



NIDA CTN 0076-ot

**Clinical Decision Support for Opioid Use
Disorders in Medical Settings: Pilot Usability
Testing in an EMR
(COMPUTE)**

Consent Form

April 17, 2018

Opioid Use Disorder Clinical Decision Support Tool Pilot Study PCP CONSENT FORM

Background:

The United States is in the midst of an epidemic of opioid misuse, but only 5% of patients with opioid use disorder (OUD) receive medication-assisted treatment. Better identification and treatment of OUD in primary care may help reduce this significant treatment gap. To address this, the National Institute for Drug Abuse has funded development and testing of an OUD clinical decision support tool (Opioid Wizard) for primary care physicians (PCPs) at Health Partners and Park Nicollet. We are seeking your participation in this NIH-funded study because (a) you are a primary adult care provider within Park Nicollet or HealthPartners, and (b) you have at least schedule 3 DEA prescribing privileges.

Procedures:

If you voluntarily sign up for the study, you will be assigned to receive (Group A) or not receive (Group B) Opioid Wizard. PCPs who are licensed to prescribe buprenorphine OUD treatment will be placed in Group A; those without such a license will be randomly placed in either Group A or Group B.

If you consent to participate in the study and are assigned to Group A, you will be asked to do the following:

1. Complete a short 20-30 minute online survey prior to the implementation of Opioid Wizard and a follow up survey approximately 6 months later.
2. Receive in-person or web-based training to learn how to use Opioid Wizard.
3. Provide regular feedback on the Opioid Wizard using a feedback button located in the Wizard itself.
4. Receive \$300 to compensate you for your time in completing the training and surveys and submitting feedback.

If you consent to participate in the study and are assigned to Group B, you will be asked to do the following:

1. Complete a short 20-30 minute online survey prior to the implementation of Opioid Wizard and a follow up survey approximately 6 months later.
2. Receive \$150 to compensate you for your time in completing the surveys.

Risks and Benefits of being in the study:

The study has no known or anticipated risks to you and there is no proven benefit to you for participating. However, we hope that using the Opioid Wizard to improve confidence in recognizing and treating OUD. There is a small but important risk that the Opioid Wizard could provide the wrong treatment advice at the wrong time. As with other clinical decision tools, the Opioid Wizard makes suggestions for patient care, and is meant to supplement but not supersede your clinical judgment. You can follow or not follow

the decision support given at any time. Like other Epic SmartForms and materials, the Opioid Wizard decision support will become part of the permanent electronic record.

Confidentiality:

To evaluate the Opioid Wizard tool, there will be chart audit validation of the CDS output, use rates will be calculated, and rates of OUD assessment, diagnosis and treatment will be measured. Information may be accessed only by HealthPartners Institute project investigators and their research team; no providerspecific data will be shared with medical group leaders. All provider and patient identifying information is purged from the data file before analysis. Although the results of the study may be published, your name will **never** be used.

Voluntary nature of study:

This activity is completely voluntary, and your compensation will occur through payroll. This payment compensates you for the time and effort required to complete study related activities. Your decision to participate will not affect your current or future relationship with HealthPartners or Park Nicollet. If you decide to participate, you are free to withdraw at any time without affecting those relationships. However, if you withdraw before all components of the study are completed, no further study-related compensation will be provided to you.

Contacts and Questions:

If you have questions at any time about this study, please contact the Principal Investigator, Dr. Rebecca Rossom, at rebecca.c.rossom@healthpartners.com or 952-883-5466, or the Project Manager, Laurel Nightingale, at laurel.p.nightingale@healthpartners.com or 952-967-5591.

Questions about your rights as a study participant, comments or complaints about the study also may be directed to the HealthPartners Institutional Review Board (IRB), 640 Jackson Street, MS 11503H. St. Paul, MN 55101, telephone: (651) 254-3391.

Statement of Consent:

I have read the consent information and I understand the risks and benefits of participating in this research project. Any questions of mine have been answered. I understand that by signing this form or clicking the “I agree” button indicates that I have read this consent form and understand what I am being asked to do.

Please print or retain a copy of this consent for your records

Printed Name:

Signature:

Date:

Your Clinic:

Email:
