UK – Bleeding Disorder Research Registry

Parent/Guardian information sheet and consent form

Your child is being invited to join the UK Bleeding Disorder Research Registry (UK-BDRR) because he or she has been diagnosed with a bleeding disorder. We encourage you to read this information sheet to understand the benefits of participation and the implications for your child, if any. If anything is unclear, or if you require more information, please ask the clinical or research team at your child's Haemophilia Centre. It may also be helpful for you and/or your child to discuss this decision with your family or friends.

In the UK, all patients diagnosed with a bleeding disorder are registered on the National Haemophilia Database (NHD). Established in 1969, the NHD aims to improve care for individuals with these conditions and currently holds records of approximately 60,000 people, both living and deceased. Managed by the UK Haemophilia Centre Doctors' Organisation (UKHCDO), a registered charity. The NHD plays a crucial role in understanding and managing bleeding disorders across the UK.

A few words about data and the National Health Service England, Wales, Scotland and Health and Social Care Northern Ireland

Recording your health information in medical and health records is necessary to ensure you receive appropriate healthcare. The recorded information essential for your care includes your name, date of birth, contact details, and depending on the region where you live, NHS or CHI or Health and Care number, medical conditions, medications, and interactions with healthcare professionals. The information also helps plan and improve health services, develop new services, and support research into various health conditions.[1]

Confidential patient information combines data that can identify your child, such as their name, with data about their healthcare or treatment. Identifiable information alone, such as contact details, is used by health services to contact you and/or your child and is not considered confidential.[2]

What is the UK Bleeding Disorder Research Registry, and what is its purpose?

Bleeding disorders are rare conditions, and understanding them requires gathering and analysing data from many people across the UK over an extended period in a database. Databases are digital filing cabinets, and by combining information from many patients

[1] Understanding the health and care information we collect - NHS England Digital

[2] Choose if data from your health records is shared for research and planning – Overview - NHS (www.nhs.uk)

https://www.nidirect.gov.uk/articles/accessing-medical-or-health-and-social-care-records
https://www.nhsinform.scot/care-support-and-rights/health-rights/confidentiality-and-data-protection/how-the-nhs-handles-your-personal-health-information

with similar conditions, the UK Bleeding Disorder Research Registry enables healthcare professionals to gain a better understanding of these disorders and how they are treated.

The registry will focus on several key areas. It will assess how many people in the UK have bleeding disorders, the types of disorders and treatments they receive, and how effective these treatments are. Additionally, the registry will also examine the complications related to these disorders, which are often influenced by the type and severity of the disorder, as well as the treatments received over a lifetime. For example, some disorders are associated with joint damage, and for other disorders, the treatment may become ineffective over time due to rejection by the immune system. The registry will also improve our understanding of the management of both rare and mild bleeding disorders, which can sometimes be under-treated or over-treated.

The UK-BDRR also looks to explore how bleeding disorders might interact with other medical conditions. For example, the registry investigates how patients with both bleeding disorders and heart conditions are treated, especially when blood-thinning medications are involved.

It is important to note that the UK-BDRR does not conduct clinical trials or offer new treatments directly. Whether your child takes part in a clinical trial is entirely between you, your child and your child's Haemophilia Centre.

How is UK-BDRR linked to the National Haemophilia Database?

Data to UK-BDRR flows from multiple sources across the UK. Information can come from the NHD, Haemtrack, the patient app used to record treatment given at home, the UK Haemophilia Centres, NHSE, NHSS, and HSCNI.

What is the National Haemophilia Database?

NHD is a database of information placed on the Health and Social Care Network servers and functions similarly to other electronic health records used in hospitals. Your Haemophilia Centre collects and securely transmits information about you to the NHD within the UK regional NHS systems. This database is focused on collecting specific data about registered patients. It includes details about the type and severity of the bleeding disorder, the clotting factors used, and specific complications that may arise. However, it is essential to note that the NHD does not gather information on all treatments or procedures, nor does it track the effectiveness of interventions across all types of bleeding disorders.

What does the NHD do with the information it collects?

The data collected by your Haemophilia Centre and the NHD is vital for understanding and managing bleeding disorders. At your local Haemophilia Centre, gathering this information helps doctors and researchers learn more about these conditions, improving how they treat and care for patients over time. This includes tracking how well treatments work and any health complications that might arise.

Nationally, this data contributes to producing detailed reports that describe how common bleeding disorders are in the community, treatments being used, and their safety and effectiveness. It also identifies regions where access to treatment is inadequate and supports the UK NHS

services to plan for sufficient resources, treatments, and funding.

Furthermore, the NHD takes measures to anonymise the data before use, which means you or other patients are not identifiable during or after the analysis. This ensures individual privacy is maintained. This anonymised data is utilised by healthcare commissioners, government bodies, pharmaceutical companies, and regulatory agencies for planning and commissioning services, producing treatment products, and ensuring adequate healthcare resources are in place. Additionally, the NHD shares this anonymous information with the European Haemophilia Safety Surveillance (EUHASS) to help monitor possible side effects of treatments across Europe.

The data also supports research into how bleeding disorders develop and progress, as well as monitoring the long-term safety and effectiveness of old and new treatments. Occasionally, the NHD links its information with other UKNHS databases to enrich the understanding of bleeding disorders and their treatments. This linking process uses NHS, or CHI or Health and Care numbers and is always conducted under the approval of the Health Research Authority (HRA), Scottish Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP), and Northern Ireland Privacy Advisory Committee (NIPAC) to ensure appropriate use of the data.

Why am I being asked to agree to have my child's information used for research?

We are seeking your permission to use your child's data for research in addition to helping with their day-to-day care. We hope this research will improve understanding and care of bleeding disorders.

The current data collection is limited to patients with severe bleeding disorders and specific complications. We hope to collect information on all bleeding disorders and a more comprehensive range of complications to enable better treatment decisions for all bleeding disorders.

Your child's personal information will not be used for research if you do not agree or sign the consent form.

The Health Research Authority defines research as any analysis that results in knowledge that is transferrable or generalisable. The analysis of data for reviewing or improving the quality of the service is not considered research.

What are the possible disadvantages, risks, and benefits of taking part?

There are no anticipated disadvantages to your child. While the research may not help your child directly, it can improve future treatments and care for others with bleeding disorders.

Do I have to agree to use my child's information for research?

No, neither you nor your child have to agree. If you decide that you do not want your child's information to be used for research, this will not affect the treatment or care they receive in any way, now or in the future. You will be asked to sign a form so that we can record your wishes about the use of your child's data for research.

What will happen to my child if they take part?

You will be asked to sign a parent/guardian consent form permitting the medical information held on your child by the National Haemophilia Database to be used

for research. Neither you nor your child will need to do anything else. There will be no additional blood tests or hospital visits.

Will my child be asked to participate in additional activities?

In some instances, your child might be asked to fill out extra questionnaires or undergo evaluations to gauge the effectiveness of specific treatments or interventions, such as pain management strategies or other support services. These activities require collecting additional information to understand treatment outcomes better.

Will my child's taking part in this study be kept confidential?

Yes, all information collected about you by the NHD is kept strictly confidential. Identifiable information, such as your name, date of birth, NHS or CHI, or Health and Care number, is not released to researchers and is only accessible to your Haemophilia Centre.

If you consent to have your information used for research, it will be managed in strict accordance with the Data Protection Act 2018 and other relevant laws. Only authorised representatives from regulatory authorities or ethics committees may access your information as necessary to verify the integrity of the research and ensure the accuracy of the data collected.

Your privacy will always be protected, and you retain the right to review the data collected about you. Should you find any errors or mistakes, you have the right to request corrections to ensure all information is accurate and up to date.

What would happen if I decided that my child would not continue with the study?

Your child's participation in this study is entirely voluntary. You or your child can withdraw your consent at any time without affecting the standard of care your child receives, and you do not need to provide a reason for withdrawing. If you or your child choose to withdraw, your child's information will no longer be used for future research, but it will still be utilised for their routine care.

To withdraw, or if you or your child have decided not to participate, you can sign a form at your local site to record your decision on our system, or you can use the national data opt-out in England and Wales through the designated website.

What is the National Data Opt-Out?

The National Data Opt-Out service allows you to stop your child's confidential information from being used for anything beyond their direct care across all healthcare conditions. Most healthcare planning uses anonymised data, as do many research projects.

Please note that this service is currently available only to residents of England and Wales.[3] If you or your child live in Northern Ireland or Scotland and wish to opt out of having your child's data used for research, please inform your child's Haemophilia Centre directly.

Can NHD use my child's data without consent?

Yes, in certain circumstances, the NHD can use your data without explicit consent. The

[3] Make your choice about sharing data from your health records - NHS (www.nhs.uk)

NHD routinely collects data from all haemophilia centres to aid in the ongoing care of patients and for healthcare planning under contracts with various healthcare commissioners. This confidential patient information is primarily used to manage individual care and to identify any treatment complication that must be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA).

In December 2024, the NHD was granted Section 251 support from the Health Research Authority. This support allows the NHD to collect, store, and process confidential data for both non-research and research purposes in England and Wales in situations where obtaining consent is not feasible. This typically applies to cases where individuals recorded in the database have either passed away or cannot be followed up with, thereby enabling the NHD to use details like the date and cause of death without prior consent. Additionally, when data is anonymised, i.e., it can no longer be linked back to any individual, consent is not required for its use in analyses.

Who is sponsoring the UK Bleeding Disorder Research Registry?

UKHCDO sponsors the UK Bleeding Disorder Research Registry. Both UKHCDO and NHD are involved in conducting research and acting as the data controllers for these activities. This means they are responsible for ensuring that the data is used properly and ethically.

How is the registry managed?

A steering committee governs the management of the registry and the research conducted. This committee is composed of representatives from various groups both affected by and involved in the treatment of bleeding disorders. It includes members of the UKHCDO executive team, NHD, centre directors, healthcare commissioner, representatives from the Haemophilia Societies, and patient representatives. The diverse makeup of the committee ensures that a wide range of perspectives influences the governance and strategic direction of the registry.

Research priorities are set based on the insights and expertise of various working parties and task forces, which focus on specific treatment areas relevant to bleeding disorders. For example, joint health in patients with severe bleeding disorders and heavy menstrual bleeding in women suffering from bleeding disorders. Their specialised knowledge helps steer the registry's research initiatives to address the most pressing needs and emerging trends in the treatment of bleeding disorders.

Where can I find more information about what data is collected?

A comprehensive list of the data routinely collected by the NHD can be found at www.ukhcdo.org/patient-information. The NHD keeps this information indefinitely, which allows for ongoing monitoring of changes in the prevalence of bleeding disorders and the effectiveness of treatment approaches over time.

How is UK-BDR funded?

The registry is primarily funded by the NHD, which is in turn funded by the National Health Service, mainly through regional NHS commissioners. Additionally, it receives grants from pharmaceutical companies that specialise in treatments for bleeding disorders. These funds are allocated to support various projects such as observational studies on bleeding disorders, their treatments, associated complications,

and long-term safety (pharmacovigilance) of new drugs after introduction into routine clinical care.

Who can access my child's information?

The UK-BDRR collaborates with other bleeding disorder registries and research groups globally. In these collaborations, data from the UK may be combined with similar data from other countries. If any information is released to researchers outside of the NHD, your child will be identified only by a code, ensuring that none of their personal information is disclosed. These external researchers can be based in the UK, Europe, or elsewhere around the world. Release of information from the NHD is strictly controlled and only occurs after approval by the steering committee.

What is done with the results of the research?

The findings from research projects conducted by the UK-BDR may be published in medical journals or presented at both national and international conferences. The publication of research findings helps clinicians worldwide better understand bleeding disorders and their treatments. Additionally, these reports are shared with pharmaceutical companies involved in developing treatments for bleeding disorders. Importantly, all published reports and presentations are anonymised, ensuring that it is not possible to identify any individual participants.

Who has reviewed the study?

This research database has been reviewed by the HRA, PBPP and NIPAC. The approval details are available to view on each of these organisation's websites by searching for NHD and UK Bleeding Disorder Research Registry. UKHCDO and NHD send a report to these organisations 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 do not expect your child to suffer any harm or injury from the use of his/her information held by the NHD for research. If your child is harmed in any manner, there is no special compensation arrangement. If your child is harmed due to someone's negligence, you or your child may have grounds for legal action, but you may have to pay your legal costs. Regardless of this, if you or your child wish to complain or have any concerns about any aspect of the way your child has been approached or treated during this consent process, the standard regional NHS Complaints mechanism is available to you is available to you and your child. If you or your child 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.org[4]

Haemophilia Society on 02073990780 or email info@haemophilia.org.uk [5]

Contact for further information?

If you or your child require any further information, please do not hesitate to discuss this information sheet with any of the nurses or doctors looking after your child. If you would like to discuss the

[4] https://www.ukhcdo.org

[5] https://haemophilia.org.uk/

information sheet with an independent group, you can contact the UK Haemophilia Society at info@haemophilia.org.uk.

Thank you for taking the time to read this leaflet.

UK Bleeding Disorder Research Registry (UK-BDRR)
Informed Consent Form – Parent/Guardian

Participant details

Patient Full Name:
Date of Birth:
Hospital Number:

	Initials
1. I confirm that I have read and understood the patient information sheet, version 2.0, for the UK Bleeding Disorder Registry.	
2. I give consent for my child's clinical data from any hospital that they attend to be provided to the UK-BDRR by their 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 child's participation is voluntary and that I can withdraw at any time without giving a reason and without my child's medical care or legal rights being affected.	
5. I consent to my child's anonymised and pseudonymised data being transferred between the collaborating research institutions and/or industrial partners for research, including safety surveillance in the UK and abroad.	
6. I understand that my child's medical information may be looked at by authorised individuals from regulatory authorities or by the ethics committee where it is relevant to my child's participation in this study. All my child's medical information will be treated as confidential.	

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