Agenda Item: Data Request – Pathways for Maine Program

Overview: Cumberland County Public Health has a desire to have correctional inmates who are released and provide consent be subject to monitoring for overdoses after release. Maine EMS is one of the data sources they are looking to monitor. They would provide names and DOBs and we would alert them if we have a match in our PCRs for a suspected overdose. I have attached what documentation they have provided thus far.

This has been approved by the MDPB.

UNIVERSITY OF SOUTHERN MAINE

Office of Research Integrity and Outreach

Date: February 2, 2025

To: Brandon Irwin, Debbie Love, Rachel Kohn
(Debbie Love)

Protocol #: IRB-2025-8

Determination Date: February 2, 2025

Administrative Check-in Date: February 1, 2027

RE: Pathways for Maine

Decision: No Human Subjects Research

Notice of Evaluation- Not Research 45 CFR 46.102 (l) and 28 CFR 46.102(d)

The Office of Research Integrity and Outreach (ORIO) has evaluated the information provided in the Request for Determination of Research Involving Human Subjects form and subsequent correspondence. Based on the information you have provided, it has been determined that the activity is not designed to develop or contribute to generalizable knowledge.

Our understanding is that you intend to conduct a comprehensive evaluation to determine if the Pathways for Maine (ME) program in the Cumberland County Jail is reducing fatal overdose deaths and recidivism among those who are incarcerated and assessed for opioid, stimulant, and substance use disorders. A U.S. Department of Justice Bureau of Justice Assistance grant and Data Use Agreements that include Limited Data Sets govern this activity. You plan to collect quantitative data using county-level, secondary data sources including Spillman, Armor data system, Maine Pretrial Services Management Information System, EMS, Portland Recovery Community Center, and Maine Department of Corrections CORIS Information System; and collect qualitative data through a combination of key informant interviews, focus groups, and feedback surveys. Findings will inform and sustain the Pathways for ME program using process, feedback, and outcome measures. All data collected will be de-identified before dissemination, and the identities of all project participants will remain confidential. You do not intend for the results of this project to be relevant outside of the Pathways for ME program in the Cumberland County Jail. If this is not accurate, please let us know immediately.

This activity is not a systematic investigation, including research development, testing, and evaluation, and/or designed to develop or contribute to generalizable knowledge; it does not fall under the definition of research as described in 45 CFR 46.102(l) or 28 CFR 46.102(d), and therefore does not require further review or determination.

The ORIO and the USM Institutional Review Board appreciate your efforts to conduct research in compliance with federal regulations established to protect human subjects in research. Please consult with the ORIO whenever questions arise about whether planned changes qualify the activity as research involving human subjects. If you

have any questions, please contact us at 207-780-4517 or email usmorio@maine.edu.

Sincerely,

Office of Research Integrity and Outreach

P.O. Box 9300, Portland, ME 04104-9300
(207) 780-4517, TTY (207) 780-5646, FAX (207) 228-8405
www.usm.maine.edu
A member of the University of Maine System

Date: 3-10-2025

IRB #: IRB-2025-8
Title: Pathways for Maine
Creation Date: 1-9-2025
End Date:
Status: Approved
Principal Investigator: Brandon Irwin
Review Board: Social and Behavioral IRB
Sponsor: US Department of Justice

Study History

Submission Type	Review Type	Decision
Initial	Administrative	No Human Subjects Research

Key Study Contacts

Member	Role	Contact
Rachel Kohn	Co-Principal Investigator	rachel_kohn@jsi.com
Debbie Love	Co-Principal Investigator	debbie_love@jsi.com
Brandon Irwin	Principal Investigator	irwin@cumberlandcounty.org
Debbie Love	Primary Contact	debbie_love@jsi.com

Initial Submission

Getting Started

About Cayuse Human Ethics

Cayuse Human Ethics (HE) is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore not all numbered sections may appear. You do not have to finish the application in one sitting. All information can be saved.

For more information about the IRB submission Process, IRB Tracking, and Cayuse HE Tasks, please contact the Office of Research Integrity and Outreach (ORIO) at: usmorio@maine.edu or 207-780-4517.

Submit protocol for review at least thirty (30) days prior to starting data collection.

FMI Collaborative Boards

IORG#: IORG 1507
Federalwide Assurances:
IRB 1953, U of Southern Maine IRB #1, Portland, OHRP Only, Active: Social Behavioral
IRB 11534, U of Southern Maine IRB #2, Portland, OHRP/FDA, Active: Biomedical

Getting Started

Throughout the submission, you will be required to provide the following, as applicable:

- CV or Resume for all research staff
- Human Subject Research training for all research staff
- Interview/Focus Group Questions
- Questionnaires/Surveys
- Recruitment Materials (e.g., flyers, email text, verbal scripts)
- Letters of Agreement/Cooperation from organizations

- Consent Forms
- Assent Forms/Parental Permission
- Methods section of your thesis or dissertation proposal
- Grants/Sub-contract
- Other files associated with the project

*required

I have read the information above and I am ready to begin my submission.

✓ Yes

Project Personnel

*required

What kind of affiliation does the Principal Investigator have with USM?

- Student
- Staff
- Faculty
- ✓ External to USM

*required

Name of USM Department or External Organization

County of Cumberland (County)

Study Personnel

Note: If you cannot find a person in the people finder, please contact the IRB Office immediately.

*required

Principal Investigator

The person listed as the PI will be required certify submissions before they are sent to the IRB for review. They will also have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications. **The PI *will be required certify submissions before they are sent to the IRB for review***

Name: Brandon Irwin
Organization: Research Integrity
Address:

Phone:
Email: irwin@cumberlandcounty.org

*required

Primary Contact

Any people listed as a PC will have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications.
Name: Debbie Love
Organization: Research Integrity
Address: CITI exp 3/30/28 , ,
Phone: BS
Email: debbie_love@jsi.com

Co-Investigator(s)

Any people listed as Co-Investigators will have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications. **The Co-PI *will be required certify submissions before they are sent to the IRB for review.***
Name: Rachel Kohn
Organization: Research Integrity
Address: CITI exp 05/13/28 , ,
Phone: MSW, MPH
Email: rachel_kohn@jsi.com

Name: Debbie Love
Organization: Research Integrity
Address: CITI exp 3/30/28 , ,
Phone: BS
Email: debbie_love@jsi.com

Investigators

Any people listed as Investigators will be able to view the study, but will NOT have edit access to the study nor be included in study communications automatically.

Other Research Team Members

Any people listed as Other Research Team Members will be NOT able to view the study, edit, nor be included in study communications automatically.
Name: Rachel Daube
Organization: Research Integrity

Address:
Phone:
Email: rachel_daube@jsi.com

*required

Is this Human Subject Research?

If no, only the Determination for Human Subject Research form will display.
If yes, attach resume and training will display.
If No or Student Classroom Project, choose "Request for Determination of Human Subject Research" under Basic Information.

✓ Yes

No

Faculty Led Student Classroom Project

*required

Study Personnel Training Documentation

Upload documentation of any required training (e.g., CITI training) for each member of study personnel

citiCompletionReport_DLove 11.6.24 (1) (1).pdf

RKOHN_citiCompletionCertificate_12153735_55240587.pdf

citiCompletionReport_14039619_67264111.Irwin.pdf

citiCompletionCertificate_10737414_46257051.pdf

*required

Study Personnel CV/Resume

Upload CV or Resume for each member of study personnel.
-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.
Rkohn_Resume_01.14.2025.docx.pdf

Resume.lrwin.pdf

D. Love resume 2025.docx.pdf

R. Daube Resume 2025.pdf

*required

Conflict of Interest

NOTE: If you answer Yes to any of the questions below and are faculty or staff for USM, you may be required to file a Conflict of Interest disclosure statement and complete Conflict of Interest CITI training. View the FCOI information on the USM website here.

*required

Do any of the involved Investigators or their immediate family have consulting arrangements, management responsibilities or equity holdings in the sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)

Yes

✓ No

*required

Do any Investigators or their immediate family have any financial relationship with the sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?

Yes

✓ No

*required

Is any Investigator(s) a member of an advisory board with the Sponsoring company?

Yes

✓ No

*required

Do any investigators receive gift funds from the Sponsoring company?

Yes

✓ No

*required

Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?

Yes

✓ No

If any of the above are yes, please explain.

Basic Information

*required

Study Site(s)

List all sites/locations involved with this project.

Participation sites are Cumberland County Jail, Portland, ME, and community organizations located in Portland, ME including the following partners: CommonSpace, Portland Recovery Community Center, Armor, Maine Pretrial Services, Cumberland County Health Department.

Collaboration Information

Please note external collaborators must ensure their institution will accept USM's review of this study.

*required

External Sites

Will any research activities occur at any External Sites in the United States? This would include locations other than where you are employed as long as they are within the United States.

Yes

✓ No

*required

External Collaborators

Will any External Collaborators be conducting research activities?

Yes

✓ No

*required

International Sites

Will any research activities occur at non-US sites?

Yes

✓ No

*required

Project Type

What type of project is this submission for?

Research Study

✓ Request for Determination of Human Subject Research: Activities Without a Plan to Conduct Research (Case Report, Quality Improvement project, Public Health project, Pilot Project) OR Research in which this Institution is Not Engaged

Select this option if **any** are true:

- You are not sure if your project requires IRB oversight.
- You need a formal determination from the IRB on if the project requires IRB oversight.
- Faculty Led Student Classroom Project

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118 Determination/Future Human Research

Select this option if **BOTH** are true:

- This research project will involve or may involve human subjects in the future, but future protocol development must take place first.
- You need documentation of IRB review in order to release your grant funds.

Clinical Trial

Clinical use of a humanitarian use device (HUD) for treatment or diagnosis consistent with approved labeling.

Maine Department of Health and Human Services

*required

Does this activity involve the Maine Department of Health and Human Services (DHHS) or its programs, services, offices, divisions, or data?

Yes

✓ No

U.S. Department of Education

*required

Will the research occur within a school district or K-12 school that receives funding from the U.S. Department of Education?

This includes all public schools and most private schools.

Yes

✓ No

Study Dates

Please provide the intended study start and end dates.
Consider: start date should be about 30 days after submission to the IRB.

*required

Start Date

02/01/2025

*required

End Date

09/30/2026

*required

Primary source of funding:

Does this project have external or internal funding source(s). Is this project have funding or another type of in-kind support) e.g., provision of drugs/study products, internal support, etc.)?

None/In Kind/Internal funding from the principal investigator's organization

Other External Funding: Private non-profit, Foundations, State Funding, etc

✓ US Government: Federally funded

Industry Sponsored: funding from a company, usually for-profit, specific to the advancement of your type of research

International/Non US

*required

Funding

*required

Name the Funder(s):

US Department of Justice

If your funding entity is not in the list, please name them here.

You must search for and choose **Other** in Find Sponsors as well as typing in funding entity.

Bureau of Justice Assistance

*required

Title of Grant (if different from protocol title):

Pathways for Maine

*required

Period of funding:

October 1, 2023 - September 30, 2026

*required

Amount of funding:

$1,000,000

*required

Attach grant materials, contracts, or agreements with the funding source.

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

Award_Package_FAW-178247 (2) (1).pdf

If applicable, USM Research Service Center Award Notification Number(s):

National Science Foundation (NSF) proposals and National Institutes of Health (NIH) with direct costs greater than $500,000 must attach a Data Management Plan in the Attachment section

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

Request for Human Subject Research Determination

*required

What is the purpose of the activity?

To implement a comprehensive evaluation to determine if the Pathways for Maine program in the Cumberland County Jail is reducing fatal overdose deaths and recidivism among those who are incarcerated and assessed for opioid, stimulant, and substance use disorders.

*required

What are the activities being conducted?

- **Formative Evaluation:** key informant interviews to identify partners' roles and responsibilities, create a process map of how a participant moves through the program, a logic model for determining impact outcomes, SWOT analysis to identify barriers (complete as of 1.31.25)
- **Data Collection:** collect quantitative data using county-level, secondary data sources including Spillman, Armor data system, Maine Pretrial Services Management Information System, EMS, Portland Recovery Community Center, and Maine Department of Corrections CORIS Information System; and collect qualitative data through a combination of key informant interviews, focus groups, and/or feedback surveys.
  Data Analysis & Dissemination: Throughout the 3-year grant, evaluation findings will be used to inform and sustain the Pathways for ME program using a combination of process, feedback, and outcome measures. Specifically, project performance will be assessed and reported using both quantitative and qualitative data sources. Quantitative data will be collected using county-level sources, such as the Cumberland County Jail Spillman Data System (Spillman); Armor Correctional Health Services Data System (AMOR); Maine Pretrial Services Management Information System (MPS-MIS); and the Maine Department of Corrections CORIS Information System (CORIS). Qualitative data will be collected through a combination of key informant interviews or focus group discussions, and feedback surveys with Peers embedded within the jail and community, community-based providers, other community partners, CCJ/corrections staff, and individuals receiving re-entry support services. Building on previously established data collection processes, the JSI evaluation team has developed protocols, data collection tools, and strategies

that are feasibly integrated into program activities with the least amount of added burden or disruption to service. Data collected will be coded and de-identified before sharing with program partners. The identities of all project participants will remain confidential. Data will be stored securely in a password-protected location.

*required

Who are the INTENDED subjects/participants?

-Do not include incidental participants.

---

*required

Included Populations

Please indicate any population(s) that will knowingly be enrolled. Check all that apply.

- ✓ Adults (18 years of age or older)
- Fetuses
- Pregnant Women
- Neonates (birth to less than 1 month)
- Children (including infants from birth to less than 1 month determined to be viable)
- ✓ Prisoners
- Cognitively Impaired Adults
- Other Vulnerable Populations
- ✓ De-identified data only
- None of the above

*required

Justification of Vulnerable Populations

Necessity of Inclusion and any Special Arrangements

This study aims to understand how those incarcerated individuals who have been assessed for opioid, stimulant, and substance use disorders are referred to and navigate the Pathways for Maine program, what support they are provided while in the program; and if the program reduces a participant's chances of overdose and recidivism upon reentry into the community.

*required

Who is the intended audience?

-How will the results be shared, with whom, and in what form?

Data collected will be provided to the Cumberland County Department of Health (CCDH) for reporting purposes to the federal funder, Bureau of Justice Assistance (BJA) through the BJA Performance Measure Tool (PMT) every quarter and reported to participating program partners through an FSTP site. Any reports and analyses will be conducted and reported in aggregate with no reference to names or other identifying information. Potential audiences include partners, advisory board, and other state leadership in Maine.

*required

If there is a Business Associate Agreement (BAA), with which healthcare provider?

Armor Health

*required

Are you using Maine Integrated Youth Health Survey (MIYHS) data?

Yes

✓ No

*required

Has this been reviewed by another IRB?

Yes

✓ No

*required

Are you requesting a determination in order to fulfill W-9 form requirements?

Incentive/payment to partcipants

Yes

✓ No

*required

Is the Activity Non-research?

§46.102 (l) (1-3)

*required

Is the activity scholarly or journalistic?

- *Scholarly and journalistic activities (*e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

Yes

✓ No

*required

Is the activity a public health surveillance activity?

-Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

Yes

✓ No

*required

Is the activity a collection and analysis of information for a criminal justice agency?

-Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

Yes

✓ No

*required

Does the project meet definition of "Research"?

As defined by 45 CFR 46, **research** is *"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."*

*required

Is the activity an investigation?

-Investigation means a searching inquiry for ascertaining facts or a detailed or careful examination.

Yes

✓ No

*required

Is the activity systematic?

-Systematic means having or involving a system, method, or plan. (including the selection of subjects, decisions about what observations to record, and an interview process)

Yes

✓ No

*required

Is the activity designed to develop or contribute to knowledge?

-Designed means done with purpose or intent. Develop means to elaborate or expand in detail. Contribute means to be an important factor in. Knowledge means truth, facts, or information.

✓ Yes

No

*required

Is the knowledge generalizable?

-Generalizable means relevant beyond the population or program from which it was collected, or universally applied/accepted, to other contexts or situations.

Yes

✓ No

*required

If the project is research, does it meet the definition of "Human Subject" research?

As defined by 45 CFR 46, a human subject is "*a living individual, about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*"

*required

Does the research involve obtaining information (or biospecimens) about a living individual?

-About means the information concerns the individual whose information is collected; the focus of the investigation is the opinions, characteristics, or behavior of the individual.
-Biospecimen means material such as urine, blood, tissues, cells, DNA, RNA, and proteins.

Yes

✓ No

*required

Does the project involve interaction or intervention with individuals?

-Interaction includes communication or interpersonal contact between investigator and participant.
-Intervention includes both physical procedures by which information or biospecimens are gathered and manipulation of the participant or the participant's environment that are performed for research purposes (for example, having participant listen to music and then having them perform memory tasks in order to investigate the effect of music on memory).

Yes

✓ No

*required

Does the project involve obtaining, using, studying, analyzing, or generating private information?

Private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place,

and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). ***Consider****: If the project only involves data and/or specimens that were pre-existing, or collected for some purpose other than this project, consider the original source of the data/specimens, how they are provided to investigators, if the data/specimens are identifiable in any way to investigators, etc.*

✓ Yes

If yes, is the private information identifiable?

-Identifiable means the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

The data are not anonymous, however, to protect privacy, a unique identifier will be used in the analytic files, and full names will not be used on any documents or databases provided to the JSI evaluation team. To protect privacy and confidentiality, the researchers are bound by JSI's system security policy which addresses all aspects of data security. JSI Key Staff will be the only ones with access to data for analysis and evaluation purposes of this Pathways for Maine study. JSI's data security policy states that all sensitive data must be protected from unauthorized access during storage and transmission. JSI Key staff will be responsible for the receipt or transmission of the data. Data gathered will assess individual-level outcomes that can be tracked during a participant's movement through the program. Data will be extracted or shared using safe file transfer protocols and stored on secure HIPAA-compliant servers. Encryption will be used as warranted to protect the personal health information and identity of all participants. Access to servers, workstations, and other equipment containing sensitive or valuable data is limited to those personnel required to use these systems as part of their jobs. Data collected for this study will be securely stored for not more than three years following the conclusion of the study. Electronic data will be removed and erased from all servers and FSTP sites.

No

*required

Does the research involve obtaining, using, studying, analyzing, or generating identifiable biospecimens?

Identifiable biospecimens means the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Yes

✓ No

HIPAA

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule applies to projects where Protected Health Information (PHI) is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research.
- Even if your project is Not Human Subject Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a Covered Entity.
- Protected Health Information (PHI) = health information + one or more of the 18 identifiers

*required

Does this project involve obtaining, using, or releasing/disclosing identifiable PHI by a Covered Entity?

✓ Yes

No

Attach recruitment material(s), questionnaires or surveys, grant/funding materials, and consent language document(s), etc.

-Word or pdf copies are best. Links, such as Google or SharePoint cannot be accessed by external reviewers.
PforME Consent Form_2024.12.31.pdf

Please include any additional information you would like to provide.

- The HIPAA Privacy Rule applies to projects where PHI is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research.
- Even if your project is Not Human Subject Research or this institution is Not Engaged in Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a Covered Entity.
- Protected Health Information (PHI) = health information + one or more of the 18 identifiers.

- If the PI is granted a HIPAA waiver of authorization, the PI has access to the PHI in its entirety.
- OR
- The PI seeks a limited data set (demographics and dates) and signs a Data Use Agreement (DUA) that the explains how the PI will keep those limited identifiers confidential and secure.
- In most situations, the PI will not need to request a waiver of authorization under HIPAA if there is a DUA.

---

*required

Health Information Collected

If not already described elsewhere, describe what health information will be collected as part of this project (e.g., blood pressure, x-rays, etc.).

In compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its associated regulations at 45 C.F.R. Part 160 and 164 (Privacy Rule) Data Use Agreements have been put in place with all partners in connection with the disclosure of a limited data set (LDS) by Covered Entity to Recipient. The recipient will conduct research using protected health information (PHI) in a LDS as defined by the HIPAA Privacy Rule regulations at 45 C.F.R. 164.514(e). Specific health information will include demographics, substance use diagnoses, and engagement in recovery and reentry services for the purposes of program monitoring and evaluation.

HIPAA Identifiers Collected

Have all 18 identifiers been removed?

Yes

✓ No

*required

Please describe.

Name and dates of services will be included in data that is submitted; however, analytic data files will only include a unique identifier and no names. Dates for services will used to determine dosage. All reports will aggregate and de-identified.

Waiver and/or Alteration of HIPAA Authorization

*required

Requesting Waiver/Alteration

Will this project in part or in full involve any waivers or alternation of HIPAA Authorization?

Yes

✓ No

Does the study involve obtaining Protected Health Information (PHI) from a "covered entity" outside of University of Southern Maine (i.e. another organization or institution)?

✓ Yes

No

Will this study involve the transfer from a covered entity as defined under HIPAA of protected health information (PHI) to you?

✓ Yes

Protection of PHI

If Yes, explain what arrangements have been made to comply with the HIPAA requirements of the entity from which the PHI will be obtained.

Covered Entity shall provide PHI to JSI as a LDS in the following format and medium: The LDS will be shared in a password-protected, secure file transfer protocol and/or encrypted electronic format. Covered Entity shall include in its Notice of Privacy Practices that it may be required to disclose PHI for the purposes of program monitoring and evaluation.

No

*required

How and What PHI is Shared

Describe how PHI will be shared and with which entities. Be sure to address the following:

- *What PHI will be shared.*
- *Who is receiving the data (e.g., Name of entity and if it is a Covered Entity).*
- *Under what authorization PHI is release (e.g., Limited Data Set under a Data Use Agreement, subject authorization, under a waiver of authorization, etc.).*

The PHI that will be shared is ....

JSI Research & Training Institute, Inc.'s key project staff will be receiving PHI data as limited data sets established by completed/signed Data Use Agreements from the following program partners: Cumberland

County Jail, Maine Pretrial Services, Armor Health, CommonSpace, and the Portland Recovery Community Center. A Data Use Agreement will be established with EMS for data sharing contingent upon IRB approval.

Storage and Maintenance of Identifiers

If not already described elsewhere, describe the plan for the maintenance of the identifiers (collected under this waiver/alteration) checked above after this project has ended. For example:

- *Destroying data*
- *De-identifying data by removing all identifiers*
- *Maintaining identifiable or coded data for storage in a Research Repository for the conduct of Future Research*

The data are not anonymous, however, to protect privacy, a unique identifier will be used in the analytic files. A separate file will be used to maintain full names and the unique identifier for each individual in the study and will not be directly linked to the analytic file. Any reports and analysis will be conducted and reported in aggregate with no reference to names or other identifying information. JSI Key Staff will be the only ones with access to data for analysis and evaluation purposes of this Pathways for Maine study. JSI's data security policy states that all sensitive data must be protected from unauthorized access during storage and transmission. Partners are responsible for unloading PHI in Limited data sets to a password-protected and encrypted FSTP site. Access to the FSTP site is overseen and managed by the principal investigators. Data collected for this study will be securely stored for not more than three years following the conclusion of the study. Electronic data will be removed and erased from all servers and FSTP sites. Data will not be banked for future use nor will the data be shared with any other entities beyond those directly involved in implementing the program or the study.

Will you be submitting a Data Use Agreement (DUA) or Business Associates Agreement (BAA)?

Yes

✓ No

Additional Documentation

Upload any additional documentation related to HIPAA Authorization, as applicable.
-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

Attachments

Project Personnel

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

Study Personnel Training Documentation

Upload documentation of any required training (e.g., CITI training) for each member of study personnel.

citiCompletionReport_DLove 11.6.24 (1) (1).pdf

RKOHN_citiCompletionCertificate_12153735_55240587.pdf

citiCompletionReport_14039619_67264111.Irwin.pdf

citiCompletionCertificate_10737414_46257051.pdf

INFORMED CONSENT TO PARTICIPATE IN AN EVALUATION OF PATHWAYS FOR MAINE PROGRAM

Title of Program: Evaluation of Pathways for Maine: Person-Centered Recovery and Reentry

Name or Project Director: Brandon Irwin, Cumberland County Department of Public Health

Name of Lead Evaluator: Rachel S. Kohn, MSW, MPH JSI Research & Training Institute, Inc. (JSI)

KEY INFORMATION

The following is a summary of key information to assist you in understanding why you might or might not want to participate in this evaluation.

- You are being asked to take part in the evaluation of the Pathways for Maine (PforME) program.
- Your participation in the evaluation is voluntary.
- If you choose not to be involved in this evaluation, you can continue to participate in the PforME program.
- The purpose of this evaluation is to determine if the PforME program brings forth positive change (reduce recidivism and reduce overdoses) in participants.
- Information is being gathered about the reentry services provided to you while you are in the PforME program to prove the effectiveness of the PforME program.
- Your participation in the evaluation is expected to last from the date you sign the consent form and while you are enrolled in the PforME program.
- Participation in the evaluation means you will participate in the regular PforME activities and schedule.
- The evaluators will be using information about you that is collected by the Cumberland County Public Health Department and the following program partners:
    - Maine Emergency Medical Services (EMS) and Licensed EMS agencies in Maine
    - Maine Pretrial Services
    - Armor Health Care
    - Cumberland County Jail
    - Common Space
    - Peer Recovery Community Center

What are my rights?

✓ Your participation in this evaluation process is **completely voluntary**

✓ You are **free not to answer** any questions that you do not want to answer

✓ You may **choose to participate or opt out of the evaluation** at any time, without any impact on your participation in the PforME program.

✓ You may **choose to participate or opt out of the evaluation** at any time, without any impact on your incarceration or your parole.

Please read this entire document about participating in this evaluation. The following pages describe in more detail the purpose, benefits, risks, and precautions of the evaluation process and inform you that you may withdraw from this process at any time. While we hope this information is complete and clear, you are encouraged to ask any questions you have about the evaluation and what is involved.

Who is the evaluation team and how is the evaluation funded?

JSI Research & Training Institute, Inc. (JSI) is a private, non-profit, public health research and consulting organization located in Bow, NH. JSI is deeply committed to improving lives through greater health, education, and socio-economic equity for individuals and communities. JSI has been hired by the Cumberland County Public Health Department to evaluate the Pathways for Maine program. This evaluation is being funded by the Bureau of Justice Assistance, Department of Justice.

What is the purpose of evaluating the Pathways for Maine (PforME) program?

The overall goal of this evaluation is to determine if the PforME program is effective at reducing recidivism and reducing overdoses for individuals who are reentering the community after being incarcerated.

How many people will take part in the evaluation?

The evaluation participants will be only those individuals with substance use diagnoses enrolled in the PforME program during the three-year BJA grant period (10/1/23-9/30/26). It is anticipated that 1,000 individuals will be screened and assessed per year. At least 100 of those individuals will be provided reentry supports and linkages to the Peer Navigator and/or Peer Recovery Specialist in the jail to bolster the continuation of treatment and recovery upon release from jail.

What is involved in this evaluation?

You do not have to do anything beyond what is expected from your participation in the PforME program. The evaluators will be collecting feedback from you about the program in order to understand how well the program met your needs pre- and post-release. You may be asked to complete a brief anonymous survey and/or participate in a facilitated discussion about your experience with PforME.

Do I have to participate in the evaluation?

No, your participation in the PforME evaluation is entirely voluntary. You may opt out of the evaluation process at any time. You do not need to give any reason or explanation for doing so. Withdrawing from the evaluation will not affect your participation in the PforME program or change the services you are eligible to receive. Withdrawing from the evaluation will not impact your incarceration or your parole.

Will anyone be informed of my participation in this evaluation?

No, all the information gathered is confidential, private, and secure. Access to all files will be restricted and stored on a secure server to protect personal health information and managed by the evaluators at JSI Research & Training Institute, Inc. The only people who will know about your participation are the Reentry Coordinator, the Project Director at the Cumberland County Department of Public Health and the evaluators at JSI. All data and results will be presented without using your name and none of the information you provide will be linked to you individually.

Will participating in the evaluation benefit me?

You may not benefit directly from the evaluation. However, your participation in the evaluation will help shape future programs.

What are the risks?

Potential risks of participating in an evaluation include: 1) **additional time required** for completing anonymous feedback surveys or individual interviews, and 2) the possibility of **personal health information being accessed by someone other than the researchers**. This evaluation project has been designed in a manner that reduces both of these risks, and to protect privacy and confidentiality. The evaluators are bound by JSI's system security policy which addresses all aspects of data security. All data will be de-identified, meaning your name and other identifying characteristics will be removed. Any project information will be stored within JSI's secured office facilities or in secured servers. Access to servers, workstations, and other equipment containing sensitive or valuable data is limited to those personnel required to use these systems as part of their jobs. JSI's data security policy states that all sensitive data must be protected from unauthorized access during storage and transmission. JSI performs full system backups nightly and includes secure off-site storage to assure data security. The evaluators are also trained in the protection of sensitive data and are bound by ethical evaluation standards and practices.

What About Confidentiality?

As mentioned above, every effort will be made to keep your personal information confidential. The results of this evaluation may be presented at meetings or in publications; however, you will not be identified in these presentations and/or publications. Your data will be used only by the evaluation team and not shared with others. If you agree to take part in this evaluation, a unique number will be assigned to you and your name will be removed from any data being used in the evaluation. The evaluators will make every effort to protect your privacy.

What are the costs of taking part in this evaluation?

There are no costs to you for taking part in this evaluation.

What about Confidentiality and Authorization to Use and Disclose Protected Health Information?

As part of this evaluation, the evaluators will look at your prison-based health records and your engagement in other prison-based services and programs. To the extent allowed by law, every effort will be made to keep your personal and medical information confidential. However, total confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law or when there is a likelihood of serious harm to yourself or another person.

JSI will use your medical information collected or created as part of the evaluation, such as medical records, behavioral health services, and other resources you have used. Some of this information may identify you by name or in another way. The JSI evaluators may obtain your medical information that they request for evaluation purposes from your physicians and your other health care providers and may also inspect and copy this information.

This consent form does not have an expiration date. You have the right to cancel your consent at any time by giving written notice to the evaluation investigator at JSI. If you withdraw your permission, you will not be able to continue in this evaluation, but you will not lose your right to continue participating in PforME. When/if you withdraw your permission, no new health information about you will be gathered after that date. Information that has already been collected may still be used for the evaluation.

What if I have more questions?

Please feel free to ask any questions about the evaluation or your rights as a evaluation participant. If additional questions come to you later, you may contact Brandon Irwin at the Cumberland County Public Health Department at irwin@cumberlandcounty.org or at (207) 749-5331, who can relay your question to the JSI evaluators.

Alternatively, if you have any questions or complaints, you may contact a person not on the research team at the University of Southern Maine, Office of Research Integrity & Outreach's Institutional Review Board at (207) 780-4517 or at usmorio@maine.edu

Volunteer Statement

By signing this form, I confirm the following:

- ❑ I have read and understand the above information.
- ❑ I have been given a chance to ask questions about the evaluation process, and these questions have been answered to my satisfaction.
- ❑ I understand that my participation in this evaluation is voluntary.
- ❑ I know that I may opt out of this evaluation process at any time without impacting my participation in the program and without penalty.
- ❑ I agree to the collection, use, sharing, and analysis of my personal health information and evaluation information collected from the Cumberland County Public Health Department and program partners as part of this evaluation by the research team.
- ❑ I agree that Maine Emergency Medical Services and the licensed ambulance service can share my personal health information.
- ❑ I understand I can request a copy of this signed consent form from JSI.
- ❑ I do not give up any legal rights I would otherwise have if I were not in this evaluation.

I voluntarily agree to participate in this evaluation.

Pathways for Maine Participant (signature) Date

Pathways for Maine Participant (please print your name)

Person who reviewed this consent form Date