

The American Thrombosis and Hemostasis Network (ATHN)

# Patient Authorization Opt In to Participate in ATHNdataset

## ATHN and Your HTC

The hemophilia treatment center (HTC) where you/your child receives care is part of the American Thrombosis and Hemostasis Network (ATHN). This means it is part of a special group of HTCs across the country called ATHN Affiliates. HTCs and ATHN want to improve the care of people with bleeding and clotting disorders. ATHN is helping HTCs to create a safe and secure national database of patient health information. The national database follows all HIPAA privacy guidelines to protect your confidentiality. From this national database, a smaller subset of patient health data, called the ATHNdataset, will be managed by ATHN.

Doctors, scientists, policymakers, and other healthcare providers need a large pool of patient information from a lot of patients to answer scientific, public health, and policy questions about the best way to treat bleeding and clotting disorders. They will use the information from the ATHNdataset to answer these questions.

Having *your/your child's* health information in the ATHNdataset will help us better understand bleeding and clotting disorders, the complications of these disorders, the social and economic costs, and the effectiveness of treatments and interventions.

All research using the ATHNdataset will be reviewed and approved using an established process that takes into account community priorities and interests.

## What am I being asked to do?

You are being asked to sign this form to provide your consent for your HTC to share your health information with ATHN and for ATHN to share your information with researchers. You are being asked to allow information about your health to be combined with that of others as part of the ATHNdataset for research. The health information will be shared with ATHN by your HTC and will *not* directly identify you. Your name will not be linked to the data in any way and your name will never be used in any reports produced as a result of studies using this data.

## What kind of information would be included?

If you agree to let your health information be included in the ATHNdataset, the information will be regularly updated to reflect your current health status. The kinds of information that will be sent to ATHN include:

- Type of blood disorder
- Date you were diagnosed
- Family history of the disorder
- Laboratory test results
- Medication issues
- Types of bleeds
- Effective treatments that stop your bleeding and clotting problems from occurring or getting worse
- Routine care and trauma
- Allergies



## How do I know my health information is secure and that my privacy will be protected?

Your treatment center is required by law to protect your health information. Your treatment center can only share your health information with ATHN if you sign this authorization form. ATHN is bound by an agreement with your HTC and is required by Federal privacy laws to protect your information. ATHN cannot and will not share your information with others without your permission, unless required by law.

ATHN will have limited data and will *not* have any information that could directly identify you. In compliance with the federal HIPAA Privacy Rule, ATHN will not receive your name or any of the other information listed below that may directly identify you or make it possible for you to be contacted by ATHN or by anyone else. If you agree to take part, ATHN will receive what is known as a limited data set, which according to the federal Privacy Rule, requires that *all 16 categories of direct patient identifiers must be removed* from shared health information.

### The following information will *not* be included in the ATHNdataset:

- **Name**
- **Postal address, other than town or city and ZIP code**
- **Telephone numbers**
- **Fax numbers**
- **Electronic mail addresses**
- **Social security numbers**
- **Medical records numbers**
- **Health plan beneficiary numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license numbers**
- **Device identifiers and serial numbers**
- **Web universal resource locators (URLs)**
- **Internet protocol (IP) address numbers**
- **Biometric identifiers, including fingerprints and voiceprints**
- **Full-face photographic images and any comparable images**

The database used by your/your child's HTC to generate the ATHNdataset is kept in an encrypted form (this means that people cannot read the information when they look at it). A backup is stored on a highly secure server. All information will be sent through a secure internet-based data transfer mechanism that is password protected and encrypted. This offers more protection and security than paper records and email.

## How will my health information be identified in the database?

The computer system used by your HTC will assign you or your child a unique, computer-generated code. Once that unique code is assigned to you, it will be used instead of your name to collect information about you. This unique code system has been applied in a number of other settings where confidentiality is a concern.



## What are the benefits of participation?

Your/your child's health information will be combined with data from thousands of patients around the country. Complete, standardized information will be available to help increase confidence in healthcare decision making and improve policies.

This will lead to:

- A better understanding of bleeding and clotting disorders,
- Increased knowledge of the genetics of these disorders,
- The ability to study treatment results in persons with bleeding and clotting disorders in order to develop better and more cost effective care
- A close watch on the safety of medicines for bleeding and clotting disorders.

You will help to improve the care of all Americans with bleeding and clotting disorders by letting ATHN use health information collected by your HTC.

## How will I be affected if I choose not to take part?

Your participation is very important. In order to do important research and advocacy, we need as much information from as many people as possible. If you decide not to sign this authorization form, your treatment center will not send any of your/your child's information to the ATHNdataset. Whatever you decide, your choice will not affect the type or level of care provided by your healthcare team.

This authorization does not have an end date. However, if you sign this document and change your mind about participation, you may revoke (take back) this authorization at any time. To do so, you must inform your HTC in writing. After that, ATHN will not receive any more data about you/your child. ATHN may still use health information it already has obtained about you for research.

For more information about ATHN, to learn about the progress of the national database and the ATHNdataset, or to share a complaint or concern, please visit the ATHN website, [www.athn.org](http://www.athn.org).

Any questions that you have about this agreement should first be directed to the following staff person at your HTC.

**Name and Position of HTC Contact:**

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**Phone Number:** \_\_\_\_\_



## The American Thrombosis and Hemostasis Network (ATHN) Patient Authorization Opt-in to take part in ATHNdataset

This authorization to take part in the ATHNdataset was presented by the staff of my clinic. I was given the opportunity to ask questions and I understand its contents and have voluntarily agreed to participate.

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Signature of Participant/ Parent/Guardian or Personal Representative

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Printed Name of Participant or Representative

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Relationship

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Signature of HTC Staff Person who explained this authorization

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Printed Name of HTC Staff Person

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Position

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Date

### CHILDREN'S ASSENT to take part in the ATHNdataset (Optional)

Though your doctors and nurses know a lot about your blood disorder, we still have a lot to learn to make sure that you and others can stay well.

In order to learn more, we would like to get some information about you, when you bleed, what makes you bleed, the factor or other medicine that you take, and any problems that you may be having.

We will not know your name and will not contact you or your parents. Only your doctors need to have that information and they might at some time want to talk to you about other questions or information that we find interesting about you in the future. We will make sure that we will not tell anyone else anything about you that would let others know that you have a blood disorder.

If you are okay with your doctors and nurses sharing your information to help us learn more so that we can help you and others stay well, please sign below.

If not, it is okay, you will still receive your treatment and medicine and no one will be mad at you.

If you change your mind later, that is okay too; just let your parents, the adult who cares for you or someone at your treatment center know.

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Child's Name (Printed)

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Child's Age

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Signature



## The American Thrombosis and Hemostasis Network (ATHN) Patient Authorization OPT-Out of the ATHNdataset

I have read and have been given the opportunity to ask questions about this form and the benefits of allowing my health care provider to share my health (or my child's) information with ATHN. At this time, I choose not to participate in the ATHNdataset for the reason(s) below.

- I need more information about ATHN
- I am concerned about my privacy and the security of my data
- I generally do not participate in research related to my disorder

Do you have other reasons? Please list them here.

### For completion by the HTC

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Name of HTC Staff Person who explained this authorization

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Position

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Date

