PATIENT CONSENT AND RELEASE FORM FOR

BUPRENORPHINE TREATMENT DURING PREGNANCY

I, _____, am currently receiving prenatal care from _____. Because I am currently prescribed buprenorphine combined with naloxone for treatment of my opioid addiction and do not wish to take methadone, my doctor has referred me to the opioid-based outpatient treatment program for treatment with buprenorphine for treatment of my opioid addiction during my pregnancy. During my pregnancy, I agree to be switched from the combination tablet of buprenorphine with naloxone to the non-combination buprenorphine tablet as recommended by national addiction treatment guidelines. _____ will provide my pre-natal care.

I have met with _____at the opioid-based outpatient treatment program and s/he has discussed with me and I understand the risks and benefits of taking buprenorphine and those associated with taking methadone 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, weigh 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 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 hospital's officers, directors, agents and employees from any liability of any kind which may arise in connection with my taking buprenorphine during the duration of my pregnancy.

_____ _____

Patient Date/Time

_____ _____

MD PRESCRIBER Date/Time

_____ _____

Witness Date/Time