PATIENT INFORMED CONSENT
SUBUTEX® (buprenorphine) Sublingual Tablets
Substitution Treatment for Opioid (Heroine) Addiction
SPECIAL ACCESS PROGRAMME

You are invited to voluntarily be treated with SUBUTEX® sublingual tablets (SUBUTEX) through the Special Access Programme (SAP) of Health Canada because you suffer from opioid addiction.

SUBUTEX, although a marketed product in some countries in Europe, is considered experimental as substitution therapy in opioid drug dependence 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 SUBUTEX 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.

EXPERIMENTAL PROCEDURES

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

SUBUTEX will be administered sublingually once daily. This means that you must place the tablet under your tongue and allow it to dissolve (i.e., melt) which will take 5 to 10 minutes. It is important not to chew or swallow the tablets as this will make SUBUTEX@ ineffective. After your first dose, your physician will increase the dose gradually until a maintenance dose that produces a clinical effect is reached. After a period of successful treatment, your physician may gradually decrease your dose. Depending on your condition, your dose may continue to be reduced until it is stopped altogether. Again, this will be discussed between yourself and your physician. Do not suddenly stop taking the tablets as this may cause withdrawal symptoms. If you are receiving methadone, your physician will reduce the dose to a maximum of 30 mg per day before switching to treatment with buprenorphine.

POSSIBLE BENEFITS

Your participation in this programme may or may not result in a direct benefit to you. SUBUTEX may reduce your heroin consumption and lead eventually to abstinence. It can also

improve your mood, your behavior and your health. However it is not possible to predict or guarantee a favorable response to this treatment.

POTENTIAL RISKS

The adverse effects most frequently observed with SUBUTEX are constipation, headache, insomnia, (i.e., difficulty sleeping) weakness, drowsiness, nausea and vomiting, fainting and feelings of dizziness and sweating. SUBUTEX can also cause a drop in your blood pressure when you go from a lying position to a sitting or standing position. Severe difficulty in breathing, liver damage and hallucinations have been reported rarely. You may feel a few signs of withdrawal during the first 48 hours but these will disappear with the gradual increase in dose. If you feel any of these side effects or any others, you should inform your physician immediately.

You should be careful when driving vehicles or operating machinery because SUBUTEX reduced 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. SUBUTEX, 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 SUBUTEX, 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: _____