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NYU Langone Health

Research Participant Informed Consent Form

Title of Study:	Randomized Controlled Trial of Relay- NYC's Nonfatal Overdose Response Program s19-01547
Principal Investigators:	Kelly Doran, MD, MHS Department of Emergency Medicine NYU School of Medicine 462 1st Avenue, Room A-345; NY, NY 10016 (212) 263-5850
Emergency Contact:	Kelly Doran (212) 263-5850

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “participants” or “research participants”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research study is to evaluate the “Relay” program, which is a program to help prevent opioid overdose that was created by the New York City Department of Health and Mental Hygiene. We are asking you to take part in this research study because you are a patient in the emergency department who is eligible to receive Relay program services.

This study is a randomized study. This means, like flipping a coin, you will be assigned to one of two possible study groups. One study group is called the “Relay program” and if you are assigned to this group, a Relay program peer Wellness Advocate will visit you today in the emergency department to provide you with overdose education, naloxone education, harm reduction information, treatment information, and other counseling and support you might need. These services are in addition to the regular services you would receive as a patient in the emergency department. The Wellness Advocate will continue to follow up with you for up to 90 days after today. The other study group is the “site-

directed care group" and if you are assigned to this group you will receive regular care and services that are delivered here in the emergency department for patients after an opioid overdose. The specific services offered vary by the particular emergency department but, at the minimum, you would receive a naloxone kit and education and a list of treatment programs. Also, if you are assigned to the "site-directed care group" you will receive information about the Relay program so that you can call them on your own if you would like to receive Relay program services after your emergency department visit; the Relay program may also call you in one year to see if you want services. There are no special requirements or criteria to be in either group. You will have a 50 percent chance of being assigned to either treatment group.

3. How long will I be in the study? How many other people will be in the study?

This study will last about 12 months and will involve your visit today as well as 3 follow-up interviews which may occur either face-to-face, or by phone. The last study follow-up visit will be 6 months from now, but researchers will continue to use other information about you from medical records and other data sources for 12 months. This research study is happening at three other emergency departments in New York City as well. About 350 people aged 18 and older will be in this study.

4. What will I be asked to do in the study?

In this study, you will be asked to complete surveys (questionnaires), receive opioid overdose information and materials, and speak with study staff after today's visit. For the surveys today the study staff will read questions out loud to you for you to answer. Your participation in this study will last for approximately 12 months and will involve your initial visit today as well as 3 follow-up interviews (1, 3, and 6 months from now) which may occur either face-to-face (in person), or by phone. You do not have to answer any questions that you prefer not to answer.

All of the questions you answer and other information you provide to us will be kept confidential—that means that we will not be sharing your answers with your doctors, family members, or anyone else who is not part of the research team. At any time in the study, you may decide to withdraw from the study. If you withdraw, no more information will be collected from you. When you indicate you wish to withdraw, the investigator will ask if the information already collected from you can be used.

If you choose to take part in the study, we will ask you to sign this consent form before completing any part of the study.

Below is a list of each study visit that is part of the study. This list includes about how long each visit should take and a list of the research procedures to be done at each visit. This section will help you understand what is expected of you at each visit.

Visit 1: Your Initial Visit

This visit will occur today during your emergency department stay; the research activities will take approximately 1 hour in addition to the time it takes for you to receive regular services in the emergency department and/or the Relay program services (if you are assigned to that group). The activities we do as part of the study today will occur during your emergency department visit, during periods when you would otherwise be waiting. If a doctor or nurse comes to provide you with care while we are talking, we would pause the study so that we do not slow down your medical treatment.

At this visit, we will:

- Assign you to one of two possible study groups. The type of opioid overdose-related treatment you receive depends on which study group you are randomly assigned to. In both groups the exact care you receive may be based on your particular needs and the practices of the specific emergency department. The two possible study groups are:
    - Relay program group: a Relay program peer Wellness Advocate will visit you today in the emergency department to provide you with overdose education, naloxone education, harm reduction information, treatment information, and other counseling and support you might need. These services are in addition to the regular services you would receive as a patient in the emergency department. The Wellness Advocate will continue to follow up with you for up to 90 days after today.
    - Site-directed care group: regular care and services that are delivered to emergency department patients after an opioid overdose. The specific services offered vary by the particular emergency department but, at the minimum, you would receive a naloxone kit and education and a list of treatment programs. Also, you will receive information about the Relay program so that you can call them on your own if you would like to receive Relay services after your emergency department visit; the Relay program may also call you in one year to see if you want services.
- Complete a survey (questionnaire) that will ask you questions about things such as your emergency department visits, experiences with drug/alcohol use, health, living situation, and other experiences in your life. Research staff will read the questions out loud for you to answer.
- Collect personal information (your name, birthdate, medical record number, and social security number if you have one). This information will be used to look up information such as information on future and past emergency department visits in health databases, described in more detail below. Providing this information is required to be a part of the study.
- Collect your contact information and information on other ways to reach you (for example, phone numbers, e-mail, social media, addresses, case workers, places you regularly visit). This will include collecting names and phone numbers for people who might help us reach you if we lose touch with you. We will not share any information about you or details about the study with these people.
- Complete a survey about the services you received today.
- Schedule your first follow-up visit and receive payment for your participation today.

Visits 2, 3, and 4: 1-Month Follow-up, 3-Month Follow-up, and 6-Month Follow-up

The 3 follow-up interviews will occur approximately 1, 3, and 6 months after today's visit. These interviews will each take between 30-60 minutes to complete. These interviews may occur face-to-face (in person) or by phone, based on your preference.

At these interviews, we will:

- Ask you questions including questions about your emergency department visits, opioid use and other drug/alcohol use, health, living situation, and other experiences in your life.

Because it is important for the study for us to be able to reach you for follow-up visits, we will attempt to contact you for these follow-up study visits using any of the contact information you give us, including by phone, mail, e-mail, social media, in person, or through contact information for friends, family members, case workers or others that you share with us. If needed, we will also look for you in the hospital or other health care settings (including through health care records), or in criminal justice or homeless services registries. If we speak to anyone else other than you about the study we will not reveal what the study is about.

We will use your personal information (such as your name, birthdate, and medical record number) to access information about you from health databases. We will look at your future emergency department visits and other health care service use in the next 12 months using health care databases including, but not limited to, Regional Health Information Systems or RHIOs (Healthix and Bronx RHIO), Medicaid, and Statewide Planning and Research Cooperative System (SPARCS). These are all names of large health care databases sometimes called “administrative databases.” We will also look up information about health services you have received from the electronic medical records for the hospitals that are part of this study. We will also use your person information to look up information about you from the vital statistics (death) database and the Relay service program database, both maintained by the NYC Department of Health and Mental Hygiene. We will only access these databases for research purposes specific to this study. Any identifiable personal information collected and/or used for the purposes of this research will not be used for future studies.

5. What are the possible risks or discomforts?

Overall, this study is considered to have minimal risk. There is a small chance that participants may become upset when discussing their personal history of addiction problems, criminal justice involvement, or other personal issues. Some questions may be of a sensitive nature and you may, therefore, feel uncomfortable as a result. If you become upset by questions, you may stop at any time or choose not to answer a question. If you would like to talk to someone about your feelings, please let the research assistant doing the survey with you know. The biggest risk related to the study is loss of confidentiality. Though this is a real risk with any research study—or anytime you give your personal information to anyone—multiple steps will be taken to protect against this risk. All study participant information will be treated as confidential and securely protected. We will store your information in special high security computer files. Only people involved in conducting the study—which includes researchers at NYU and the other study sites, as well as researchers at the NYC Department of Health and Mental Hygiene—will be able to access your information. All researchers are trained in protecting your personal information. The police, social workers, your doctors, and other people who are not part of the research team will <u>not</u> be allowed to access the data we collect about you. This includes the fact that parole boards will not take into account your participation in the research in making decisions regarding parole.

6. What if new information becomes available?

If during the course of the study the researchers learn that one of the two study groups appears to be much better for patients’ health than the other group, the researchers may choose to halt (stop) the study. In that case we will attempt to contact participants to inform them and potentially offer additional services.

7. What are the possible benefits of the study?

We do not expect this study itself to benefit you directly. We hope that this study will help us learn more about reducing and preventing overdoses, as well as help us learn how to improve overdose prevention programs like Relay. By participating in this study, you will help us learn how to better help future emergency department patients.

8. What other choices do I have if I do not participate?

You may choose to not participate in this research study. In other words, participating in the study is optional. If you do not participate in this study, you will be offered Department of Health and Mental Hygiene Relay program services (you may decline these services if you chose to). You will also receive other care as you regularly would in the emergency department.

9. Will I be paid for being in this study?

You will be paid $75 for completing study procedures today, $30 for completing the 1-month study interview, $30 for completing the 3-month study interview, and $50 for completing the 6-month follow-up interview. You will receive these payments once you finish the study procedures, even if you decide not to answer certain questions that you find to be too sensitive to answer, as long as you have answered most of the questions and have provided your name, birthdate, and contact information. If you choose to leave or are withdrawn from (taken out of) the study for any reason before finishing the entire study, you will be paid for each completed visit.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise the study principal investigator, Dr. Kelly Doran, using the contact information on the first page of this document. If your payment in a year is $600.00 or more, you will need to provide your Social Security number or Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may still be in the study but will not receive any payment. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00.

10. Will I have to pay for anything?

There will be no cost to you for being in this research study. Services that you receive as part of your regular care in the emergency department will be billed to you or your insurance as they normally would.

11. What happens if I am injured from being in the study?

There is no risk of being injured from this study.

12. When is the study over? Can I leave the study before it ends?

The 6-month follow-up visit will be our last direct contact with you as part of the study, but researchers will continue to track services and outcomes using health care and other administrative databases (including Healthix and Bronx RHIO) for 12 months after today. The overall study (for all participants) is expected to be completed in 2022 or 2023.

The study investigators, study sponsor or government monitors, or the NYU School of Medicine IRB can take you out of the study without your permission at any time for the following reasons:

- The study staff finds out you do not meet the eligibility requirements of the study.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop or change the study.

It is your choice to be in this study. No one can force you to be in the study. No one can force you to stay

in the study. You can leave the study at any time. Leaving the study will not affect the care you receive, including services you receive from the Relay program.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health or any of the other research study sites. In compliance with policies and procedures and with HIPAA, only those individuals with a job purpose can access your medical records. We are not providing medical services as part of this study and we will not be putting any new information into your medical record.

The study records are being kept separately from your medical records. As noted earlier, study researchers may access your medical records either to help us find you for follow-up visits or to collect information such as information on your future emergency department use, only as specifically relevant to the study.

This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with researchers in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
The following information may be used in connection with this research:

- Information you provide to researchers today and in the future, including your answers to interview questions, and your personal and contact information. This information will only be used for the research purposes described on this consent form.
- The study consent form.

In addition to the study researchers from NYU School of Medicine and other study emergency departments, the study research team also includes select staff from the NYC Department of Health and Mental Hygiene. Study team members will be able to use your information for the research purposes described above.

Apart from this, your information will not be shared with others unless they are part of the study research or oversight teams.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study.
- The study sponsor: Center for Disease Control (CDC).
- The Data & Safety Monitoring Board for the study and the Institutional Review Board.
- The Department of Health and Mental Hygiene
- Other study sites involved in the research

Some people or groups who get your health information might not have to follow the same privacy rules that we follow at NYU School of Medicine. We share your health information only when we have to. We ask anyone who receives this information from us to protect your privacy. Once your information is shared outside NYU School of Medicine, we cannot promise that it will remain private, though all entities that receive your information as part of this study will follow protocols to keep your information confidential and private.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your research records will be kept for at least six years after the study is over or as long as the sponsor requires them to be kept. They will be stored in a place that will not allow anyone to see them without permission. Because research is an ongoing process, we cannot give you an exact date when we will destroy your research records.

15. Data Sharing with Collaborators

We will be providing the NYC Department of Health and Mental Hygiene with information about people who participate in the study, including personal information (such as your name and date of birth), contact information, and information about whether you receive naloxone at today's visit. Sharing this information is necessary so that the Department of Health and Mental Hygiene can provide us with data to help determine outcomes of the study; can monitor activities related to the Relay program; and can contact participants after the study is over to receive Relay services (if they are not received at today's visit). We will also be providing a list of names and birthdates of people who have participated in the study to the Relay hotline call center; the call center will not be provided with any other information about you.

Finally, we will use your basic personal information (including your name and date of birth), to obtain access to your medical records for research purposes, including through the New York State Health Information Network of New York (SHIN-NY). NYU researchers will work with

Healthix and Bronx RHIO, which are part of the SHIN-NY network, for the purpose of obtaining data relevant to this research study. Healthix and Bronx RHIO are not-for-profit organizations, certified by the New York State Department of Health that collect and share information about people's health electronically with their healthcare providers to improve the quality of care. This can help collect the medical records you have in different places where you get health-care, and make them available electronically to these researchers.

- This information may relate to sensitive health conditions such as alcohol or drug use problems, birth control and abortion, genetic (inherited) diseases or tests, HIV/AIDS, mental health conditions, incarceration, sexually transmitted diseases, medication and dosages, diagnostic information, allergies, substance use history summaries, clinical notes, discharge summary, employment information, living situation, social supports, claims encounter data, lab tests, and trauma history summary. NYU researchers will only be permitted to use health information that is necessary for the research study you have agreed to participate in. However, while locating this information and copying it into its own research database, NYU researchers may gain incidental access to all of your electronic health information available but will take steps to minimize access to information that is not required for the research study.

- Information about you comes from places that have provided you with medical care or health insurance ("Information Sources"). This list of Information Sources may change over time. A complete list of current Information Sources is available from the Healthix and Bronx RHIO websites. You can obtain an updated list of Information Sources at any time by checking the Healthix website at www.healthix.org or call 877-695-4749 and at the Bronx RHIO website at www.bronxrhio.org or call 718-708-6633.

- Healthix, Bronx RHIO and any Information Sources will not benefit financially as a result of sharing of your information

- If you suspect someone should not have seen or gotten access to information about you via the study, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If your concern relates to access to your information via Healthix or Bronx RHIO, you can visit their websites (www.healthix.org and www.bronxrhio.org) or you can follow the complaint process of the Federal Office for Civil Rights at the following link: http://www.hhs.gov/ocr/privacy/hipaa/complaints/

- All of these groups are trained in protecting your personal information and keeping it private.

Any electronic health information about you may be re-disclosed by study researchers to others only to the extent permitted by state and federal laws and regulations. This is also true for health information about you that exists in a paper form. Some state and federal laws provide special protections for some kinds of sensitive health information, including HIV/AIDS and drug and alcohol treatment. Their special requirements must be followed whenever people receive these kinds of sensitive health information. NYU, Healthix, Bronx RHIO and persons who access this information through Healthix must comply with these requirements.

Disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases). You should understand that we are required to take the necessary action, including reporting to authorities, if needed to prevent serious harm to yourself, children, or others. For example, this would apply in the case of you telling us about current child abuse or considering suicide.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research, team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.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.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Participant (Print)	Signature of Participant	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date