

Study Title:UK Bleeding Disorder Research Registry (UK-BDRR)

Patient Information Sheet for Young People (11-15 years) 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.

What is the purpose of the UK-BDRR?

Bleeding disorders are rare, so we need to gather information from lots of people across the UK over a long time to understand them better. By combining information from many people, doctors and researchers can learn more about these disorders and how to treat them.

This study will help us understand bleeding disorders better and improve the care for people who have them. We want to find out more about what causes bleeding disorders, how they affect your life, and what the best treatments are.

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4 copies: 1 to patient, 1 to electronic medical notes, 1 to site file, 1 to NHD

What is the National Haemophilia Database (NHD)?

The NHD is a register of people in the UK with all types of bleeding disorders. Your Haemophilia Centre 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).

What does the NHD do with the information it collects?

Your Haemophilia Centre and the NHD collect important information to help understand and manage bleeding disorders. When your local centre gathers this data, it helps doctors and researchers learn more about these conditions. This means they can improve treatments and care for patients over time. They can see how well treatments work and spot any health problems.

Across the country, this information helps create reports about how common bleeding disorders are, which treatments are used, and how safe and effective they are. It also shows where people might not be getting enough treatment. This helps the NHS plan for enough resources, treatments, and funding.

The NHD removes personal details from the data, so you and other patients can't be identified. This keeps your privacy safe. The anonymous data is used by health planners, government bodies, medicine companies, and regulators to plan services, make treatments, and ensure there are enough healthcare resources.

The data also supports research into how bleeding disorders start and progress. It helps check the long-term safety and effectiveness of old and new treatments. Sometimes, the NHD links its data with other NHS databases to learn more about bleeding disorders and treatments. This uses NHS numbers and is always approved by the Health Research Authority (HRA) to make sure the data is used properly.

What is the link between the UK-BDRR and the NHD?

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The UK-BDRR collects data from several places. Most of the information comes from the NHD and other hospital records.

Why are we doing this research?

In addition to helping with your day-to-day treatment, the information collected about you is combined with information from other people with bleeding disorders, and this helps us look at the causes and treatment of bleeds in more detail. This way of combining information is a form of 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 better understanding of these disorders and their treatment.

The UK-BDRR 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.

What is done with the results of research done by NHD?

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 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. Your Haemophilia Centre will continue to use your information to help 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 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 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?

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All information collected by the NHD about you is kept strictly confidential whether you agree to use your information for research. If you agree to allow your information to be used for research, it will be handled in accordance with the Data Protection Act 1998, GDPR and all other laws. 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 always be respected.

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. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this consent process, the standard 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, don't hesitate to get in touch with UKHCDO or Haemophilia society

UKHCDO on +44 (0) 161 850 8102 or email: support@ukhcdo.org1

Haemophilia Society on 02073990780 or email: info@haemophilia.org.uk 2

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 contact the UK Haemophilia Society on info@haemophilia.org.uk.

Thank you for taking the time to read this leaflet.

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

Participant details

Patient Full Name:

Date of Birth:

Hospital Number:

Please tick the boxes if you agree:	Initials
1. I confirm that I have read and understood the patient information sheet, version 2.0, for the UK-BDRR.	<input type="checkbox"/>
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.	<input type="checkbox"/>
3. 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.	<input type="checkbox"/>
4. 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.	<input type="checkbox"/>
5. 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.	<input type="checkbox"/>

Name of Patient

Signature

Date

Name of Parent/Guardian

Signature

Date

Name of Person taking consent

Signature

Date