Title: Linking Individuals Needing Care for Substance Use Disorders in Urban Emergency Departments to Peer coaches (LINCS UP)

NCT#: NCT05847621

Date: 04/11/2025

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of approximately 600 people who are being studied, at Emory and Grady Health System.

Why is this study being done?

This study is being done to answer the question: How effective are peer recovery coaches for hospitalized patients living with substance use disorders. You are being asked to be in this research study because you have a history of substance use and are a patient being seen in the emergency department or admitted to the hospital.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for 90 days (4 study visits). The researchers will ask you to do the following: answer questions regarding your current and past substance use, social background, ED and hospital visits, and engagement with recovery resources. ALL of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. If you are enrolled into the peer coaching arms of the study, you will meet with a peer recovery coach who will initiate linkage with community recovery organizations and follow up with you after discharge to ensure a successful linkage and promote your recovery.

What are the risks or discomforts you should know about before deciding?

The study will take time. The procedure that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Discomfort discussing sensitive information, such as substance use
- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study
The alternative is not to participate.

Costs
The study sponsor will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care.

There is more information in the "Costs" section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject

Title: Linking Individuals Needing Care for Substance Use Disorders in Urban Emergency Departments to Peer coaches (LINCS UP)

IRB #: Study00005553

Principal Investigator: [redacted], MD. Department of Emergency Medicine.

Funding Source: Centers for Disease Control and Prevention

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?
The purpose of this study is to determine the effectiveness of peer recovery coaches for patients seen in the emergency department or hospitalized who are living with substance use disorders.

What will you be asked to do?

After enrollment, you will be randomized (procedure like flipping a coin) to one of three study arms:
- Usual care: You will be provided with list of community-based recovery resources
- In-Person peer: A peer recovery coach will come to see you at bedside. They will perform an interview and provide linkage to community-based recovery resources. They will also follow up with you after discharge to ensure a successful linkage and promote your recovery.
- Telehealth peer: You will be connected to a peer recovery coach through a secure video call on a tablet device provided by the study team. They will perform an interview and provide linkage to community-based recovery resources. They will also follow up with you after discharge to ensure a successful linkage and promote your recovery.

In all study arms, you will be asked to answer a series of questions regarding your current and past substance use, social background, ED and hospital visits, and engagement with recovery resources. It should take about 45 minutes to answer these questions. We will also ask you to provide contact information (phone number and address) so that we can contact you to complete follow up visits. If you are willing, we would also like to collect alternative contact information,

such as social media (i.e. Facebook, Instagram, Twitter) and Epic myChart through which we could contact you from a study-specific account.

Besides today's visit, you will be asked to complete a similar series of questions in 7, 30, and 90 days (total of 4 study-related visits). These visits will each take about 30 minutes and can be done over the phone or in-person, based upon your preference.

If you do not have a phone: We can provide one for you so that you can complete study activities. This phone is intended to be used only for study purposes, specifically to complete follow up calls. Phones will be loaded with a 30 day prepaid plan providing unlimited talk and text functionality, but no data plan, within the next several days. You can use this phone to contact us, and we will use it to contact you for 7 and 30 day follow up calls. We will then "top up" the phone with an additional 30 day plan shortly before the 90 day visit. Phones will not be replaced if lost, stolen, or otherwise damaged. You will be responsible for any additional costs of phone service beyond the two 30 day plans provided during study follow up periods.

Who owns your study data ?

If you join this study, you will be donating your data. You will not be paid if your data are used to make a new product. If you leave the study, the data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.
The most common risks and discomforts expected in this study are:
Temporary psychological discomfort associated with discussing substance use.

Rare but possible risks include:
Breach of confidentiality. The study team will take steps to protect the safety of your information.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may not benefit from joining the study. Your condition may improve while you are in this study or it may get worse. This study is designed to learn more about the effectiveness of peer recovery coaches for hospitalized patients with substance use disorders. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will get $25, loaded onto a reusable card known as a clincard, for each completed study visit, for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $100 total, if you complete all study visits.

What are your other options?

If you choose not to join this study, you can get care outside of this study. You may be referred to community recovery resources if your treating physician deems it necessary. You will still be eligible for medical treatment of substance use disorders, for example buprenorphine if you are living with opioid use disorder. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the Centers for Disease Control and Prevention for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory and Grady Health System will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory and Grady Health System received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory and Grady Health System from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory and Grady Health System, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory and Grady Health System. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

Medical Record

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An

Emory and Grady Health System medical record will be made for you if an Emory Atlanta and Grady Health System provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Grady Health System medical record you have now or any time during the study.

Emory and Grady may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Grady medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: Drug Abuse Screening Test, Education level, Timeline Follow Back, University of Rhode Island Change Assessment, Housing and Employment, Social Connection and Isolation Panel.

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Greenphire

We are planning to provide compensation to you by a personal payment card. We issue this to you free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. You will be paid following each time your child completes a visit. The card scheme is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it.

Please ask if you have any questions or concerns about the card.

We would also like the option of compensating you in the form of cash, check or gift card if ClinCard accessibility is not available. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options. You will need to fill out a W-9 form.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your PHI from health care entities and to use and disclose your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or disclosed for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.
- Information regarding engagement with recovery resource organizations, including services provided (e.g. group counseling, housing resources, syringe services).
- Details of assessment and/or enrollment at substance use treatment facilities, including diagnoses, medications prescribed, and non-medical treatment (e.g. counseling).
- Emergency department visits and hospitalizations

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and disclose your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

We will also use your IIHI to determine linkage and engagement with community-based recovery organizations and clinics, particularly pertaining to substance use.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- The Principal Investigator and research staff will disclose your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- Recovery Resources of Atlanta Midtown, R2ISE, Aniz Inc, the Georgia Council on Substance Abuse, and other organizations that we link you to as part of the study will use your IIHI to determine engagement with their recovery services.
- Centers for Disease Control and Prevention is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

The following people and groups will use your IIHI to make sure the research is done correctly and safely:

- Emory and Grady offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, the Emory Office for Clinical Research, and the Grady Health System Office of Research Administration.
- Government agencies that regulate the research including: Office for Human Research Protections, Centers for Disease Control and Prevention
- Public health agencies
- Research monitors and reviewer
- Accreditation agencies

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be disclosed to the new institution and the institution's oversight offices.

Expiration of Your Authorization
Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the IIHI already collected as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers,

Sponsor, and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact [redacted]

We will give you emergency care if you are injured by this research. However, Grady Health System has not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. Joseph Carpenter at [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted] or [redacted]

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at [redacted]

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**