**NIDA CTN PROTOCOL 0102-XR**

**Rural Expansion of Medication Treatment for Opioid Use Disorder**

 **Randomized Controlled Pilot Trial of Extended-release Buprenorphine (XR-BUP) vs. Sublingual Buprenorphine-naloxone (SL-BUP) in Rural Settings**

**SITE INTEREST SURVEY**

**Instructions**: To be completed by site personnel (with support from the Local Node as needed). Once complete, save the Site Interest Survey by inserting the site name/abbreviation in front of the current file name (e.g., ClinicABC\_CTN0102-XR\_SiteInterestSurvey) and send it back to Dr. Sherry Larkins at RuralMOUD@mednet.ucla.edu before the close of business **January 31, 2023**.

Site Name:

Site Location (full address):

Node Affiliation, if applicable: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Site Contact Name:

Email: Phone:

**Type of treatment program** (check as many as apply):

☐Intensive Outpatient ☐Federally Qualified Health Center (FQHC)

☐Primary Care Clinic ☐Community Health Center

☐General Substance Use Disorder Treatment Program

**What types of MOUD does your site offer?** Check all that apply.

☐ Sublingual buprenorphine-naloxone (SL-BUP)

 ☐ Extended-release buprenorphine (XR-BUP)

 ☐ Extended-release Injection naltrexone (XR-NTX)

**Patient Characteristics**

1. In the last 6 months, how many new patients/clients did your site engage in medication treatment for opioid use disorder (MOUD) with:
	1. SL-BUP: #
	2. XR-BUP: #
	3. XR-NTX: #
2. How many *current* patients/clients are in MOUD at your site are being treated with:
	1. SL-BUP: #
	2. XR-BUP: #
	3. XR-NTX: #
3. Please describe current referral sources for your MOUD program (e.g., criminal justice system, ER):
4. Demographics of Clinic Patients (current caseload) *Estimates are acceptable if data are not available.*

|  |  |
| --- | --- |
|  | **Percent (%)** |
| **Gender** |  |
| Female | % |
| Male | % |
| Other | % |
| Unknown or Not Reported | % |
| **Race** |  |
| American Indian/Alaska Native | % |
| Asian | % |
| Native Hawaiian or Other Pacific Islander | % |
| Black or African American | % |
| White | % |
| More than One Race | % |
| Unknown or Not Reported | % |
| **Ethnicity** |  |
| Hispanic or Latino | % |
| Not Hispanic or Latino | % |
| **Non-English speaking** | % |

1. Based on the study inclusion/exclusion criteria and other protocol requirements, how many eligible participants could your site **enroll (randomize) per month**? #
	1. What have you considered in coming up with this number?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is your site willing to engage in community outreach to bring new patients with OUD into your clinic if necessary to meet recruitment goals?

☐Yes ☐No

1. Will you be participating in any other studies at the same time as CTN-0102-XR? ☐Yes ☐No
	1. If so, will the other studies compete for this population? ☐Yes ☐No
2. What is the typical psychosocial treatment your site provides or arranges for a patient on BUP?
	1. Is it the same or different for patients on XR-BUP (if applicable)?
3. How is MOUD treatment financed at your site? Percent of patients with:
	1. Medicaid: %
	2. Medicare: %
	3. Commercial insurance: %
	4. Other sources such as grants: %
	5. Self-pay (cash): %

**Staffing**

1. Have you met with staff to discuss the CTN-0102-XR protocol? ☐Yes ☐No
2. Who will serve as the site Principal Investigator (PI)? The PI is expected to serve as “study champion,” and would monitor site progress, serve as a resource to the research staff, and be able to respond rapidly and effectively to site issues that may arise during the study.
3. How long has the site PI worked for the site?
4. Please provide a brief description of the potential site PI’s qualifications (including type of professional licensure, if applicable) and previous experience in clinical trials.
5. Will the site PI have time to oversee, supervise, and advocate for the study? ☐Yes ☐No
	1. Comments:
6. How many X-waivered providers do you have on staff?
	1. How many X-waivered providers would be available to work as a study medical clinician?
7. On a scale of 0-10, how would your staff feel about randomizing interested, consenting patients to receive different formulations of BUP (i.e., extended-release buprenorphine and sublingual buprenorphine)?

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |  |  |
| Very skeptical or resistant | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | Highly enthusiastic |  |

Comments:

1. Do you have staff with research experience already on your team? ☐Yes ☐No
	1. Do you have CTN-experienced research staff on your team? ☐Yes ☐No
	2. If hiring of research staff is anticipated, describe how many weeks you anticipate it would take to fill the position(s), once funds are in place. What if any challenges have you experienced in filling similar positions in the past? How would you overcome those challenges?
2. If a participant becomes incarcerated, visits may be completed at the detention facility if permitted by facility policies. Are clinic staff/Research Assistans appropriately trained in conducting interviews with incarcerated individuals? ☐Yes ☐No
	1. If no, do you have plans in place to train staff? ☐Yes ☐No
3. Please list recent CTN and non-CTN studies (in particular medication studies in the past 5 years) that your site has participated in (if applicable), providing the study population and the target and actual randomization numbers for your site.

*One study per row – add rows as needed*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Name | Sponsor | Study Population | Target randomization | Actual randomization |
|  |  |  |  |  |
|  |  |  |  |  |

**Facilities**

1. Does your clinical practice site have a private space (e.g., office) available to conduct interviews?

 ☐Yes ☐No

1. Does your site have a medical exam room that can be used for research?

 ☐Yes ☐No

1. Is space and internet access available to accommodate study monitors? ☐Yes ☐No
	1. If no, can space be made available on a periodic basis? ☐Yes ☐No
2. Does your site have space and equipment (i.e., centrifuge) for the collection, preparation, and storage of research lab samples?

 ☐Yes ☐No

1. Please briefly describe your site’s system for receiving, storing, and dispensing scheduled drugs (e.g., buprenorphine) provided for research purposes:
2. Does your site have a secure space for storing study medications?

☐Yes ☐No

1. Does your site have space for a locked filing cabinet to securely store participant records?

☐Yes ☐No

1. Will the Research Assistant have access to a secure high-speed wireless internet connection?

☐Yes ☐No

* 1. If yes, describe how reliable the wireless internet connection has been over the past 6 months:

1. Does your clinic have Electronic Health Records?

 ☐Yes ☐No

* 1. If yes, what system/interface does your site use (e.g., EPIC)?
1. Does your site have access to IT support services? ☐Yes ☐No
	1. If no, describe who would be responsible for helping to resolve an internet outage:
2. Do clinic computers have access to Facebook or other social media (for locating participants if participant cannot be located by other means)?

 ☐Yes ☐No

1. What is your set of procedures for managing after-hours emergencies?

**Regulatory Environment**

The study plans to use a Single Institutional Review Board (IRB), the Biomedical Research Alliance of New York (BRANY).

1. Is your clinic willing and able to work under a single IRB?

☐ Yes ☐ Nod

1. Does your clinical practice site have a Federal-wide Assurance (FWA) from the Office of Human Research Protections? ☐Yes ☐No
	1. If no, is the clinical practice site willing to obtain one? ☐Yes ☐No

**General**

1. Does your site have a clinical standard operating procedures (SOP) manual?

☐Yes ☐No

1. Is your site CARF-accredited or JACHO-accredited?

☐Yes ☐No

1. Is your site part of a larger hospital system?

 ☐Yes ☐No

* 1. If yes, provide name:
1. Are you aware of any upcoming events such as relocations, office space modifications, staffing changes, or legal/regulatory changes which may occur during the course of this study?

☐Yes ☐No

* 1. If yes, please describe:
1. What additional resources would you need in order to participate?
2. What concerns do you have about the project?
3. Anything else we should know or consider?