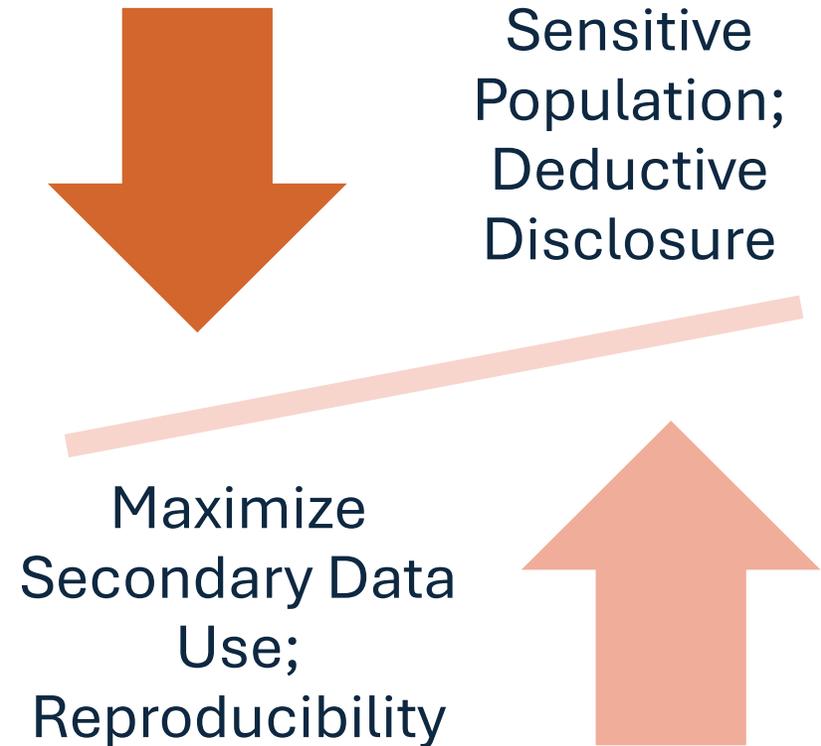# Data Governance Discussion for JCOIN 1.0

Why are we here?

- Consider implications of data archiving moving forward
- **Individual Hub Data:** You determine access decisions for your trial
- **Common Data Elements combined data set:** Need to make a shared decision, including general plans re: data structure (e.g., can study be included as variable?)
- **Estimated N** = 3,160 Individuals in Baseline data set

Balancing Goals and Risks

Sensitive Population; Deductive Disclosure

Maximize Secondary Data Use; Reproducibility

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Four Data Access Determinations

- Open access (no authentication required but may include click-through assent to terms of use)
- Registration-only access (authentication required, typically includes agreement to abide by terms of use)
- Controlled access (requires approval process, and may include additional limitations)
- Enclave access (data may not leave enclave)

From Phil Shumm

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JCOIN CDE Secondary Data Set Proposal

Goal: Streamlined process and minimize need for ad hoc approvals from JCOIN SC in the future

- Request and approval by NAHDAP only

- Agreement to terms of use (including NAHDAP's standard terms)

- Determine additional terms of use:
  - Proposed use
  - IRB approval
  - Approved data safety and management plan (DSMP)
  - Confirmed destruction of data at end of project

From Phil Shumm

- Determine if data can leave virtual workspace

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JCOIN Quantitative CDEs

- **Demographics/SES:** Age, gender/orientation, race/ethnicity, marital status, pregnancy, children, education, income, health insurance coverage, homelessness. (Optional: Receipt of public assistance and other non-job income)

- **Quality of Life (PROMIS 29+2/PROPr):** Physical Functioning, Anxiety, Depression, Fatigue, Sleep Disturbance, Ability to Participate in Social Roles and Activities, Pain Interference, Cognitive Function, Pain Intensity

- **Risk of Harm & Consequences:** Risky sex/HIV risk, injection drug use, violence/victimization, suicidal thoughts (all of these items are optional but with near-universal endorsement)

- **Infectious Diseases:** HIV/AIDS, HCV, HepB, TB, STI

- **Substance Use:** Opioids, marijuana, alcohol, other substances (detailed list), opioid overdose, receipt/use of naloxone

- **Service Utilization:** By type of provider, for substance use, mental health, and physical health, including receipt/use of prescribed medications (optional: treatment satisfaction)

- **Criminal Behavior and Arrests**

- **Incarceration / Justice involvement**

- **Surveys of Staff in Correctional Settings** (optional but with near-universal endorsement)
  - Organizational readiness for change
  - Staff attitudes toward MOUD
  - Sustainability of tested interventions

Considerations:

- Trial Identification:
  - Identifying individual trials would require everyone to make same decision for their trials, so may not make sense
  - What features of trials could we code that would be meaningful and support expanded data use without effectively becoming a trial identifier?
    - E.g., MOUD effectiveness, Linkage Facilitation, Implementation

- Other Variables with De-Identification Risks
  - Should there be any linkage to qualitative data?
  - What is the appropriate level of granularity for geospatial data?
  - What strategy should be used to minimize risk regarding participant age?

- Key Question: How should this CDE dataset be structured to maximize data reuse while minimizing risks?

Adapted from Phil Shumm

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Opportunity: CDE Baseline Publication

- Identify coauthors (ideally for each hub) who can help work through these questions and refine vision for shared dataset
- Two main products:
  - CDE Baseline (& Follow-Up?) Paper Establishing Base Descriptives
    - Staff Level Data
    - Individual Level Data
  - CDE Datasets for Archiving
- Logistics:
  - Need volunteers
  - Mir Ali from NIDA can support (& lead if no volunteers)
  - Suggestion: In addition to lead authors, include JCOIN 1.0 Consortium as corporate author

Qualitative Data

- Inclined to leave this up to individual PIs
- Suggest you include link to Syracuse on NAHDAP page
- Any other discussion, thoughts on this?

Next Steps

1. Identify hub data access determination preference by early Nov: patient-level, stakeholder-level, qualitative data

2. Determine additional information required by JCOIN SC in data access requests

3. Schedule JCOIN SC 1.0 meeting to discuss range in preferences

4. Determine final data access determination selection by Jan 2025