

Sample Patient Consent Form to Participate in NovoSeven User Registry Registry for rFVIIa Usage in Non-hemophilia Bleeding Indications

PURPOSE AND BACKGROUND

There are increasing anecdotal/case series of use of recombinant factor VIIa (rFVIIa) in non-hemophilia bleeding situations. However, no formal method exists to collect this data in a systematic manner. Based on the recommendations of the NovoSeven Usage Advisory Board (NAB), a registry of usage of rFVIIa in such conditions has been established (Novoseven in Critical Care Evaluation - NICE Registry) for documentation of clinical data. The purpose of this registry is to collect information from physicians across India on the use of rFVIIa in patients with bleeding conditions that is not due to hemophilia, a condition where your body lacks a clotting protein.

This registry is maintained by the Department of Haematology, Christian Medical College, Vellore, on behalf of the Novoseven Advisory Board (NAB). You* /your child are/is being asked to participate in this program because you/your child are /is between the ages of 0 months (newborn) and 20 years of age and you/your child have/has been treated with a medication called rFVIIa (recombinant factor VIIa, NovoSeven) to treat your bleeding condition.

*This study may involve minors, therefore you is defined as meaning you, yourself or you, a minor and your relatives.

PROCEDURES

If you agree to be part of this study, the following things will happen. You will be assigned a unique code that will only be known to the database staff/personnel. All information collected will be recorded under this unique code. Personal information such as your age, race and gender will be gathered. Information regarding the type of bleeding you had, the treatment that was given, its duration and the outcome will be recorded. Information about the use of rFVIIa will also be

collected - how much was used, how often, whether it was successful in controlling the bleeding and whether you developed any side effects from this medication. Your doctor would have discussed with you the use of this medication and its side effects before its use. Information will be gathered regarding any laboratory testing done to see if there is an underlying reason for your bleeding condition and any follow-up laboratory studies that have been done.

RISKS AND DISCOMFORTS

This is an information collection study, there is no anticipated physical risks or discomforts associated with your participation.

BENEFITS

You may receive no medical benefit from your participation in this study. However, it is hoped that the information gained in this study will help doctors have a better understanding of this medication and its use in patients with bleeding conditions.

ALTERNATIVES

Not to be a part of this study.

CONFIDENTIALITY

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your participation in the study and information in your study records may be disclosed to your doctors and nurses, and may be disclosed as otherwise provided by law. However, your name will not be used in any published reports about this study.

EMERGENCY TREATMENT AND COMPENSATION FOR INJURY

Since this is an information gathering study, we expect that you will not be physically injured in any way by being part of this study. If you have any questions about these issues, or believe you have been treated carelessly, in the study, please contact the treating clinician for more information.

NEW FINDINGS

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risk or benefits resulting from participation in the research or new alternatives to participation that might change your mind about participating.

WITHDRAWAL

Your participation in this study is strictly voluntary. You have the right to withdraw your participation at any point in this study without prejudice to your future health, care or other services to which you are otherwise entitled.

QUESTIONS

You or your legally authorized representative may ask questions and request information about this project at any time.

CONSENT

You will be given a copy of this consent form to keep. By signing this consent form, you are not waiving any of your legal rights, claims, or remedies.

I have read (or someone has read to me) the information in this consent form. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. By signing this consent form, I acknowledge the risks of participation and willingly agree to receive (have my child receive) the treatment outlined above.

Name of Subject (type or print) : _____

Signature of Subject or legal guardian(s) Date: _____

Name of Witness (type or print) _____ Date: _____

_____ Date: _____