

## COMMON QUESTIONS

*(continued)*

Still, some side effects may be harmful and some may be unknown. The medication may interact with other prescription or over-the-counter medications or illegal drugs or alcohol to produce side effects. You should ask the medical clinician before taking any medication. You will complete a form that will list the side effects for the medications you will take.

### 5. Is the information I provide confidential?

Much of the information collected during the study is sensitive. There is a small risk that others who are not involved in the study will see it. However, the investigators and their staffs are well trained in keeping the information confidential. You will also be given an ID number that will be used on all forms instead of your name. In addition, all information collected from the participants will be kept in locked areas in the clinic.

### 6. What if I decide to drop out?

This study is entirely voluntary. You can withdraw at any time with no penalty to you.

## FOR MORE INFORMATION

For more information on the National Institute on Drug Abuse Clinical Trials Network, visit the NIDA web site at "<http://www.drugabuse.gov>".

For information on other Clinical trials, the National Institutes of Health has created a web site to help patients, family members, and the general public obtain information about government sponsored clinical trials. You may log on to "<http://www.clinicaltrials.gov>" to learn about ongoing or new trials of all types of health related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The web site is maintained and updated regularly by the National Library of Medicine.

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## STARTING TREATMENT WITH AGONIST REPLACEMENT THERAPY



**Should I Join ?**

## WHAT IS THIS STUDY ABOUT?

For many years, people with heroin and other opioid addictions have been treated with medication. The most common medication has been methadone. However, in October 2002, the FDA approved a newer drug called BUP/NX (buprenorphine naloxone) as an alternative to methadone treatment.

Since that time, the FDA has asked for a study that compares the impact of these two medications on the liver. By participating in this study, you will help answer important questions about the safety of these medications.

## WHO CAN PARTICIPATE?

You will be eligible to participate if you: Are at least 18 years old; Are dependent on opiates; Want to be treated with a medication therapy; and Are not allergic to the medications used in the trial and do not have any medical or psychological disorder that would make participation dangerous.

## WHAT IF I WANT TO JOIN?

The first step is to contact the research clinic for an appointment. At this visit, the study will be explained to you in detail and you will be asked questions about your drug/alcohol use and your medical history.

If you still qualify, you will have a physical exam, a blood test to check your liver function and make sure you are healthy (and a pregnancy test if female), a urine test for drugs of abuse and kidney function, a breath sample to test for alcohol use, and a confidential test for HIV. You will be given the results of all of these tests and will be given counseling or referrals if appropriate.

If all study criteria are met, you will be assigned at random (for example, by the flip of a coin) to receive either methadone or BUP/NX. You will be asked to take the medication every day up to 32 weeks.

The study medication will be given daily with take home doses depending on clinic procedures. In addition, you will be given medical tests, asked questions about the medication and your behavior, and provided drug abuse counseling normally offered by the clinic. During this period you will be asked for 10 blood samples to test for liver and kidney function.

Once a week, you will be asked for a urine sample to check kidney function and to test for drugs such as heroin, cocaine, etc.

## COMMON QUESTIONS

### 1. How long will I be in the study?

You will be in this study for 32 weeks (at least 24 weeks on medication).

### 2. How many other people will be in the study?

Approximately 1,000 people will be participating in the study across 9 sites in the United States.

### 3. Will I receive anything for participating?

You will be given cash or gift certificate to cover your travel expenses and time. You will receive a bonus if you attend scheduled study visits and complete all required tests and follow-up assessments. If you stop being in the study before it ends, you will be paid for all appointments you keep. Neither you nor your insurance company will be billed for any of the services or medications used in this trial.

### 4. Does the medication have any side effects?

You may have side effects from the medications used in this study. While you are in the study, you will be watched for known side effects.