1. Explanation of the purpose of this research

Either to prevent or stop bleeding, you/your child need(s) treatment with factor VIII concentrate. All factor VIII treatment with factor VIII concentrates, whether made by the NHS or imported from abroad, are prepared from plasma obtained from several thousand donors. Although all donors are carefully screened before their plasma is accepted, and all concentrates are heated to destroy any HIV virus (AIDS virus). The risk of transmission of other viruses has not yet been entirely eliminated.

The main problem which remains to be overcome is the elimination of the chance of transmission of the virus which causes non A, non B hepatitis (NANBH). With the main objective of removing the risk of NANBH, the factor VIII concentrate which is being used in this study has been purified and heated by new methods. It is expected to have a reduced or absent risk of virus transmission. The only way to prove this, however, is to carry out regular blood tests in people who have received treatment with this new concentrate. Because people who have never previously been treated with concentrate (such as you/your child) are thought to be at most risk of NANBH, the study is at present limited to this group.

2. Plan of the study

Before treatment with factor VIII, a blood sample will be taken and the first of 3 injections of a course of hepatitis B vaccine will be offered (if you/your child have not previously been vaccinated against hepatitis B). After treatment with factor VIII, a blood sample and brief clinical examination will be needed at least every 2 weeks for 4
months and then once a month for a further 2 months. The amount of factor VIII you/your child need(s) will depend on circumstances, and for at least 6 months after the first injection any more treatments which are needed will be with the same type of concentrate.

3. **Alternative possibilities for treatment**

Why treatments other than factor VIII concentrate are not felt to be appropriate in you or your child's case will be explained. If you choose not to participate in this study, we shall in any event recommend frequent clinical and blood test follow-up.

4. **Potential benefits**

Judging from the freedom from ill-effects observed using many batches of this material, preliminary studies using many batches of this 8Y concentrate suggest that it has fewer risks than products which were previously available for the treatment of haemophilia. If this is confirmed both you/your child and other patients will benefit.

5. **Potential risk and discomforts**

All products made from human blood carry a risk of transmission of infection. Although experience with this concentrate has so far been very good a thorough study in many (perhaps at least 60) patients in different hospitals is required and until this is done it cannot be assumed to be without risk. Like other factor VIII concentrates, it may occasionally cause transfusion reactions. The need for frequent blood tests after treatment may be inconvenient and mildly uncomfortable.

6. **Any questions you may have**

Either Dr. Rizza, or any of the medical or nursing staff of the Haemophilia Centre who are involved in this study, will be glad to
answer any questions you may have, now and at any time in the future.

7. Confidentiality

Records relating to this study will be kept in the Haemophilia Centre and will be made available to professional staff involved in the study. Copies of records, with names removed and code numbers inserted, will be made available to the Blood Products Laboratory, Elstree (the manufacturer of the concentrate) and also (on request) to collaborating investigators in other hospitals. It is possible that officials from the Department of Health may also wish to inspect the records. At the end of the study, results will be reported in a scientific journal. The identity of patients will not be disclosed in this report, which will be given to you on request after it has been published.

8. Reimbursement of expenses

Any reasonable expenses you may incur as a result of participation in this study will be reimbursed.

9. Your right not to participate

You are free not to participate in this study. If you do agree to participate you may withdraw your consent and discontinue participation at any time without jeopardizing your medical care in any way. We shall let you know the findings of the study as it progresses, so you will always be aware of any new information which becomes available which may affected your decision to continue participation.
Statement of Consent

I have read the above and understand the nature of the study and the possible risks. I am willing to participate/I am willing to let my child ( ) participate in the study.

Name.................................. Witness' name ..................................

Signature................................ Witness' signature .....................

* Optional as some local Ethics Committees prefer patients not to sign the statement of consent.

Copy 1 to be filed in patient's study record
Copy 2 to be given to patient or his parents

21.09.87