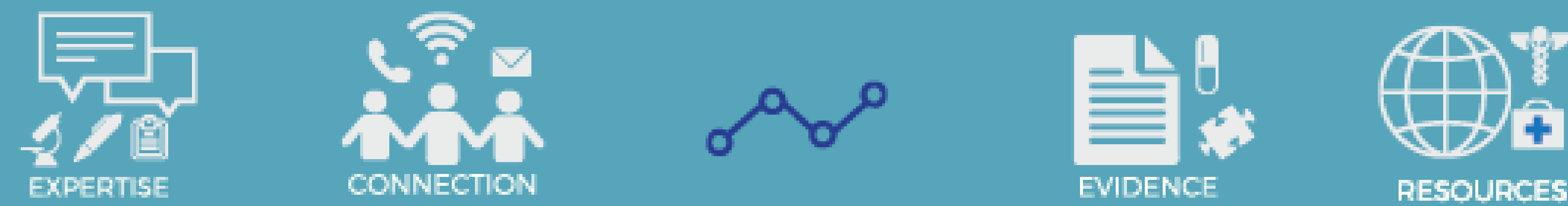


## Optimizing Patient Centered-Care: A Pragmatic Randomized Control Trial Comparing Models of Care In the Management of Prescription Opioid Misuse

### WHAT IS CRISM ?

The Canadian Research Initiative in Substance Misuse (CRISM) is Canada's only dedicated research network for substance use interventions in building national and regional infrastructure for clinical, health services, and population health research in substance use and addictions.



### OPTIMA TEAM

#### Steering Committee

CRISM Nominated Principal Investigators (NPIs), Dr. Julie Bruneau, Dr. Benedikt Fischer, Dr. Cameron Wild and Dr. Evan Wood, will act as the Steering Committee that will be consulted as needed to provide oversight and high-level direction from a research perspective. Dr. Bruneau, NPI for the QM Node, has been designated as the Chair of the Steering Committee. The Lead Regional Principal (Lead RPI) Investigator will also join this committee.

#### Regional Principal Investigators

<b>British Columbia Node</b> Eugenia Socias, MD & Keith Ahamad, MD	<b>Ontario Node</b> Bernard Le Foll, MD, PhD
<b>Prairie Node</b> Ron Lim, MD	<b>Quebec-Maritimes Node</b> Didier Jutras-Aswad, MD, MSc (Lead RPI)

Dr. Didier Jutras-Aswad, has been designated by the Steering Committee as the Lead RPI, responsible for overall trial implementation and for providing oversight at a national level, as well as for initiating and ensuring regular communication with RPIs.

#### National Research Coordinator

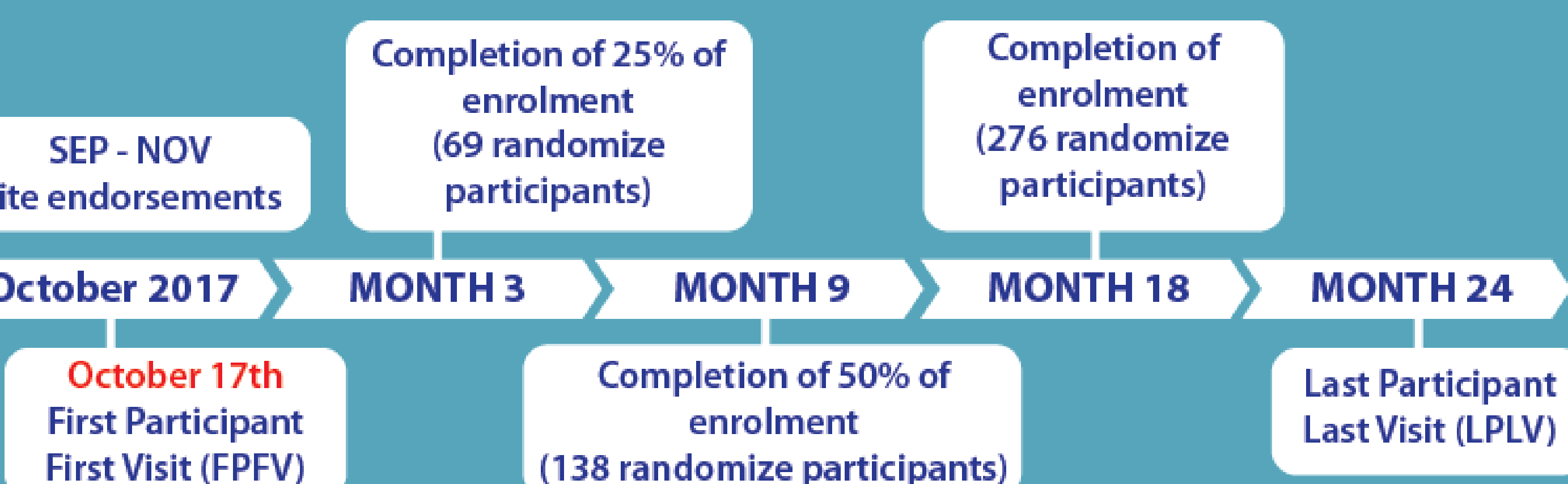
Jill Fikowski, MPH

#### Medical Monitors

<b>British Columbia Node</b> Scott MacDonald, MD	<b>Ontario Node</b> Bernard LeFoll, MD
<b>Prairie Node</b> Avininder Aulakh, MD	<b>National &amp; QM Node</b> Suzanne Brissette, MD

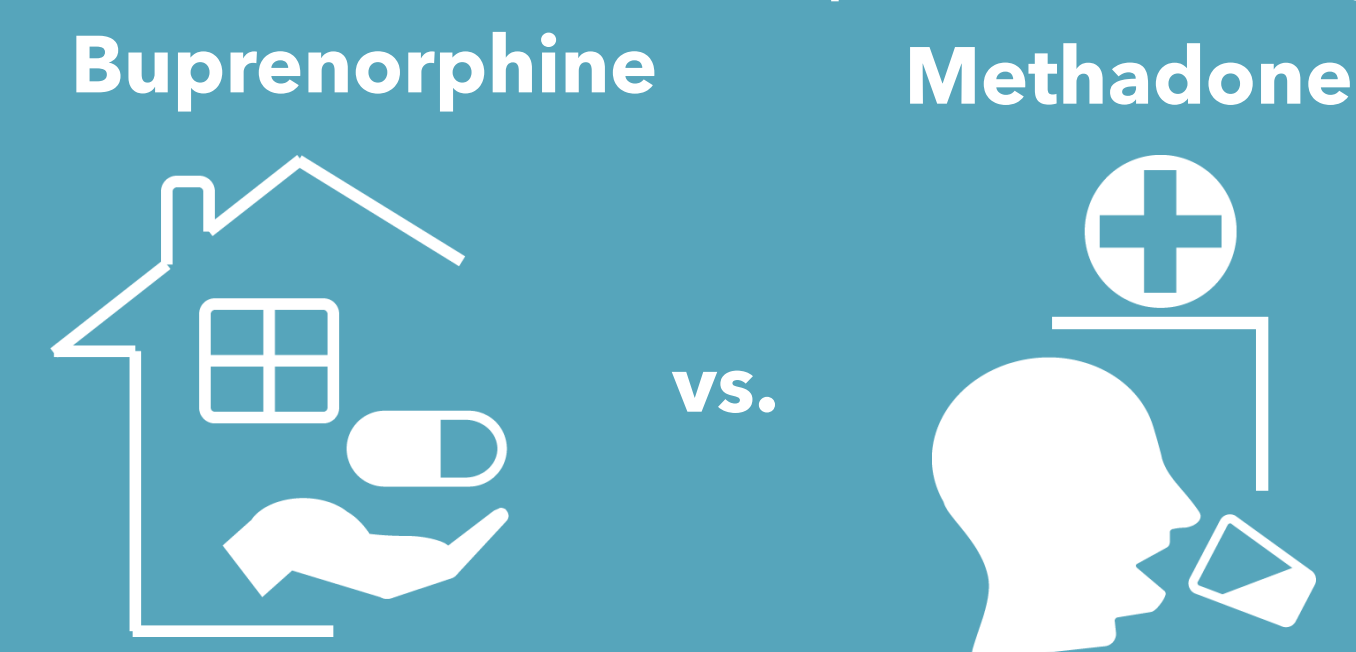
#### Regional Study Coordinators

<b>British Columbia Node</b> Katrina Blommaert, MPH	<b>Ontario Node</b> Jose Trigo, PhD
<b>Prairie Node</b> Denise Adams, PhD	<b>Quebec-Maritimes Node</b> Amel Zertal, MSc



### OBJECTIVES

- Compare and evaluate effectiveness of two models of opioid agonist treatment in real-life clinical practice settings :



### ADDRESSING RESEARCH GAPS :

- Randomized controlled trials evaluating opioid agonist treatments are done almost exclusively among heroin users
- There is a lack of study comparing buprenorphine/naloxone vs. methadone in real-world setting according to each drug safety profile
- Long-term opioid agonist treatment (e.g. > 6 months) is accessed by fewer than 10% of individuals with opioid use disorder

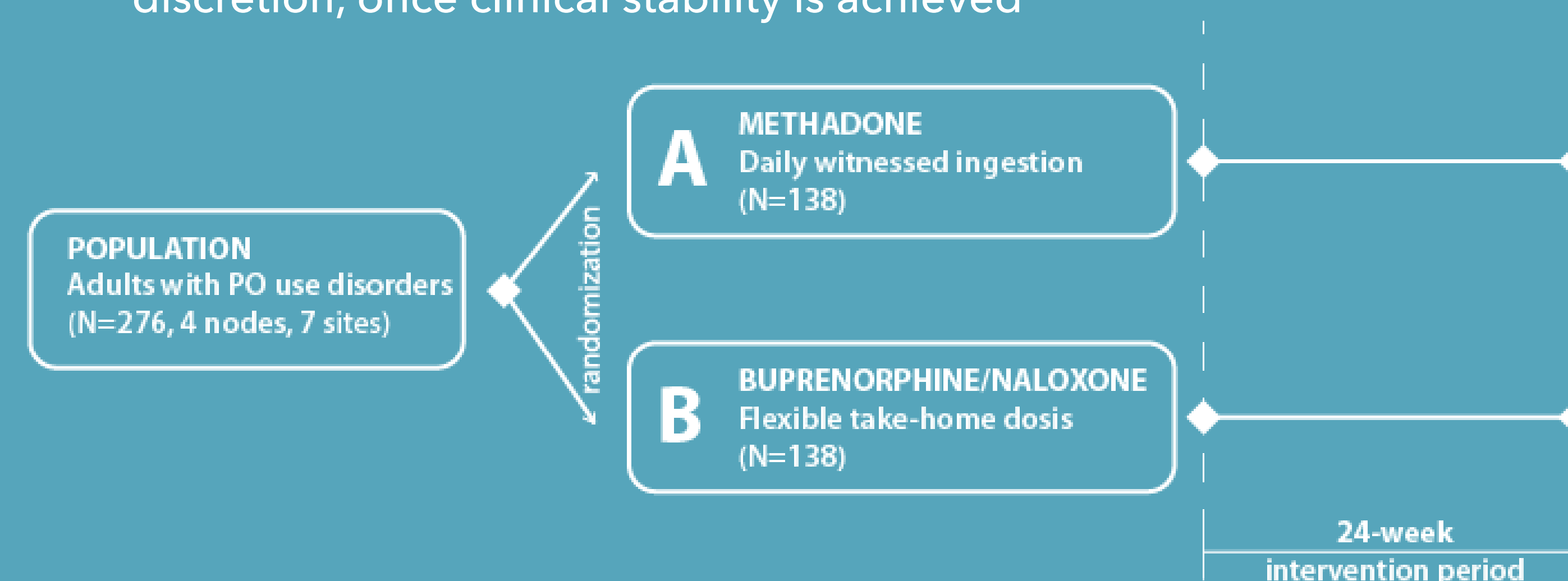
### PRIMARY HYPOTHESIS

**Buprenorphine/naloxone** flexible take home dosing is non-inferior to **methadone** standard model of care in treating prescription opioid use disorder, as measured by the mean percentage of opioid-free urine drug screens during 24 consecutive weeks

### STUDY DESIGN

Participants will be randomized to receive either:

- Methadone** provided via initial daily witnessed ingestion as per local guidelines
- Buprenorphine/naloxone** maintenance therapy provided via flexible take-home dose regimens dispensed as per the physician's discretion, once clinical stability is achieved



### DURATION

Up to 28 weeks, including a 24-week intervention period and up to 4 weeks for randomization

**Research visits** take place every 2 weeks (including collection of urine samples) for the 24-week intervention period

**Clinic visits** take place at physician discretion or as needed by the participant



7 clinical sites across Canada

- Multi-centered
- Open label
- 2 arm
- Randomized trial
- N = 276

### INCLUSION CRITERIA :

- 18-64 years
- Meet DSM-5 criteria for Prescription Opioid Use Disorder which requires opioid agonist therapy
- Willing to access a substitution treatment
- If female of childbearing potential, willing to practice effective birth control

### EXCLUSION CRITERIA :

- Serious medical, mental health or other substance use disorder making participation hazardous
- Heroin reported as most frequently used opioid
- Currently pregnant/breast feeding
- Current prescription with medications that may interact with study medications

### ANCILLARY STUDIES :

- Ancillary study 1:** Take Home Naloxone Survey : Compare THN programs awareness, uptake, and use at the national level  
Dr. Katherine Rittenbach (Principal Investigator)  
Dr. Elaine Hyshka (Co-Investigator)  
Dr. Carla McLean (Co-Investigator)
- Ancillary Study 2:** Patient Experience Study : Examines trial-specific, individual, social influences on protocol adherence and completion  
Dr. Lindsey Richardson (Principal Investigator)
- Ancillary Study 3:** Pharmacogenomics Study : Assess the correlation between genetic variants and treatment response  
Dr. Bernard LeFoll (Principal Investigator)  
Dr. Rachael Tyndale (Co-Investigator)
- Ancillary Study 4:** Cost-Effectiveness Study : Determine the response in HRQoL to treatment, identify health determinants and social costs, compare buprenorphine/naloxone and methadone  
Dr. Bohdan Noysk (Principal Investigator)  
Dr. David Whitehurst (Co-Investigator)
- Ancillary Study 5:** Sexual Functioning Study : Compare BUP/NX and methadone regarding sexual dysfunction in men and women, and determine its impact on treatment attrition.  
Dr. Sherry Stewart (Principal Investigator)  
Dr. Natalie Rosen (Co-Investigator)  
Dr. Amanda Hudson (Co-Investigator)

### OUTCOME MEASURES :

#### Primary outcome measure

- Opioid use

#### Secondary outcome measure

- Retention

- Adherence
- Safety
- Treatment satisfaction
- Patient engagement