**C1 Esterase Inhibitor Home Infusion**

DRAFT

**Patient Consent and Participation Agreement**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(patient’s or caregiver’s name) understand that C1 Esterase Inhibitor is a human blood product and although the product has undergone viral inactivation processes, there is still a small risk that it may contain unknown agents that may transmit disease.

I have been advised of the potential benefits, risks, advantages and disadvantages of C1 Esterase Inhibitor home infusion therapy. Alternatives have also been discussed.

I am aware that the costs of C1 Esterase Inhibitor are covered by the Canadian Blood Services, but that I am responsible for the costs of the infusion supplies (needles, tubing etc)

I realize that to be successful in home infusion of C1 Esterase Inhibitor I will need to complete a training program. I have read the information provided on C1 Esterase Inhibitor home infusion and I understand the benefits, risks and alternatives to C1 Esterase Inhibitor home infusion. By signing below, I agree:

1. To attend initial training sessions as required
2. To obtain, transport and store C1 Esterase Inhibitor according to instructions as well as to ensure proper needle disposal guidelines
3. To carry out the infusions as instructed
4. To keep accurate infusion logs and to return completed logs to the C1 Esterase Inhibitor Home Infusion Program (Clinic Nurse / Transfusion Safety Officer)
5. To demonstrate knowledge of possible adverse reactions to C1 Esterase Inhibitor and how to manage them should they occur
6. To report any major adverse events immediately to my Immunologist and/or nearest Emergency Department
7. To attend follow-up appointments with my Immunologist, at least annually

I understand that I may be asked to withdraw from the Home Infusion Program and use the Hospital Emergency Department for therapy if there is non-compliance with the C1 Esterase Inhibitor Home Infusion Program guidelines and/or other problems that would alter my judgment regarding C1 Esterase Inhibitor treatments and/or my HAE management. I also understand that I have the right to remove myself from this program at any time.

**Patient’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**CERTIFICATION BY THE PHYSICIAN OBTAINING CONSENT**

I have explained the benefits, risks and alternatives to C1 Esterase Inhibitor, specifically as it relates to the Home Infusion Program. In my opinion, the person signing the consent understand the content of this consent.

**Physician’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** *(print)*

**Physician’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**