Attachment F
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 medicine 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) medicine.

Before a medicine 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 medicine are listed in a label included in the product's packaging. FDA has developed a draft label for naloxone as an OTC medicine. The next step is to study whether people understand the label instructions so that they can use the medicine effectively in an emergency overdose situation.

About the Study

This study involves conducting individual, in-person interviews to make sure the information in the label is clear and easy to follow. These are the 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**, i.e. general population consumers, including pregnant women.

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.

How You Can Help

[*FACILITY NAME*] is working with our study team to recruit participants for the study. [*FACILITY NAME*] 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:

- [*FACILITY NAME*] 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 [*LOCATION*].
- So that we don't bias the results, we're advertising this as a study about the label for a medicine that may become available without a prescription. **Please do not share this flyer with patients or tell them that the medicine is naloxone.**
- People who participate will get a $50 Visa gift card at the end of the interview as reimbursement for time and travel expenses.
- The study is voluntary and clients' services will not be affected in any way if they choose not to participate.

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.