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STAMINA.

Informed Consent Statement for Project STAMINA:

Development and Testing of a Health Navigation Approach for Linking Syringe Service Program Clients to Medication for Addiction Treatment

Institution: Chestnut Health Systems: Lighthouse Institution

Principal Investigator/Researcher Name and Title: Dennis Watson, PhD (Chestnut Health Systems); James Swartz, PhD (University of Illinois at Chicago)

Title: Project STAMINA: Development and Testing of a Health Navigation Approach for Linking Syringe Service Program Clients to Medication for Addiction Treatment

Address and Contact Information: 221 W. Walton St. Chicago, Illinois 60610
Study Phone Number: (800) 571-9717

Sponsor: Arnold Ventures

About this Research Study

This research study seeks to find out how to best connect people living with opioid use disorder to treatment. You are being asked to participate in this research study because you are **(a)** an adult who **(b)** expressed interest in receiving medication for opioid use disorder at a Community Outreach Intervention Projects (COIP) service site in Chicago, IL and because you **(c)** were screened to have symptoms of opioid use disorder, **(d)** are not reporting severe opioid withdrawal symptoms, and **(e)** can communicate in English, and **(f)** reside in Cook County, Illinois. Approximately 400 participants will be enrolled in this study.

Taking part in this study is voluntary

Your participation in this study is voluntary. You may choose to say "no" to this study or to stop participating at any time. Deciding not to participate or to stop participating later will not result in the loss of any services and will not affect your relationship with Chestnut Health Systems, University of Illinois at Chicago (UIC), University of Illinois Hospital System (UI Health), or Community Outreach Intervention Projects (COIP). You have the option not to participate in the study and receive direct regular referral to treatment at your COIP service site.

What will I be asked to do during the study?

If you agree to be in the study, you will be *randomly placed in one of two groups*: **(1)** a group that will be connected with a treatment provider using video technology or **(2)** a group that will be scheduled to visit a health care provider's office in-person.

1. If you are assigned to the first group, you will use an iPad to speak virtually to a Mile Square Health Center (MSHC) provider who will conduct an intake assessment (i.e. telemedicine). They will provide you with the type of treatment they think is appropriate. They will discuss the medication options for opioid use disorder and talk with you about which option fits best for your medical and personal needs. If you are prescribed a medication, it will be sent to the MSHC central location for pick-up. You will be provided with transportation assistance to pick up the initial medication from the pharmacy; transportation to pick up your medication will be provided by a HIPAA compliant ride share company and you will be given a bus pass for your return trip.

What will I be asked to do during the study? cont'd

2. If you are assigned to the second group, you will receive a referral to an in-person appointment with a MSHC provider. This appointment will be scheduled by research staff today; the appointment will occur at a MSHC location of your choice within 24-72 hours. During this appointment, the provider will conduct an intake assessment with you and provide you with the type of treatment they decide to be clinically appropriate.

Regardless of which group you are randomly assigned to, we will also ask you to participate in data collection for the study:

1. You will be asked to complete an in-person questionnaire that a researcher will read to you from a computer screen. A list of the types of questions they will ask is included in the next section. You will be asked to complete a questionnaire 2 times: today during enrollment and 3 months after today. The first questionnaire will be completed today, in-person with a researcher, in a private location where others cannot overhear. For the second questionnaire, you will be asked to come back to COIP to complete a urine drug screen (described below under #3), and after your drug screen, you will be connected by phone to a Lighthouse Institute staff person who will complete your questionnaire. All questionnaire data will be stored in the online data collection and storage tool, REDCap.

If you are unable to return to COIP to do the questionnaire by phone, you will be offered the option to do the questionnaire by phone offsite from COIP and to return to COIP by the end of the next business day to complete your drug screen (described below under #3).

2. Researchers will also ask you to provide detailed information to help Lighthouse Institute staff locate you for future interviews. This information will only be used to help locate you, we will not use it as research data. We will ask you for contact information for yourself and others who may assist in reaching you if your contact information changes, including: friends, family members, or service providers you may know. This information will also be stored in REDCap for security purposes. Additionally, we will ask to take a photo of you for tracking purposes. The photo will be stored in Box Health, a secure storage system. In the same manner as the contact information, this photo will only be used by Lighthouse Institute staff to help locate you for follow-up data collection.

What will I be asked to do during the study? cont'd

a. Consent to be Photographed: Additionally, if you participate in this study, we will ask to take a photo of you for tracking purposes. The photo will be stored in Box Health, a secure storage system (in the same manner as the contact information). This photo will only be used by Lighthouse Institute staff to help locate you for follow-up data collection and to make sure the person they are speaking with is you. The photograph may be shown to individuals who can help locate you, but they will only be told that researchers are trying to locate you for a health study that you'd agreed to participate. At the end of the study, your photo will be destroyed.

3. Additionally, today, we will ask you to take a urine drug screen. You will be asked to take the urine drug screen again at your 3-month data collection. As described above, you will be asked to return to COIP to answer the questionnaire over the phone with Lighthouse Institute staff. During this visit, you will be asked to do a urine drug screen. All drug screen results will be stored in REDCap. If you are assigned to the telemedicine group, the baseline urine drug screen results will be shared with the telemedicine provider who will record them in your medical record because it is required for prescribing medication for an opioid use disorder over video technology.

As described under #2, if you are unable to return to COIP to do the questionnaire by phone, you will be offered the option to do the questionnaire by phone offsite from COIP and to return to COIP by the end of the next business day to complete your urine drug screen. The drug screen can be completed onsite only and must be completed by the end of the next business day.

4. You <u>may</u> also be asked to meet for a third time to do a follow-up interview with a researcher. If so, the interview will be conducted in-person, in a private location where others cannot hear the discussion, or by telephone. The interviewer will ask questions about your treatment experiences and will audio record the interview. These interviews and transcriptions will be stored on Box Health, which is a secure, online storage system. Participants who are asked to do the final, follow-up interview will be chosen based on factors we believe to be important as we learn more about people from their follow-up visits. If asked, you can refuse to do this interview and still participate in all other data collection activities.

What will I be asked to do during the study? cont'd

5. Lastly, we will request to receive information about you from the following existing databases: Mile Square Health Center and Family Guidance Center records (*dates of OUD treatment, types of medication for OUD prescribed, treatment details regarding compliance*), Illinois Prescription Drug Monitoring Program (*names, dates, and details of controlled medications prescribed and dispensed*), and Illinois Vital Records. While your involvement in the study will last only 3-4 months, this data will be accessed for 6 months from the date of your enrollment.

What data will be collected on me?

A summary of the data collected on you is listed below.

- Full name
- Date of birth
- SSN
- UI Health Medical Record Number (MRN)
- Structured questionnaire
    - Demographic information (gender, race, ethnicity, sexual orientation, military involvement)
    - Education, employment, income
    - Drug and alcohol use
    - Family and living conditions
    - Health
    - Social support
    - Substance use treatment experiences and motivation
    - Quality of life
    - Trauma exposure
    - History of crime and criminal justice involvement
    - Contact information for yourself, as well as others who may assist in reaching you if your phone number, address, or email change.
- Urine Drug Screen Results
- Follow-Up interview
    - Substance use treatment experiences

What data will be collected on me? cont'd

- Recovery experiences

- Opioid Use Disorder Treatment Data from Mile Square Health Center healthcare provider. *These data are pulled for the purpose of verifying any opioid use disorder treatment that you engaged in at Mile Square Health Center. This helps us understand specific details of this care.*
  - Date(s) of Opioid Use Disorder Treatment
  - Type(s) of Medication for Opioid Use Disorder (MOUD) prescribed
  - Treatment details regarding treatment compliance
- Opioid Use Disorder Treatment Data from Family Guidance Center healthcare provider. These data are pulled for the purpose of verifying any opioid use disorder treatment, specifically methadone treatment, that you engaged in at Family Guidance Center. This helps us understand specific details of this care.
  - Date(s) of Opioid Use Disorder Treatment
  - Type(s) of Medication for Opioid Use Disorder (MOUD) prescribed
  - Treatment details regarding treatment compliance
- Illinois Prescription Monitoring Program (PMP) Data. *These data are pulled for the purpose of verifying whether you have been prescribed or given any controlled substances, which include the medications for opioid use disorder treatment. This helps us understand whether you engaged in treatment involving medication.*
  - Names of controlled substances prescribed or dispensed
  - Details of prescriber or dispenser
  - Dates associated with prescriptions or dispensations
- Illinois Vital Records. *These data are pulled for the purpose of verifying possible death and cause of death, as drug use carries this risk.*
  - Date of death
  - Cause of death

How much time will I spend on the study and will I be compensated?

The two structured questionnaires and contact information questions that will be completed today and 3 months after today will take approximately 45-60 minutes each. The saliva drug screen will take approximately 3-10 minutes.

Today, if you are randomized to the group who receives telehealth care, the intervention will take an additional 15-60 minutes after data collection (depending on provider availability). Thus, from when we met today through the end of all intervention steps, this process today could take 2-3 hours.

You will receive $50 for your time and effort completing today's data collection activities. At 3 months, you can receive $35 ($25 for completing the questionnaire and $10 for completing the drug screen). All payment is provided in VISA gift cards at the end of each activity. We will also reimburse you for your travel to & from COIP at the 3- month data collection activities by providing you with two, single ride Chicago Transit Authority (CTA) cards for each visit.

If asked to meet for a third time to do a follow-up interview with a researcher, the interview will last 30-60 minutes and will happen sometime within one month of your 3-month questionnaire. You will receive $35 for completing this interview, which will be given in a VISA gift card at the interview's end. If this interview is conducted by telephone, the gift card will be mailed to an address you provide.

If you do not finish the study, you will be compensated for the data collection visits you have completed. If you complete all study activities, you will receive a total of $85 over the course of your participation. If asked to take part in the in-person follow-up interview, you will receive a total of $120 over the course of your participation.

What about Corona Virus (COVID)-19 Safety?

In the event that **(1)** Chicago restricts in-person interaction by closing non-essential businesses due to COVID-19, or that **(2)** Lighthouse Institute experiences difficulties successfully contacting participants and completing the 3-month follow-ups due to COVID-19, the study will put into effect the following safety precautions:

What about Corona Virus (COVID)-19 Safety?

- The 3-month REDCap questionnaires will be completed over the telephone from any location.
- The 3-month drug screen will only be requested of a randomly selected subsample.
- The payment provided to participants at follow-up will only be $25 for the REDCap questionnaire, and the $10 for the drug screen will only be provided to the random subsample asked to do the drug screen at follow-up.
- The final qualitative interviews completed at 3-months with a subsample of participants will be conducted by telephone.
- The payment will be mailed to an address provided by the participant. To ensure you can get this gift card, it is very important that you give us a reliable mailing address when we ask for it today.

Are there any benefits to taking part in the study?

All participants will receive referrals and access to treatment, but participants assigned to telemedecine may benefit from receiving more immediate access to treatment and medications.

This study will increase knowledge regarding treatment linkage for opioid use disorder. We intend for this study to contribute to the science on substance use disorder treatment, and routes to improve recovery-related outcomes, which may inform future program development.

What are the main risks of the study & how are the risks minimized?

Potential risks to taking part in this study include:

- Breaches of privacy (others outside of the study may find out you are a subject receiving treatment for opioid use disorder) and/or confidentiality (others outside of the study may find out what you did, said, or information that was collected about you during the study).
- You might also be uncomfortable or feel distress related to some of the more sensitive interview questions asked such as those about substance use, past involvement in substance use treatment, treatment motivation, and criminal justice involvement.

What are the main risks of the study & how are the risks minimized? cont'd

In order to minimize these risks:

- The questionnaire data will be stored on a secure, password protected data management system that only research team members may access (i.e. REDCap).
- The participant photo will be stored on a password protected server (i.e., Box Health). These files will be labelled with your study ID and will only be accessible by the study team members.
- Any audio recordings will also be stored on a password protected server (i.e., Box Health). These files will be labelled with your study ID. All transcription will be de-identified, and once transcribed, the audio files will be deleted.
- Once your data is received from Mile Square Health Center, Family Guidance Center, Prescription Monitoring Program (PMP) data, and Illinois Vital Records, these data will be stored in separate password protected university folders that are only accessible by the research staff at UIC. These data will be labelled with your study ID.
- Your data (all types) will be stripped of all direct and indirect identifiers after analysis. The code/master list (identifiers) will be destroyed. When the results of the study are published or discussed in conferences, no one will know that you were in the study.
- You can skip and/or not respond to any questions in the questionnaire or interview that may make you uncomfortable, and you will be allowed to only share the information you feel like sharing.
- You may end the questionnaire or interview at any time without consequence.
- If there is noticeable distress, the research staff might ask you if you are OK with proceeding before continuing and/or refer you to a COIP staff person who can connect you with any desired follow-up services.

What about confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and state rules might require us to tell certain people about you.

What about confidentiality? cont'd

For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis by:

- Representatives of the committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The sponsor of the research study, Arnold Ventures

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

- if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
- if you consent to the disclosure, including for your medical treatment;
- if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
- for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Questions about the study?

For questions, concerns, or complaints about the study, please contact Dennis Watson (Principal Investigator) at 221 W. Walton St. Chicago, Illinois 60610 or (312) 664-4321.

Questions about the study? cont'd

If you have questions about your rights as a study subject or if you have questions or concerns regarding your privacy rights under HIPAA; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the Chestnut's Institutional Review Board (IRB) at kwright@chestnut.org.

Can I withdraw from the study?

If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty. The researchers, Dr. Dennis Watson and Dr. James Swartz, may still use your information that was collected prior to your written notice. The researchers and/or funder also have the right to stop your participation in this study without your consent if they believe it is in your best interests or if you were to object to any future changes that may be made in the study plan.

Your Authorization for release of health information for this research study expires at the end of the study but can be canceled sooner if you decide to withdraw.

If you choose to no longer be in the study and you do not want any of your future information to be used, or if you change your mind and wish to cancel this Authorization at any time, you will need to notify the researchers in writing at the address listed below. You may also call (312) 664-4321 to reach Dr. Dennis Watson.

Dr. Dennis Watson
221 W. Walton St. Chicago, Illinois 60610

Additional Detailed Information Pertaining to the Study:

How will my health information be used and protected?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form, you are authorizing Dr. Dennis Watson and Dr. James Swartz and their research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

How will my health information be used and protected? cont'd

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically include: full name, address, date of birth, phone number, email address, dates of enrollment and data collection activities, treatment details regarding compliance, medications prescribed and dates of treatment, Illinois controlled substances prescribed to you (e.g. suboxone, methadone), and Illinois vital records data.

The researchers will not need to access health information from your doctors not at UIC.

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study;
- With the sponsor/funding agency of the research: Arnold Ventures

The researchers, Drs. Dennis Watson and James Swartz, agree to protect your health information and will only share this information as described within this research consent/authorization form. When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

Cost of Participating in Research

You or your insurer will be responsible for paying for the cost of your standard medical care for in-person or telehealth visits. All follow-up OUD care and prescribing will be billed to you or your insurer. You will be responsible for all deductibles and co-payments as you normally would if you do not participate in research. If you do not have insurance, you will be billed for the amount you have to pay. The healthcare provider you will be referred to can assist you in obtaining insurance if you do not have it already. If you are not eligible for insurance, Mile Square Health Center operates on a sliding scale for patients who have limited ability to pay.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

Signature of Subject

I have read the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form. Your signature below indicates that you are providing both consent to participate in the study and authorization for the researcher to use and share your health information for the research.

_____ _____

Signature Date

_____

Printed Name

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent

(Proceed only if participant previously verbally consented to audio recording of opioid use disorder treatment options discussion)

Optional Permission Regarding Consent to Use Quality Assurance Audio Recording as Data

If you are willing to allow researchers to use the previously recorded audio of your discussion of medication options for opioid use disorder and medication preference as research data, please initial below. This provides researchers permission to transcribe the audio file, name the document with your unique study identification number, store it Box Health (in the same, secure manner as your other data), and use it alongside the questionnaire and other health data collected. Allowing researchers permission to use this recording as research data is not a requirement for participation in this study.

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Participant Initials