PHYSICIANS AGREEMENT
SUBUTEX® (buprenorphine) Sublingual Tablets
Special Access Program

I acknowledge the following items as terms of use of this drug:

1. I am responsible for the correctness and completeness of the data provided in my request for SUBUTEX® sublingual tablets (SUBUTEX) through the Special Access Programme (SAP) of Health Canada.
2. I have read the SUBUTEX Product Monograph and I am familiar with its contents.
3. I am aware that the safe use of SUBUTEX in human pregnancy has not been established. Since chronic use of buprenorphine by the mother may be responsible for withdrawal syndrome in neonates, I understand that SUBUTEX is not recommended during the 2nd and the 3rd trimester of pregnancy. I am aware that buprenorphine studies in animal models (rats and rabbits) have evidenced fetal toxicity.
4. I am aware that SUBUTEX is contraindicated in women who are breastfeeding.
5. I understand that the current approval by Health Canada and RB Pharmaceuticals Ltd. (RBP) is limited to a maximum of six (6) months of treatment (at the discretion of RBP), and that any prolongation will be subjected to a new request and a new approval, which will not be automatically granted.
6. Should I choose in my sole professional discretion to administer SUBUTEX to this patient, I understand that the product provided under this SAP may only be used for this specific patient.
7. As the treating physician, I remain solely and fully responsible for the decision to administer SUBUTEX in this patient as well as for the administration and potential consequences thereof.
8. I understand the need to perform a full medical and physical evaluation before the administration of SUBUTEX and confirm that I have performed the necessary evaluations for this patient prior to this request.
9. I certify that I am qualified to prescribe SUBUTEX to this patient by training and certification.
10. I certify that any tablets of SUBUTEX provided by RBP as part of this SAP will be administered *only* to this patient and auditable records of such dispensing must be maintained and available upon request.
11. I certify that any unused or expired product shall be returned to RBP.
12. I understand the standard RBP Adverse Event reporting requirements and will adhere to these.
13. I have noted and agreed to the recommendation of RBP to inform my local Ethics Committee of the administration of SUBUTEX in this patient under the SAP of Health Canada, if applicable.
14. I confirm that I have fully informed the patient/legal guardian of the risks associated with the use of SUBUTEX treatment and that I have obtained written confirmation of the understanding and agreement of the patient/legal guardian of such risks, in the form of the attached Patient Consent Form provided to me by RBP.

15. I will ensure that all laws and regulations with regard to this SAP are respected, in particular the law of personal data.
16. I understand that any observed violation of the above conditions will result in immediate suspension of the approval of RBP for my request for SUBUTEX under the SAP of Health Canada.

By signing, I agree to the above conditions:

Date: _____

Name (Please Print): _____

Signature: _____

Physician's License No.: _____