

# COR Plus

## PATIENT CONSENT AND RELEASE FORM FOR BUPRENORPHINE TREATMENT DURING PREGNANCY

NAME: \_\_\_\_\_

D.O.B. \_\_\_\_\_

RECORD # \_\_\_\_\_

I, \_\_\_\_\_, agree to receive substance use disorder treatment from COR Plus. During my pregnancy, I agree to be switched from the combination tablet of buprenorphine with naloxone (Suboxone®) to the non-combination buprenorphine tablet (Subutex®) as recommended by national addiction treatment guidelines. My obstetrician will provide my pre-natal care.

I have met with Dr. \_\_\_\_\_ at COR Plus and he/she has discussed with me and I understand the risks and benefits of taking buprenorphine during my pregnancy.

I have been informed that the federal Food and Drug Administration (FDA) has not approved the use of buprenorphine for the treatment of opioid addiction in pregnant women. Whereas, methadone has been FDA approved for the treatment of opioid addiction during pregnancy and there is over 40 years of experience showing methadone treatment to be safe and effective during pregnancy. Therefore, it is currently believed that methadone is safer than buprenorphine for the treatment of opioid addiction during pregnancy.

Although small research studies have been completed in Europe and research is now being conducted in the United States on the effects of buprenorphine on pregnant women and their unborn children, currently there is too little information available to say that buprenorphine is safe during pregnancy.

There have been studies of the effects of buprenorphine on laboratory animals. Buprenorphine has caused some bone problems in laboratory animal embryos and fetuses after injections of buprenorphine but not when the same amount of buprenorphine was given by mouth. A possible problem of taking any opioid (heroin, methadone or buprenorphine) during pregnancy is that after birth the child may suffer a withdrawal syndrome called Neonatal Abstinence Syndrome. Babies with Neonatal Abstinence Syndrome may suffer from sleep disturbances, feeding difficulties, tremor, sneezing, irritability, vomiting, weight loss and seizures. A large proportion of these children will require hospitalization, often for long periods of time.

I understand these risks and benefits and have decided to take buprenorphine (Subutex®) rather than methadone. I understand that medical knowledge on the actual or potential risks of buprenorphine on pregnant women and unborn children is not at all certain. I accept responsibility for this decision.

On behalf of myself and my unborn child, I hereby release and agree to hold harmless, the program, the prescribing doctor, and the program's officers, directors, agents, and employees from any liability of any kind which may arise in connection with my taking buprenorphine (Subutex®) during the duration of my pregnancy.

As part of ongoing client satisfaction surveys and future research, I understand some information from assessments, evaluations, diagnosis and other portions of my file may be submitted to third parties or utilized by COR Plus. I understand that personal identifying information will not be shared, however, general information (age, race and sex) may be.

\_\_\_\_\_  
Patient

\_\_\_\_\_  
Date/Time

\_\_\_\_\_  
Physician

\_\_\_\_\_  
Date/Time