Study Information for Providers

The Opioid Epidemic

The United States is in the midst of an "opioid epidemic" and the number of overdoses is increasing dramatically. Naloxone, a prescription medication that reverses the effects of opioid overdose, is one tool to help combat overdose. Now efforts are underway to make naloxone available as an over-the-counter (OTC) medication.

Before a medication can be available OTC, the Food and Drug Administration (FDA) needs to establish that it is safe to use without the supervision of a licensed clinician and that the public understands how to use it. Instructions for using the medication are listed in a label included in the product's packaging. FDA has developed a draft label for naloxone as an OTC medication. The next step is to study whether people understand the label instructions so that they can use the medication effectively in an emergency overdose situation.

Phase 1 of the Study

The first phase of this study involves testing the understanding of the draft label by conducting 36 interviews with people from four different groups (9 in each group) and to use the results to revise the label to improve clarity and comprehension. These are the four groups of people we're interested in recruiting for the study:

- **Prescription opioid users,** including those in drug treatment programs, and family/friends who are not prescription opioid users themselves (who we are calling "associates")
- **Heroin users,** including those in drug treatment programs, and their associates
- **Adolescents who are prescription opioid or heroin users,** including those in drug treatment programs, and their adolescent associates
- **All-comers**, including pregnant women.

How You Can Help with Phase 1 of the Study

SouthLight is working with our study team to recruit participants for Phase 1 of the study. SouthLight will advertise the study to clients by posting flyers and distributing palm cards in your facilities. Please mention the study to clients who may be eligible and provide them with the study palm card if they appear to be interested. The card includes the study's toll-free number so people can contact us if they wish to be screened to participate in the study.

Here are some key things to know about the study:

- SouthLight staff will **not** screen clients for the study; clients must initiate the screening process by calling the study's toll-free number.
- The interview will last about 45 minutes and take place at one of the SouthLight offices.
- So that we don't bias the results, we're advertising this as a study about the labeling for a medication that may become available without a prescription. **Please do not share this flyer with patients or tell them that the medication is naloxone.**
- People who participate will get $60 (cash/cash equivalent) at the end of the interview.
- The study is voluntary and clients' services will not be affected in any way if they choose not to participate.

RTI International and Concentrics Research are an ideal team to conduct this culturally competent and rigorous study.

- Over the past 30 years, RTI has gained an in-depth understanding of the personal and societal factors that lead to initiation and continued use of illicit drugs.
- Concentrics Research is an industry leader in label comprehension studies and has designed and conducted more than 300 label comprehension studies for FDA and others needing FDA approval.

Thank you in advance for your support!

We're really excited about the public health impact of this project. If you have any questions, please contact the Project Director, Claudia Squire, at 919-541-6613 or cms@rti.org.