Study Title: Facilitating In-Hospital Opioid Treatment Program Intakes to Support Hospital to OTP Linkage among Hospitalized Patients with Opioid Use Disorder: An Implementation Trial in Four Hospitals

Protocol (COMIRB) Number: 26-0455

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Version Number: 03-02-2026 V1

Version Date: 03-02-2026

Sponsor (if any): NIH/NIDA (pending)

1. Study Rationale

Hospitalization represents a critical intervention point for individuals with OUD, particularly following overdose or infection-related admissions. However, structural barriers—including fragmented workflows, regulatory complexity, and lack of coordinated intake processes—limit successful linkage to ongoing methadone treatment.

Recent federal regulatory changes permit hospital-based clinicians to complete OTP intake medical evaluations prior to discharge, eliminating duplicative visits and reducing delays in treatment initiation.[1-4] Preliminary institutional data demonstrate that completion of intake during hospitalization increases OTP linkage rates to 75–80%, compared to approximately 40% under usual discharge referral practices.[5]

2. Background

The United States continues to experience an unprecedented opioid overdose crisis, with more than 100,000 drug overdose deaths annually in recent years.[6] Opioids—particularly synthetic opioids such as illicitly manufactured fentanyl—account for the majority of these fatalities.

The post-hospital discharge period represents a particularly high-risk window. Individuals with opioid use disorder (OUD) experience markedly elevated mortality risk in the weeks following discharge, with overdose risk peaking within the first 30 days. Mortality rates during this period may be 10–20 times higher than those observed in the general population.

Methadone treatment reduces all-cause mortality by approximately 50% and overdose mortality by more than 60%.[7] Despite this evidence, linkage to opioid treatment programs (OTPs) after hospitalization remains suboptimal, with only 30–40% of hospitalized patients successfully engaging in ongoing OTP treatment.

Recent federal regulatory changes under 42 CFR Part 8 now permit hospital-based clinicians to conduct OTP intake medical evaluations during hospitalization, eliminating duplicative intake visits and reducing delays in treatment initiation.[1] Implementation science frameworks emphasize that regulatory change alone is insufficient; structured facilitation is required to achieve sustained adoption.[8-22]

Implementation Framework: PRISM/RE-AIM

HOTPIN-IF is guided by the Practical, Robust Implementation and Sustainability Model (PRISM) and evaluated using RE-AIM dimensions (Reach, Effectiveness, Adoption, Implementation, Maintenance). PRISM informs assessment of intervention characteristics, organizational context, external environment, and sustainability infrastructure. RE-AIM provides measurable implementation and effectiveness endpoints.[23-25]

3. Objectives

The purpose of HOTPIN-IF is to rigorously evaluate whether structured Implementation Facilitation (IF) improves hospital-to-community continuity of care for patients with opioid use disorder (OUD) by increasing completion of in-hospital opioid treatment program (OTP) intake medical evaluations and subsequent linkage to methadone treatment within 7 days of hospital discharge.

The conceptual model posits that Implementation Facilitation improves clinician adoption and workflow integration of in-hospital intake processes, which increases intake completion rates, thereby mediating improvements in 7-day OTP attendance. Improved linkage is hypothesized to reduce early post-discharge mortality and acute care utilization.

Primary Effectiveness Objective

To determine whether Implementation Facilitation increases the proportion of eligible hospitalized patients with OUD who attend a partnering OTP and receive at least one observed methadone dose within 7 days of hospital discharge.

Effectiveness Objectives

Objective 1: Increase 7-day hospital to OTP linkage

Objective 2: Increase 30-day OTP engagement

Objective 3: Increase 90-day OTP retention

Objective 4: Reduce 90-day emergency department (ED) and hospital readmissions from time of index hospital discharge

Objective 5: Reduce 90-day opioid overdose mortality following the time of the index hospital discharge

Objective 6: Reduce 90-day all-cause mortality following the time of the index hospital discharge

Implementation Objectives

REACH Objective: Identify the proportion and characteristics of hospitalized patients with OUD who receive all four HOTPIN clinical activities and successfully link to an OTP.

ADOPTION Objective: Identify the extent to with ACS clinical complete each HOTPIN clinical activity before vs. after the HOTPIN IF period.

IMPLEMENTATION Objective (Fidelity). Identify the fidelity, quality, consistency, adaptations, and cost of delivering the intervention; specifically, fidelity to core IF activities; adaptations over time; intensity and efficiency of EF engagement; and implementation costs.

MAINTENANCE Objective. Measure sustained completion of HOTPIN clinical activities during the maintenance phase after active facilitation ends.

4. Study Design

Study Aim: To implement HOTPIN-IF at four diverse hospitals using a hybrid type 2 effectiveness-implementation design and evaluate both (1) its effectiveness compared to usual care in improving hospital-to-OTP linkage and engagement and (2) its implementation, adoption, reach, fidelity, cost, and sustainability using the RE-AIM framework.

Primary Effectiveness Hypothesis:
Compared to the usual care phase, the post–HOTP IN-IF evaluation phase will demonstrate higher rates of 7-day OTP linkage (primary outcome).

Secondary Effectiveness Hypotheses:
Compared to usual care, the post–HOTP IN-IF evaluation phase will demonstrate higher rates of:

- 30-day OTP engagement
- 90-day OTP retention
- Reduced 90-day acute care encounters (ED visits and rehospitalizations)
- Reduced 90-day all-cause mortality

- Reduced 90-day opioid overdose mortality

Implementation Hypotheses:

Compared to usual care, HOTPIN-IF implementation will result in:

- Higher completion of HOTPIN clinical activities (Adoption)
- Higher fidelity to core Implementation Facilitation (IF) activities
- Measurable and sustainable implementation during the maintenance phase (Maintenance)
- Broad and representative patient participation in linkage efforts (Reach)
- Quantifiable implementation costs to inform scalability (Implementation)

Study Design

We will conduct a hybrid type 2 effectiveness-implementation trial using an incomplete stepped-wedge cluster randomized cross-sectional design, also referred to as a balanced staircase design. Hospitals (clusters) will be randomly assigned to the timing of HOTPIN-IF initiation.

5. Study Population

Population: The study population includes hospitalized adults with opioid use disorder (OUD) admitted to one of four participating hospitals with established Addiction Consultation Services (ACS) and partnering Opioid Treatment Programs (OTPs). Patients will be enrolled during the 12-month usual care phase and the 12-month evaluation phase of the stepped-wedge trial design.

Inclusion Criteria: Eligible participants must meet all of the following criteria:

- Age ≥18 years.
- Hospitalized adult diagnosed with DSM-5 opioid use disorder (OUD), confirmed by ACS clinician assessment and documentation in the electronic health record (EHR).
- Eligible for methadone treatment for OUD as determined by the ACS team, including absence of medical contraindications to methadone initiation.
- Not currently enrolled in an Opioid Treatment Program (OTP) at the time of hospitalization.
- Anticipated discharge to the community (i.e., not directly transferred to a correctional facility or other institutional setting that precludes OTP attendance).
- In alignment with site eligibility criteria described in the parent grant, participating ACS teams must routinely initiate methadone for OUD and anticipate enrolling at least 15 eligible patients per month into the study.

Exclusion Criteria:

- Active enrollment in an OTP at the time of hospital admission.
- Incarceration at the time of discharge or planned discharge to a correctional facility where linkage to a community OTP cannot occur.
- Medical instability that precludes safe initiation of methadone or completion of HOTPIN clinical activities, including severe uncontrolled medical or psychiatric conditions as determined by the treating clinical team.
- Inability to provide necessary information for OTP intake completion due to altered mental status without recovery prior to discharge.

Strategies for Recruitment and Retention:

All study sites have an ACS. If a patient with OUD is experiencing opioid withdrawal, the ACS team member will offer methadone or buprenorphine, both medications for OUD. After the patient's opioid withdrawal is stabilized, the ACS team member and the patient will discuss his/her OUD treatment goals. If the patient is interested in continuing methadone after hospital discharge, he/she will be offered study participation. If the patient was started on BUP but prefers methadone, the ACS clinician will complete a low dose buprenorphine to methadone transition and will offer study participation.

Once the patient expresses interest in study participation, the ACS team member will contact the Research Service Professional (RSP) for study screening and enrollment. The RSP will meet with the

patient in the hospital to screen for study inclusion and to describe the study. If the patient meets inclusion criteria and would like to enroll, they are required to provide written informed consent, including a Release of Information (ROI) for medical and substance treatment records required to measure study outcomes. This ROI is necessary because records from federally-funded substance treatment facilities are protected by Title 42 of the Code of Federal Regulations (42 CFR) to ensure patient confidentiality.

The RSP will conduct a baseline assessment to include validated questions about socio-demographic data, substance use and treatment history, route of substance use, medical history, and health care utilization using validated questions from the Addiction Severity Index Lite.[26-28] Patients will receive a $25 gift card for completing study enrollment activities which are anticipated to take between 45 to 60 minutes. Active patient study participation is limited to this single face-to-face interaction in the hospital.

Recruitment and Enrollment Feasibility.

Eligible hospitalized patients will be identified through routine ACS consultation workflows and EHR-based screening processes. Each participating site has the ability to provide patient-level hospital data and OTP linkage data through established EHR and data-sharing infrastructures.

Research Services Professionals (RSPs) at each site will support patient enrollment, consent procedures when required, and data abstraction. Enrollment will occur during hospitalization.

Follow-up will be conducted using objective data sources, including hospital EHR records, partnering OTP verification of intake attendance, and linkage confirmation within 7 days post-discharge. Secondary outcomes including 30-day engagement, 90-day retention, 90-day acute care utilization, and 90-daymortality will be ascertained through EHR review and, where applicable, National Death Index linkage.

Because primary outcomes rely on objective EHR and OTP verification rather than participant self-report, loss to follow-up is expected to be minimal. Retention is further supported by established ACS–OTP partnerships and existing data infrastructure across sites.

6. Study Assessments and Procedures

Overview of Study Flow: This study is a hybrid type 2 effectiveness-implementation trial using a staircase cluster randomized design across four hospitals. Sites participate in: (1) a 12-month usual care phase, (2) a 12-month HOTPIN-IF evaluation phase, and (3) a 3-month maintenance phase. Patient-level outcomes are followed for 90 days post-discharge.

Screening Procedures: Hospital-based identification of potentially eligible patients with opioid use disorder (OUD) will occur via EHR review and clinical service involvement.

- Clinical eligibility for methadone will be determined by a licensed medical clinician (e.g., addiction medicine physician or advanced practice provider).
- Safety assessments may include electrocardiogram (ECG) review for QTc prolongation and review of relevant medical comorbidities and medication interactions.
- If QTc remains prolonged or contraindications are identified, patients will not be enrolled and will receive appropriate alternative clinical care.

Enrollment and Baseline Assessments: A trained Research Services Professional (RSP) will obtain informed consent and complete enrollment documentation.

- Baseline measures include demographic characteristics, insurance status, medical comorbidity, and substance use history.
    - The Addiction Severity Index-Lite (ASI-Lite) will be administered at baseline and entered into REDCap.
    - Participants may receive a $25 incentive for completion of enrollment procedures.

Effectiveness Outcomes (Patient-Level):

- *Primary Outcome:* 7-day hospital-to-OTP linkage.

- *Secondary Outcomes:* 30-day OTP engagement, 90-day OTP retention, 90-day acute care utilization, and 90-day mortality.
    - Data sources include hospital EHR, OTP EHR, and state death records. No direct participant follow-up visits are required after discharge; outcomes are ascertained through record review.

Implementation Outcomes (RE-AIM Framework):

- *Reach*: Proportion and representativeness of patients who receive HOTPIN activities and link to OTP care.
- *Adoption:* Degree to which clinicians complete HOTPIN clinical activities before and after implementation.
- *Implementation*: Fidelity to core facilitation activities, adaptations, intensity of facilitation, and cost using time-driven activity-based costing.
- *Maintenance:* Sustained completion of HOTPIN activities during the maintenance phase.

Instruments Used:

- Addiction Severity Index-Lite (validated instrument).
- Acceptability of Intervention Measure (AIM).
- Intervention Appropriateness Measure (IAM).
- Feasibility of Intervention Measure (FIM).
- Implementation Facilitation Time Tracking Log.
- Semi-structured debriefing interview guide.

Biological Specimens:

No research biological specimens are collected in this study. All clinical tests (e.g., ECG) are part of routine care.

Restrictions: There are no research-imposed fasting, dietary, or medication restrictions. All clinical management decisions are part of routine medical care.

Schedule of Activities:

Schedule of Activities (Participant + Site Activities)			
Timepoint / Phase	**Participant Procedures**	**Site / Staff Procedures**	**Measures Collected**
Screening (Inpatient)	Identification of potentially eligible hospitalized patients with OUD; clinical safety evaluation for methadone eligibility as indicated.	EHR review; ECG/QTc assessment if clinically indicated; confirmation of medical eligibility by licensed clinician.	Eligibility confirmation documentation.
Enrollment / Baseline (During Usual Care & Evaluation Phases)	Informed consent; Release of Information; baseline questionnaire including ASI-Lite; demographic and clinical assessment.	REDCap data entry by RSP; documentation of HOTPIN clinical activities in EHR.	Baseline demographics, comorbidities, substance use characteristics.
Usual Care Phase (First 3 Months)	No additional participant burden beyond baseline.	Validation of EHR dot-phrase/checkbox documentation via manual chart review; refinement of EHR query.	Baseline adoption measurement; HOTPIN clinical activity completion.
HOTPIN-IF Implementation Phase	No additional participant visits beyond clinical care.	Implementation Facilitation activities; IF Time Tracking Logs; monthly debriefings with local champions; clinician surveys (AIM, IAM, FIM).	Fidelity, adaptations, implementation intensity, clinician adoption measures.
7 Days Post-Discharge	No direct contact (record-based ascertainment).	OTP record verification of linkage; EHR review.	Primary Outcome: 7-day OTP linkage.

30 Days Post-Discharge	No direct contact (record-based ascertainment).	EHR and OTP review for engagement.	Secondary Outcome: 30-day OTP engagement.
90 Days Post-Discharge	No direct contact (record-based ascertainment).	EHR extraction; acute care utilization review; state death record linkage.	90-day OTP retention; acute care encounters; mortality.
Maintenance Phase (Post-Implementation)	No direct contact beyond routine clinical care.	Assessment of sustained HOTPIN activity completion; continued EHR extraction.	Maintenance of adoption; sustainability outcomes.

7. Risk/Benefit Assessment

Risks: The study poses minimal risk as it evaluates workflow implementation rather than experimental pharmacologic intervention. There are no additional risk related to enrollment of pregnant people for this reason. Potential risks include confidentiality breaches associated with EHR data collection and possible workflow delays during implementation transition periods.

Benefits: Participants may benefit from improved coordination of care, earlier initiation of methadone treatment, and reduced risk of post-discharge overdose. At the system level, the study may produce scalable implementation strategies to reduce mortality among hospitalized patients with OUD.

Given the strong evidence supporting methadone treatment and the minimal incremental risk introduced by structured facilitation, the anticipated benefits outweigh potential risks. Confidentiality protections, secure data storage, and ongoing monitoring mitigate identified risks

8. Unanticipated Problems

Unanticipated Problems (UPs) are defined as incidents, experiences, or outcomes that are: (1) unexpected in nature, severity, or frequency given the approved protocol and participant population; (2) related or possibly related to participation in the research; and (3) suggest that the research places participants or others at greater risk of physical, psychological, economic, or social harm than previously recognized. Serious Adverse Events (SAEs) that are unexpected and related or possibly related to research participation are considered UPs.

Clinical Safety–Related Unanticipated Problems

Although HOTPIN-IF primarily evaluates implementation processes and linkage outcomes using routine clinical care pathways, unexpected clinical risks could include methadone-related adverse events such as QTc prolongation, cardiac arrhythmia, sedation, respiratory depression, or severe drug–drug interactions.

Post-discharge overdose or unexpected clustering of early mortality temporally associated with implementation of expedited OTP linkage pathways may also constitute a UP if a relationship to study procedures is suspected.

Privacy and Confidentiality Unanticipated Problems

Because the study relies on hospital EHR review, OTP EHR data transfer, state death record linkage, REDCap data storage, and release of information documentation, potential UPs include unauthorized access to identifiable patient data, data breaches, improper transmission of protected health information, or documentation errors affecting confidentiality.

Any breach involving substance use disorder treatment records, particularly those governed by 42 CFR Part 2, would qualify as a UP if it increases social, economic, or legal risk to participants.

Implementation-Related Unanticipated Problems

Implementation strategies may create unforeseen workflow disruptions, including discharge delays, miscommunication between inpatient teams and OTPs, or incorrect documentation of HOTPIN clinical activity completion. If such disruptions result in patient harm or increased risk, they would qualify as UPs.

Concerns regarding undue influence or perceived coercion to enroll in OTP intake due to hospitalization status would also be considered UPs if they increase psychological or social risk.

Economic or Social Harms

Unexpected insurance coverage interruptions, employment or legal consequences, or stigma resulting from confidentiality lapses could constitute UPs if related to study procedures.

Aggregate Safety Signals

An unexpected increase in adverse outcomes relative to historical usual care rates—such as higher-than-anticipated emergency department visits, rehospitalizations, low retention with increased utilization, or disproportionate harms in specific subgroups—may constitute a UP and prompt protocol review or modification.

Reporting and Monitoring

The study team will monitor participants for unanticipated problems (UPs). A UP is any untoward medical event associated with the study procedures, if the nature, severity, or frequency of the event is not consistent with the risk information previously described or provided for the study procedures. UPs will be reported to the IRB as soon as possible, but in no event later than 5 working days after the PI first learns of the event.

Protocol deviations that increase participant risk, including privacy risks, will also be reported. UPs will be evaluated to determine whether modifications to consent, procedures, or safeguards are necessary.

9. Data Analysis

Study Outcomes

a. *Primary Effectiveness Outcome*: 7-day hospital-to-OTP linkage, defined as documented attendance at an opioid treatment program (OTP) within 7 days of hospital discharge.

b. Secondary Effectiveness Outcomes:
- 30-day OTP engagement
- 90-day OTP retention
- 90-day acute care utilization (emergency department visits and rehospitalizations)
- 90-day all-cause mortality and opioid-related mortality

c. Implementation Outcomes (RE-AIM Framework):
- *Adoption:* Completion of HOTPIN clinical activities before vs. after implementation
- *Implementation Fidelity:* Delivery of core Implementation Facilitation (IF) activities
- *Reach:* Proportion and representativeness of eligible patients who link to OTP
- *Maintenance:* Sustained HOTPIN clinical activity completion during maintenance phase
- *Implementation Costs:* Direct and indirect costs using time-driven activity-based costing

Quantitative Analysis Plan

Descriptive Statistics:

Categorical variables will be summarized using frequencies and percentages. Continuous variables will be presented as means with standard deviations (SD) if normally distributed, or medians with interquartile ranges (IQR) and ranges if non-normally distributed.

Inferential Statistics:

Primary and secondary effectiveness outcomes will be analyzed using generalized linear mixed models (GLMMs) to account for clustering by hospital site and time period within the staircase cluster randomized design. Binary outcomes (e.g., 7-day linkage) will use a logit link function.

All statistical tests will be two-tailed with a Type I error rate (alpha) of 0.05. Effect estimates will be reported with 95% confidence intervals.

Models will adjust for fixed effects of time period and site, with random effects to account for within-site clustering. Sensitivity analyses will assess robustness to potential intracluster correlation assumptions.

Qualitative Analysis

Qualitative data from monthly debriefings and implementation interviews will be analyzed using a structured thematic analysis approach. A coding template based on core IF activities will guide deductive coding, while inductive coding will identify emergent themes. Two analysts will independently code transcripts/notes, reconcile discrepancies through consensus, and refine the coding framework iteratively. Findings will be organized by implementation phase and mapped to RE-AIM domains.

Data required from the EHR for study outcomes (patient participants):

- Names, initials
- Account number, medical records numbers
- Dates related to an individual (e.g., date of birth, date of clinic visit, date of diagnosis, etc.) unless only year is used
- Social Security Numbers (or any part of the SSN).
- Any other unique identifying number, characteristic or code
- Telephone Numbers

We require names, SS, DOB to link clinical trial participants' to the National Death Index (1) to link mortality outcomes; (2) for hospital to OTP linkage data, and (30 for participant ED or hospital readmission data following the index hospital discharge.

Data required for recruitment for surveys/focus groups

- Email addresses to send out recruitment emails for survey and focus group participation.

Power and Sample Size Justification

Sample size and power were determined based on the primary outcome of 7-day OTP linkage within a staircase cluster randomized design. Power calculations accounted for clustering at the hospital level, time effects, and expected intracluster correlation (ICC). Monte Carlo simulation methods were used to model expected linkage rates under usual care and post-implementation conditions, incorporating conservative ICC estimates consistent with similar implementation trials.

Assuming a two-sided alpha of 0.05 and adequate patient enrollment per site during 12-month usual care and evaluation phases, the study is powered to detect a clinically meaningful increase in 7-day OTP linkage rates. The 12-month periods were selected to ensure sufficient outcome events per site and time interval to maintain statistical power while accommodating logistical implementation constraints.

Secondary outcomes will be analyzed with the available sample and are expected to have adequate precision for effect estimation, though the study is primarily powered for the 7-day linkage outcome.

10. Future Research of Stored Specimens

NA

11. Informed Consent Process

Informed Consent for Hospitalized Adult Participants: Informed consent will be obtained by a trained Research Services Professional (RSP) or other trained study personnel listed on the IRB protocol. Consent will occur during hospitalization after clinical stabilization in a private setting. Research staff will coordinate with the clinical team to avoid interfering with medical care.

The RSP will explain study purpose, procedures, risks, benefits, confidentiality protections, voluntary

participation, and compensation (if applicable). Participants will be informed that participation does not affect access to methadone or OTP referral. Teach-back methods will be used to assess understanding. Written informed consent and a signed Release of Information (ROI) for OTP record verification will be obtained per 42 CFR Part 2. Participants will be offered a photocopy of the signed consent form.

Non-English Speakers: IRB-approved translated consent forms (e.g., Spanish) will be used when available. On-site certified medical interpreters will facilitate consent discussions. If a translated long-form consent is unavailable, short-form consent procedures will be used in accordance with institutional IRB policy. Interpreter involvement will be documented.

Research in Children: This study enrolls adults aged 18 years and older. Children will not be enrolled. Parental permission and child assent procedures are not applicable.

Adults Unable to Consent: Because participants are hospitalized, capacity may fluctuate. The RSP will confirm stability and understanding using teach-back methods. If capacity is uncertain, the ACS physician will assess decisional capacity. Participants lacking capacity will not be enrolled until capacity returns. No enrollment via legally authorized representatives (LARs) is planned.

Re-Consent: If protocol modifications require updated consent, participants will be re-consented using the most current IRB-approved form. Participants may withdraw at any time. If withdrawn, no new data will be collected; previously collected data may be retained unless removal is requested and permissible.

Clinician and Staff Consent:

- **Survey:** For clinician surveys (AIM, IAM, FIM), participants will receive an information sheet with a consent form embedded in the survey describing the study, including risks, benefits, voluntary participation, and contact information for questions before they proceed to take it (will be delivered electronically). Survey participation is voluntary, and survey responses will be de-identified unless explicit consent for identification is provided. *We are requesting a waiver of signed consent for survey participants and focus group participants.*
- **Focus groups:** For clinician focus groups, participants will be provided with an information sheet describing the study, including risks, benefits, voluntary participation, and contact information for questions. Study staff will review the information verbally and allow time for questions. Participants will be asked whether they would like written documentation linking them to the study. If a participant requests written documentation, a signed consent form will be provided. If not, verbal consent will be documented in the research record by study staff. Focus group participation is voluntary, and responses will be de-identified unless explicit consent for identification is provided.

- *We are requesting a waiver of signed consent for survey participants and focus group participants only.*

Consent Documents to be Submitted

- The following documents will be submitted to the IRB
    - Adult participant informed consent form for the clinical trial with HIPPA authorization
    - Release of Information (ROI) form (42 CFR Part 2)
    - Clinician survey information sheet and consent
    - Clinician focus group consent script
    - Recruitment scripts for participation in clinical trial to be distributed to hospitalized patients with OUD
    - Recruitment scripts to be sent out via email for both survey and focus group

12. Confidentiality and Privacy

This study involves collection of participant-level data through baseline questionnaires, hospital electronic health records (EHR), opioid treatment program (OTP) records, state death record linkage, and implementation documentation. No research biological specimens are collected. Because the study involves substance use disorder (SUD) treatment information, enhanced federal confidentiality protections under 42 CFR Part 2 apply where applicable.

42 CFR Part 2 Protections:

OTP treatment records are protected under 42 CFR Part 2, which provides heightened confidentiality protections for substance use disorder treatment information. Disclosure of Part 2-protected records requires written patient authorization unless an exception applies.

Participants will sign a specific Release of Information (ROI) authorizing communication between the hospital and OTP and permitting research verification of linkage and engagement outcomes. Part 2-protected information will not be redisclosed except as permitted by regulation. All redisclosures will include the required prohibition-on-redisclosure notice.

HIPAA Authorization and Privacy Protections:

This study complies with the Health Insurance Portability and Accountability Act (HIPAA). A HIPAA Authorization will be included within the consent form or as a separate document if required by COMIRB. The authorization will describe: (1) the specific health information to be used or disclosed; (2) who may disclose and receive the information; (3) the purpose of disclosure; (4) expiration of authorization; and (5) the participant's right to revoke authorization.

Data Security Measures:

Paper consent forms and ROI documents will be stored in locked cabinets within secured research offices. Electronic data will be stored in REDCap, a HIPAA-compliant, password-protected database hosted on secure institutional servers. Data are encrypted in transit and at rest.

EHR and OTP data extracts will be transferred via secure institutional file transfer systems and stored on encrypted, access-controlled network drives. Multi-factor authentication is required for system access. Portable storage devices will not be used.

Identifiers and Coding Procedures:

Each participant will be assigned a unique study ID. Direct identifiers (name, medical record number, date of birth, contact information) will be stored separately from analytic datasets.

A master linkage file connecting identifiers to study IDs will be maintained in a separate encrypted file. Access to this file (the 'code key') will be restricted to the Principal Investigator and designated data manager using role-based access controls. Analytic datasets shared with collaborators will contain only coded data.

Access to Data and Records:

Access to identifiable data will be limited to authorized study team members, including the Principal Investigator, Research Services Professionals, data analysts, and designated implementation facilitators as necessary.

Regulatory authorities, including the Colorado Multiple Institutional Review Board (COMIRB), NIH, and study monitors or auditors, may review records under confidentiality agreements and institutional oversight.

Data Sharing and Release of Information:

De-identified datasets may be shared with collaborating institutions under executed Data Use Agreements (DUAs). Public data sharing under the NIH Data Management and Sharing Policy will involve fully de-identified data consistent with HIPAA Safe Harbor standards.

Personally identifiable information will not be released to third parties without explicit participant authorization except when required by federal, state, or local law.

Certificate of Confidentiality

As an NIH-funded study, HOTPIN-IF is automatically covered by a Certificate of Confidentiality under 42 U.S.C. §241(d). The study team will not disclose identifiable information except when participants consent or when disclosure is required by law (e.g., mandatory reporting of child abuse, threats of harm, or other legal obligations).

Data Retention and Destruction (COMIRB Requirements)

In accordance with COMIRB policy and institutional requirements, research records will be retained for a minimum of at least 6 years after study closure or longer if required by sponsor regulations. If FDA-regulated components are introduced, records will be retained for at least 2 years after final marketing application approval or study discontinuation, whichever is later.

Identifiers will be retained only as long as necessary for linkage and verification. When no longer required, identifiable linkage files will be securely destroyed using institutional data destruction protocols.

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