PATIENT INFORMED CONSENT
SUBLOCADE® (buprenorphine extended-release injection)
SPECIAL ACCESS PROGRAMME

You are invited to voluntarily be treated with SUBLOCADE® buprenorphine-extended release injection through the Special Access Programme (SAP) of Health Canada because you suffer from moderate to severe opioid use disorder.

SUBLOCADE, although a marketed product in United States of America, is not commercially available in Canada. The physician and the team who suggested this program to you will discuss this information with you.

This consent form contains information about SUBLOCADE and the Special Access Programme. Once you understand the programme, you will be asked to sign this form if you agree to participate. You will be given a copy of signed consent form to keep as a record. By signing this document, you do not alter your legal rights, but you indicate that you understand the information and that you give your consent to the medical procedures to be performed and to take part in the programme.
Please read this consent form carefully. Do not hesitate to ask any questions about any of the information in it.

ADMINISTRATION
You will be seen in the clinic regularly to receive your medication (SUBLOCADE). Your clinical status will be evaluated regularly by your physician who will also verify your compliance to the therapy.

SUBLOCADE will be administered **ONLY** to you by a healthcare professional as an injection just under the skin (subcutaneously) of the stomach area (abdomen). **It is not to be given to you any other way.** SUBLOCADE is injected as a liquid. After the injection it forms a solid mass (called a depot). It must not be given to you through the vein (intravenously) or into a muscle (intramuscularly). **Serious harm or death could result if it is given to you intravenously.**

SUBLOCADE is used to treat patients (18 years or age and older) who have moderate to severe opioid use disorder. SUBLCADE is for patients who are currently taking a transmucosal buprenorphine-containing product for at least 7 days. SUBLOCADE is a drug treatment plan that should be used along with counselling and psychosocial support.

SUBLOCADE contains buprenorphine. It works in a similar way as other opioid drugs that are used in the treatment of pain. When you stop taking opioid drugs, you can experience withdrawal. SUBLOCADE helps control the symptoms you feel when you are in withdrawal.

SUBLOCADE is an extended-release solution for injection available in pre-filled syringes: 100 mg/0.5 mL and 300 mg/1.5 mL. Before you start SUBLOCADE, your healthcare provider will start you on a transmucosal buprenorphine-containing product (8 mg-24 mg buprenorphine a day) for at least 7 days. Following initial treatment, you will be transitioned to SUBLOCADE staring with 300

mg/1.5 mL for 2 months, followed by a maintenance dose of 100/0.5 mL. Your healthcare professional may increase your maintenance dose if needed. Once you stop taking SUBLOCADE, your healthcare professional should monitor you for several months for sings and symptoms of withdrawal. If you experience withdrawal, your healthcare professional may give you other medication to treat it. If you miss a dose of SUBLOCADE, see your healthcare professional right away.

POSSIBLE BENEFITS
Your participation in this programme may or may not result in a direct benefit to you. SUBLOCADE may manage your opioid use disorder. However, it is not possible to predict or guarantee a favorable response to this treatment.

POTENTIAL RISKS
These are not all the possible side effects you may feel when taking SUBLOCADE. If you experience any side effects not listed here, contact your healthcare professional. Side effects may include: pain or itching where you got the shot, drowsiness, insomnia, dizziness, fainting or feeling faint, feeling tired, nausea, vomiting or a poor appetite, dry mouth, headache, problems with vision, weakness, itching, sweating, constipation, low sex drive, impotence (erectile dysfunction), and infertility. Talk with your doctor or pharmacist about ways to prevent constipation when you start using SUBLOCADE. Side effects that may occur at the injection site include: itching, pain, redness, bruising, and swelling.

You should be careful when driving vehicles or operating machinery because SUBLOCADE reduces level of alertness. The sedative effect can be worsened if you also take alcohol or other drugs such as sedatives (i.e., anxiety or sleeping pills) and thus render driving and use machines dangerous. Alcohol should be avoided and sedatives taken only if prescribed by your physician. You should tell your physician, before starting buprenorphine, if you are taking pain killers and cough medicines containing certain opioid-related substances, certain antidepressants, sedative antihistamines (anti-allergy pills) and antipsychotic drugs.

ALTERNATIVES TREATMENTS
If, after consideration of these potential benefits and risks, you do not wish to participate in this programme, your physician will discuss the best possible accepted treatment for you. You do not need to participate in this programme to receive treatment for your condition.

PAYMENT FOR PARTICIPATION
You will not be paid for participation in this programme. SUBLOCADE, will be provided without charge.

CONFIDENTIALITY OF RECORDS
If results of such a program are reported in medical journals or at meetings, the identification of those taking part is withheld. Any information that we learn about you will be used responsibly and will be available only to authorized users. In addition to health care staff who usually have access to your medical records, the Health Authorities and representatives of the company supplying the SUBLOCADE, Indivior Canada Ltd., may inspect your medical records. A copy of this consent form will be kept in your medical record and one will be given to you.

PATIENT STATEMENT

I have had ample time to read and consider all the information contained in this consent form. The proposed program has been clearly explained to me, and I understand that I will be informed of any significant new findings during this treatment. I voluntarily consent to participate in this programme with the treatment stated above, with an understanding that not all risks of such treatment may be completed known. I understand that my participation is voluntary and refusal to participate in this program will involve no penalty or loss of benefits. I also understand that I may withdraw my consent and discontinue further participation at any time without penalty and without prejudice to future or alternative medical treatment at this institution and that
Dr. _____ if he/she deems it to be in my best interest, may terminate my participation at any time.

Patient Signature: _____ Date: _____

Signature of Witness: _____ Date: _____

Signature of Physician: _____ Date: _____