your treatment facility. RTI is a nonprofit research organization founded in 1955. The study is led by Dr. Laura Dunlap, a research scientist at RTI. Dr. Dunlap has conducted research with RTI for over 20 years. This study is being conducted on behalf of the National Center for Injury Prevention and Control, part of the Centers for Disease Control (CDC).

What about my privacy?
Study records that identify you will be kept confidential as required by law. The U.S. government has a privacy rule to protect the privacy rights of patients and research subjects. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The privacy rule protects the confidentiality of your personal health information.

Is the MAT Study different from the treatment I am getting here?
Your treatment center is helping the RTI study team to reach out to clients like yourself so we can see if you want to be part of the MAT Study. The MAT Study does not affect or interfere with the treatment plan provided by your clinician. Your treatment provider will never know the answers you give on your surveys.

MAT Immediate Danger Protocol

Someone Expresses an Interest in Hurting or Killing Themselves or Someone Else or they are in Immediate Danger

It is highly unlikely, but someone may spontaneously tell you that they are planning to seriously hurt or kill themselves or someone else, or that they feel they are in immediate danger. For example, a person could tell you that s/he is going to hurt someone or is themselves at risked of being harmed.

- If a respondent provides credible information that they may kill or seriously harm some else, or they are at risk of harm you should report this to [project staff member] to discuss the appropriate course of action unless there is immediate danger which necessitates calling authorities (911 or other local emergency response number) to report the incident without delay. You will use the following script:

  "*We are conducting a research study, and during an interview the participant expressed an interest in harming or killing someone. I am alerting you because I believe that this person might pose a credible threat and that the person they threatened to harm is in immediate danger.*"

- You must also complete and submit an incident report form by e-mail to the project's Principal Investigator (Dr. Laura Dunlap) and data collection manager (Ellen Stutts) at TheMATStudy@RTI.org on the same day as the incident, and also attempt to contact Dr. Dunlap and Ms. Stutts via phone (using the contact information on the front page of this document) on the same day of the incident with a description of what you witnessed, and the actions that you took.

- Dr. Dunlap will be required to submit a report to the chair of the IRB Committee within 2 business days of receiving the completed Incident Report Form.

- Observe the Distressed Respondent Protocol for handling the situation in the moment.

Distressed Respondent Protocol

While having a respondent become distressed during the questionnaire process is very unlikely, field staff must be prepared to respond appropriately.

Standard Distressed Respondent Protocol

If a respondent becomes visibly upset (as evidenced by crying, shaking, trembling voice, anger, agitation, extreme frustration, etc.), during the questionnaire, you will follow the Standard Protocol in stages. The Standard Protocol is only for distressed respondents that have not expressed suicidal or self-harm ideation and intent. The protocol for respondents who mention current and serious suicidal thoughts is outlined below.

Stage 1: At the first sign that a respondent (R) might be upset or distressed, you will say:

> *"Answering these questions appears to be upsetting to you. Would you like to stop the questionnaire, or take a short break?*

If the R wants to stop the questionnaire, you will stop and thank the R for his or her time, and provide the R with the full payment for participation. The R will continue the questionnaire only if the R indicates they just want to take a break and only if signs of distress are no longer displayed. You can provide R with telephone contact information for the National Suicide Prevention Lifeline, which is a national network of local crisis centers that provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. The telephone number is 1-800-273-TALK.

Stage 2: If the questionnaire continues and the R becomes upset a second time, you will say:

> *"Would you like to stop the questionnaire or take another short break?"*

If the R wants to take a break, you will let him/her break until the R seems composed, at which time you will say:

> *"Would you like to continue or would you like to stop the questionnaire?*

If the R wants to stop the questionnaire:

- Stop the questionnaire,
- Thank the respondent for their time,
- Provide the full payment
- Provide R with telephone contact information for the National Suicide Prevention Lifeline (1-800-273-TALK) if you have not done so already.
- Complete the Incident Report Form template with a detailed description of events, and email it to the project's Principal Investigator (Dr. Laura Dunlap) and data collection manager (Ellen Stutts) at TBATheMATStudy@RTI.org

within 24 hours of the occurrence of the event. Do not include any identifying information about the respondent in the report that is sent to RTI.

- Within 2 business days of receiving the completed Incident Report form, Dr. Dunlap will consult with the IRB to determine if a report to the IRB is required.

Stage 3: If the questionnaire continues and the R becomes upset a third time, you will say:

"Answering these questions appears to be upsetting to you. Let's stop the questionnaire.

In stopping the questionnaire, you will:

- Stop the questionnaire,
- Thank the respondent for their time,
- Provide the full payment,
- Provide R with telephone contact information for the National Suicide Prevention Lifeline (1-800-273-TALK).
- Ask the respondent if there is someone they would like you to contact to help them.
- Immediately after leaving the respondent, complete the Incident Report Form template with a detailed description of events, and email it to the project's Principal Investigator (Dr. Laura Dunlap) and data collection manager, Ellen Stutts, at TheMATStudy@RTI.org within 24 hours of the occurrence of the event. Do not include any identifying information about the respondent in the report that is sent to RTI.
- Within 2 business days of receiving the completed Incident Report form, Dr. Dunlap will consult with the IRB to determine if a report to the IRB is required.

Suicidal Ideation and Intent Protocol

There are questions in the MAT Client Questionnaire that ask respondents about their history of suicidal ideation and intent. You will not know the respondent's answers to these questions; they are private. You shall not ask how a respondent answered these questions.

However, there is a chance that a respondent may choose to self-disclose information to you that indicates they are at risk of harm to self. If a respondent voluntarily discloses feelings of current and serious suicidal thoughts, observe the protocol outlined below.

Step 1: When a respondent reveals to you that they have suicidal or self-harm ideation and intent, immediately end the interview.

Step 2: Do not ask for details about their feelings, ideation, or plans. Instead, you will say:

"You just told me that you have thoughts about your death or dying. Do you have a doctor, counselor, or someone you can talk to about how you are feeling? I strongly suggest you contact this person so you can talk to him or her about how you have been feeling, especially about the thoughts you've been having about death and dying.

There is also a national hotline number you can call where counselors are available to talk any time of the day or night. Their toll-free number is 1-800-273-8255. Can you write that number down for me?

Would you be willing to either call your health professional or the hotline? Okay."

Step 3: Ask the respondent if there is someone they would like you to contact to help them.

Step 4: Immediately after leaving the respondent, record concise notes of the event and contact your field supervisor. Complete and file a Distressed Respondent Report with your field supervisor informing him or her that a toll-free number referral was given, the respondent's case ID, interviewer's ID, date, time, a detailed description of the interaction between the interviewer and respondent, and if the appropriate protocols were followed.

Study Incident Report Form

Instructions: Do not include any identifying information about the respondent in the report that is sent to RTI International

Date of Event:

Facility location:

Name and contact info of facility staff person reporting event:

Description of Event:

Description of Actions Taken by Facility Staff (in response to event):

Description of Any Deviations from Approved Data Collection Procedures:

Status of Situation (as of the date of this report):

Recommendations for Further Action (if any):