Study Title:UK National haemophilia Database Research Registry (UK-NHD-RR)

PATIENT INFORMATION SHEET FOR YOUNG PEOPLE (11-15 YRS) WHO ARE ABLE TO GIVE CONSENT

Please read this information sheet carefully and talk it over with your friends/parent/s or the person who looks after you before you decide whether you want to be part of this research. You can also talk to your doctor or specialist nurse at your Haemophilia Centre if you want to or if you would like to have more information. This leaflet explains why we are asking you to help and what it will involve for you.

Why am I being asked?

You are being invited to take part in research because you have a bleeding disorder which means you are more likely to have bleeds. If you have a bleed you are given treatment to stop the bleeding or you may be on regular treatment to prevent bleeds happening in the first place.

We are asking everyone in the UK of all ages who has a bleeding disorder whether they want to take part. Information on you and your bleeding disorder and the treatment of it is held on the UK National Haemophilia Database (NHD). The research that the NHD is doing is co-ordinated by the UK Haemophilia Centre Doctors' Organisation (UKHCDO) using the information held by the NHD.

What is the National Haemophilia Database (NHD)?

The UK NHD is a register of people in the UK with all types of bleeding disorders. Your Haemophilia Centres sends information within the NHS secure system about you and your bleeds and treatment to the NHD. This database is held within the NHS but is managed by the national group of doctors who look after people with bleeding disorders (called the UKHCDO). The 'sponsor' of the database is the Manchester University NHS Foundation Trust (MFT) and they are also the data controller. Therefore MFT and the NHD are responsible for looking after your information and using it properly and the data helps the

NHS plan services for people with bleeding disorders in the UK. You can find out more about how we use your information at www.ukhcdo.org or ask your doctor or specialist nurse.

As well as helping with your day to day treatment the information about you on the NHD is combined with information from other people with bleeding disorders and this helps us to look at the causes and treatment of bleeds in more detail. This way of combining information is a form of research and before we do this we have to ask you whether you are OK for this to happen and whether you consent to your data being used in this way.

Why are we doing this research?

This research will help us to understand bleeding disorders better and to improve the care of people who have bleeding disorders. We want to find out more about the causes of bleeding disorders, how they affect your life and what the best treatment is. Bleeding disorders are rare conditions and by collecting as much information as we can about the treatment of people with bleeding disorders, we are able to get a much better understanding of these disorders and their treatment.

What types of research does the National Haemophilia Database do?

The National Haemophilia Database does not change your treatment - it just looks at what happens to you when you have your routine treatment. We look into the number of people with bleeding disorders in the UK, the treatment they receive, how well this treatment works and whether the treatment causes any problems. It also collects other information related to your bleeding disorder such as joint scores and genetic results. Many people record any bleeds and the treatment they have at home on Haemtrack. Your information on Haemtrack will also be used for research if you agree.

As part of the research of the NHD, reports are prepared for companies that make treatments for bleeding disorders. These reports help the companies to plan how much treatment is needed and how well their treatments are working and whether there are any complications. In these reports it is not possible to identify you as an individual. The information released in these reports is agreed by a Committee that includes

representatives who are patients themselves. The companies then pay for these reports and this helps to fund the NHD.

UKHCDO and NHD do not undertake any clinical trials and whether you take part in a clinical trial is entirely between you and your Haemophilia Centre.

What is done with the results of research done by the National Haemophilia Database?

The results of the research may be published in medical journals or presented at national and international meetings to help doctors and nurses around the world get a better understanding of bleeding disorders and their treatment. Reports are also given to companies that make the treatments for bleeding disorders. It will not be possible for anyone to work out who you are in any of these reports or publications as all the reports are anonymised. The information that can be used to identify you such as your name, date of birth or NHS number is never released by the NHD to researchers either in the UK or outside.

Do I have to take part?

No, taking part is up to you. It's OK if you don't want to take part. If you decide not to take part this won't change the treatment or care you receive in any way, now or in the future. If you decide not to agree for your information to be used for research your Haemophilia Centre will continue to use your information to help to look after you on a day to day basis and your information will be used to help plan health care within the NHS.

What if I don't want to take part anymore?

It's ok if you decide to take part and then change your mind. You can stop taking part at any time and you don't have to say why. You just need to tell one of the nurses, doctors or ask your parent/s or the person who looks after you to let us know. This won't change the treatment you have in any way and you can still keep coming to the hospital to see the doctors and nurses if you need their care.

What will I be asked to do if I take part?

You will be asked to sign a consent form to give permission for the medical information held on you by the NHD to be looked at for research projects and reports. You won't have to do anything else and there won't be any changes to the treatment you have.

What are the possible benefits of taking part?

This research may not help you directly, but we hope that it will help improve treatment for people with bleeding disorders in the future.

Will anyone else know I'm taking part?

Your family, doctors and nurses at your Haemophilia Centre and the people who work at the National Haemophilia Database will know you're taking part. All your information will be kept safe and no one outside these places will be able to identify you from the research.

Will my taking part in this study be kept confidential?

All information which is collected by the NHD about you is kept strictly confidential whether or not you agree to your information being used for research. If you agree to allow you information to be used for research, your information will be handled in accordance with the Data Protection Act 1998, GDPR and all other laws. You have the right to ask to see the data that has been collected about you and if you think anything is incorrect, to have it corrected. Representatives of regulatory authorities or the ethics committee will be allowed to see your information as required to ensure the research is being properly conducted and that the data collected is accurate. Your privacy will be respected at all times.

Who has reviewed the study?

This research programme has been reviewed by North West - Haydock Research Ethics Committee, and the reference number is 19/NW/0009**.** UKHCDO and NHD send a report to the ethics committee each year to say what research has been done with the information held by the NHD. This report will be published on the UKHCDO website.

What happens if there is a problem?

We would not expect you to suffer any harm or injury from the use of your information held by the NHD for research. If you are harmed in any way there is no special compensation arrangement. If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this consent process, the normal National Health Service Complaints mechanism is available to you. If you have any concerns or as an initial point of contact if you have a complaint, please contact the Patient Advice and Liaison Service (PALS) at the address given below;

PALS office:

Telephone: 0161 276 8686

Address: PALS, The Chief Executive, MFT, Headquarters, Cobbett House, Oxford Road, Manchester, M13 9WL

or UKHCDO on +44 (0) 161 850 8102or email support@ukhcdo.org

Contact for further information?

If you require any further information please do not hesitate to discuss this information sheet with any of the nurses or doctors looking after you. If you would like to discuss the information sheet with an independent group you can contacted the UK Haemophilia Society on info@haemophilia.org.uk.

Thank you for taking the time to read this leaflet.

UK Bleeding Disorder Research Registry (UK-BDRR)

Consent form for Young Persons (11–15 years) able to give informed consent

Patient Details

Patient Full Name:
Date of Birth:
Hospital Number:

Please tick the boxes if you agree:	Patient Initials
1. I confirm that I have read and understood the patient information sheet, version 2.0, for the UK-BDRR.	
2. I give consent for my clinical data from any hospital that I attend to be provided to the UK-BDRR by my haemophilia centre or other researchers who have access to relevant information.	
3. I hereby give permission for UK-BDRR to share my personal identifiers (name, H & C number and Date of Birth) with the Business Services Organisation (Health and Social Care NI) to allow BSO to trace patients using the supplied identifiers to match mortality data in respect of deceased patients hence ensuring accurate mortality data and thereby contributing to UK wide research regarding bleeding disorders	
4. I understand that my involvement in this study is voluntary and that I can withdraw at any time without giving a reason and without my medical care or legal rights being affected.	
5. I consent to my data being transferred between the collaborating research institutions and/or industrial partners for research, including safety surveillance in the UK and abroad, and I will not be identifiable in this exchange.	
6. I understand that my medical information may be looked at by authorised individuals from authorities or by the ethics committee where it is relevant to my participation in this study. All my medical information will be treated as confidential.	

Name of Patient	Signature	Date
Name of Parent/Guardian	Signature	Date
Name of Person taking consent	Signature	Date