

## Using Birth Control

are able to become pregnant to participate in this study. There are other less common methods that are acceptable for this study, and can be described to you by the research staff.

Method	Rate of preventing pregnancy
--------	------------------------------

Pill	99%
Mini-pill	96%
Norplant	99%
Shots	99%
<sup>1</sup> Gels, foams, or creams that kill sperm	80%
Diaphragm	85%
<sup>1</sup> Male condom	80-90%
Complete abstinence from intercourse	99+%
Female condom	75-85%
IUD	97-99%
Sponge	85-90%
Emergency contraception	90-95%
Natural family planning	65-95%
Female sterilization	99%
Male sterilization	99+%

NOTES: The pregnancy prevention rate may increase if you use two of the methods instead of one. For example, the rate for a male condom with gels, foams, or creams that kill sperm may be higher than the rate for a condom alone.

<sup>1</sup> Gels, foams, or creams that kill sperm, or condoms must be used along with diaphragm to be acceptable for this study.

## For More Information

More information on the National Drug Abuse Treatment Clinical Trials Network can be found at [www.drugabuse.gov](http://www.drugabuse.gov). Go to [www.Clinicaltrials.gov](http://www.Clinicaltrials.gov) to learn about other studies sponsored by the government. Information on who can take part and where and why the study is being done are available. Instructions on how to apply for studies are also on this site.

National Institute on Drug Abuse  
Center for the Clinical Trials Network  
6001 Executive Blvd., MSC 9557  
Bethesda, MD 20892-9557  
Telephone: 301-443-6697

PURPOSELY LEFT BLANK  
FOR CTP SITE  
CONTACT INFORMATION



STOP  
SMOKING  
STUDY *Now That  
I Have  
Joined*



**NIDA** NATIONAL INSTITUTE  
ON DRUG ABUSE

NATIONAL INSTITUTES OF HEALTH  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Introduction

Welcome to the study! By joining this study you will be offered treatment for nicotine addiction in addition to treatment for substance abuse. Smoking cessation treatment will be provided for some of the study participants during the study, and for others after the study.

There are certain things you should do to get the most benefit from your research participation. You agreed to do these things when you chose to take part in this study.

- \* Take part in substance abuse treatment at this clinic
- \* Visit the clinic for study visits each week for 9 weeks
- \* Attend follow-up visits at 9, 13 and 26 weeks

If you are in the group that receives smoking cessation during the study:

- \* Attend weekly smoking cessation counseling sessions
- \* Use the NicoDerm CQ patch as directed
- \* Contact study staff if you have problems with NicoDerm CQ
- \* If female, take steps to prevent pregnancy while using NicoDerm CQ

## Taking Your Medication

The NicoDerm CQ skin patch is expected to decrease the withdrawal symptoms you might feel when you quit smoking. If you stop smoking on your target quit date and use the patch every day as directed, your chances of quitting smoking will increase. Quitting smoking can be difficult, but counseling and support from the study staff, friends, and family can help.

If you are unable to quit smoking or slip back to smoking after quitting, talk to your study counselor about setting a new quit date. If you smoke while you are using the patch, you may experience bad effects from too much nicotine. If you are not smoking and still have bad effects from the patch, contact your study doctor or nurse. It is important that you do not use any over-the-counter or prescription smoking treatments while you are using NicoDerm CQ.

## Attending Study Visits

This study requires that you come to the clinic weekly for study visits. These visits will include:

- \* Questions about smoking and drug and alcohol use
- \* Urine and breath samples to check for cigarette, drug and alcohol use
- \* Questions about responses to the nicotine patch
- \* Check of heart rate, blood pressure and weight (vital signs)

If you are in the stop smoking treatment group, you will have counseling sessions for smoking 1-2 times per week for 9 weeks. These sessions are an important part of the study. If you miss many of your study visits or counseling sessions, you may be discontinued from the study.

You will need to return to the clinic for follow-up visits at 9, 13 and 26 weeks after the “quit date”. These visits will include:

- \* Questions about smoking and drug and alcohol use
- \* Urine and breath samples to check for use of drugs, alcohol and cigarettes
- \* Check of vital signs

You will need to play an active part in your health care. You will need to contact your study doctor, nurse or research assistant if you have serious health problems between visits. Health problems could be side effects of the NicoDerm CQ or symptoms of smoking withdrawal. Some of the side effects or symptoms could be harmful if not treated. You should not wait until your next study visit to report side effects if they are serious. The nurse and research assistants will ask you how you have been feeling during the study visits even if you have not reported any side effects or problems in the past.

## Using Birth Control

If you are a woman who is able to become pregnant, you should know that the NicoDerm CQ skin patch is in the FDA pregnancy category C. That means that risk to an unborn baby cannot be ruled out because there have been no adequate, well-controlled studies of this medication in pregnant women. You should do everything you can to avoid becoming pregnant while you are using NicoDerm CQ. You should also know that, according to the Surgeon General, cigarette smoking can be harmful during pregnancy. Therefore, you will have pregnancy tests done before and during the study. If you do become pregnant, you should tell your doctor or the study staff as soon as possible so that your doctor can discuss your options with you. You can still be in the study, but will not receive the nicotine patch.

Even though male latex condoms may be the best means of disease control, they may not be the best means of preventing pregnancy. The following table lists common birth control methods. It also lists the rates at which they keep someone from getting pregnant. Discuss these methods with your study nurse or doctor when you are making choices about birth control and methods for stopping the spread of sexually-transmitted diseases, including HIV. The items in bold indicate those methods which are acceptable and necessary for women who