



April 2014

**RE: Becoming an ATHN Affiliate
Agreement to Participate in ATHN**

Dear HTC Medical / Pediatric Director:

The American Thrombosis and Hemostasis Network (ATHN), a non-profit corporation, was founded in July 2006 for the purpose of advancing and improving the care of individuals affected by bleeding and thrombotic disorders. To fulfill its purpose, ATHN is creating formal relationships with the federally-funded hemophilia treatment centers (HTCs) and thrombosis sites, and ultimately, other qualified provider organizations that share the vision, mission and values of ATHN and commit to collect data through ATHN. Centers would be known as “ATHN Affiliates.”

The network of affiliates is central to the development of ATHN as a valued community resource. They help shape the direction of ATHN and will benefit from projects and support services available through ATHN.

This letter outlines the structure of the ATHN Affiliate relationship. We hope that after reviewing this letter, you will choose to join us in making our vision a reality.

The Benefits of Participation

By becoming an ATHN Affiliate, a center has a voice in ATHN Governance, access to collaborative projects and services as well as support services consistent with ATHN’s vision, mission and values which are reflected in Appendix A. ATHN will establish a mechanism for assessing and supporting data management requirements for its affiliates. A sample listing of other ATHN network management services is attached in Appendix B of this letter agreement. It is recognized that the breadth and scope of such services will evolve over time as the needs of ATHN Affiliates shift and as ATHN’s financial and operational capabilities change.

Characteristics and Commitments of an ATHN Affiliate

As an ATHN Affiliate, your center would be expected to support the vision, mission and values of ATHN, to use your best efforts to demonstrate the characteristics required of an affiliate and to adhere to the commitments made. For your reference, the characteristics and commitments are

listed in the Appendix C. Again, it is agreed that the network of affiliates may from time to time recommend changes to the required characteristics included in Appendix C.

As an ATHN Affiliate, you will designate a Principal Investigator (PI) to represent your organization in votes by ATHN and to serve as a primary contact for communications. We also ask that you provide center statistics that will enable ATHN to adequately describe the network participants. Current PI, alternate contact and center statistics are specified in Appendix D, and should be updated in writing, as appropriate.

Data Access, Privacy and Security

ATHN and you, as an ATHN Affiliate, agree to protect the confidentiality of any information that might enable a third party to determine the identity of patients ("Patient Identifying Information") and to use best efforts not to communicate any Patient Identifying Information to ATHN directly or indirectly. A separate Data Use and Business Associate Agreement (DUBAA) details obligations and responsibilities to comply with new requirements set forth in a January 17, 2013 final regulation implementing the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).

The database infrastructure, including the WebTracker patient management system for hemostasis and thrombosis, will be hosted in a secure environment with security protections that prevent unauthorized data access or data loss. You retain all rights, title and interest in data generated by your practice. A HIPAA compliant limited dataset (i.e., ATHNdataset) will be provided to ATHN for patients who have authorized the sharing of a non-identifiable limited data set with ATHN or patients who have consented to participate in a study conducted through ATHN and who have signed the appropriate Patient Authorization or Informed Consent. ATHN retains all rights, title and interest in any compilation, including any compilation incorporating data from you, subject to the limitations in the paragraph above.

Acknowledging and Promoting Participation

ATHN and ATHN Affiliate are encouraged to communicate the existence of this relationship to respective constituencies. We do ask that ATHN have the right to approve any written or electronic materials issued publicly, such as press releases, articles, audio-visuals, brochures or other materials that describe or promote ATHN services. Such approval will not be unreasonably withheld.

We mutually agree that except as specifically set forth in this letter agreement, neither ATHN nor you as an ATHN Affiliate shall make use of the other's name, logo, service marks, study protocols or other materials without prior written consent of the other.

The Term of Our Relationship

Once signed, this letter agreement summarizing the ATHN Affiliate relationship will be effective as of the date it has been executed by both ATHN and you and will remain in effect for a period of five (5) years from the effective date. This agreement will renew automatically for successive five-year periods thereafter unless terminated at any time, with or without cause, by giving written notice to the other's address set forth in this agreement, not less than sixty (60) days prior to the expiration of the initial term or any renewal term. In addition, either you or ATHN may terminate this agreement immediately, if any regulatory agency promulgates any rule, regulation or order that in

effect or application prohibits or substantially impedes ATHN from running the network of affiliates, or makes its operation subject to terms and conditions unacceptable to ATHN or to you, as an ATHN Affiliate.

If our relationship is terminated, you agree to cease using ATHN materials, staff support or systems within 60 days and return materials to ATHN. Both you and ATHN will immediately cease identifying you as an ATHN Affiliate. All data will remain previously submitted will remain in the database.

Other General Terms

Of course, neither ATHN nor ATHN Affiliate has the right or authority to obligate the other, nor to incur any liability in the name of or on behalf of the other. With respect for our relationship, neither ATHN nor ATHN Affiliate will assign this agreement, its rights, duties or obligations without the written consent of the other.

NEITHER ATHN NOR ATHN AFFILIATE WILL BE LIABLE TO THE OTHER FOR ANY CLAIM WHETHER IN CONTRACT, TORT OR OTHERWISE, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL LOSS OR DAMAGES ON ANY CLAIM IN CONNECTION WITH THIS AGREEMENT. NEITHER ATHN NOR ATHN AFFILIATE WILL BE LIABLE FOR LOSSES OR DAMAGES RESULTING FROM FORCE MAJEURE EVENT.

This agreement is covered by the laws of the State of Illinois.

< SIGNATURE PAGE FOLLOWS >

Signing this letter agreement, you and ATHN confirm acceptance of the relationship as of the date and year written below.

American Thrombosis and Hemostasis Network (ATHN)



NAME: Diane J. Aschman
TITLE: President and CEO
ADDRESS: 72 Treasure Lane
Riverwoods, IL. 60015

DATE: April 29, 2014

NAME of ATHN AFFILIATE (HTC):

HTC Number: _____
ADDRESS:

ATHN Affiliate signer:

NAME:
TITLE:
ORGANIZATION:

DATE:

ATHN Affiliate signer 2 (optional):

NAME:
TITLE:
ORGANIZATION:

DATE:

Appendix A

ATHN Organizational Profile

Vision

ATHN's vision is to advance and improve the care of individuals affected by bleeding and thrombotic disorders.

Mission

ATHN provides stewardship of a secure national infrastructure and dataset, adherent to all privacy guidelines, which will be used to support clinical care and outcomes analysis, research, advocacy and public health reporting in the hemostasis and thrombosis community.

Values

The organization's core values are:

- Improving clinical outcomes and care
- Facilitating continuity of care
- Fostering collaboration
- Maintaining confidentiality
- Conserving resources through a common infrastructure

ATHN will foster collaboration with patients, providers, suppliers, government agencies and nonprofit organizations in the thrombosis and hemostasis community.

Appendix B

Sample Network Management Services¹

A Voice in ATHN Governance

- Guaranteed to be represented by at least six ATHN Affiliates on the ATHN Board
- Eligible to nominate and to be nominated for the ATHN Board of Directors, one of the ATHN committees or working groups
- Ability to serve on ATHN Research Review Panels
- Ability to vote on policies regarding data access, research agendas, criteria for becoming/remaining an ATHN Affiliate
- Right to determine disposition of data in the event of dissolution of ATHN

Access to Collaborative Projects and Studies

- A collaborating participant in the national ATHNdataset
- Full access to one's own data, with access to the broader database per data access rules/regulations/policies
- Option to participate in special projects and studies
- Invitation to the ATHN annual data summit
- Eligibility for application for data manager support
- Potential to become principal investigator for ATHN projects
- Right to propose projects and/or take a leadership role in projects that may utilize the ATHN national infrastructure or the ATHNdataset
- Centralized project management services provided by ATHN for designated projects

Support Services

- Templates for development of institutionally accepted IRB submissions and patient consent forms for participation in ATHN
- Patient education/recruitment tools
- Eligibility for data manager training
- Eligibility for virtual help desk
- Quarterly update

¹ ATHN may provide network management services for its ATHN Affiliates directly or through a third party.

Appendix C

Characteristics of ATHN Affiliates

Collaboration, competence, commitment and compliance are characteristics to be demonstrated by all ATHN Affiliates. Evidence of these characteristics is listed below.

Collaboration

- Work cooperatively with other ATHN Affiliates, ATHN management and other participating entities in fulfilling projects and studies to which it has agreed to participate
- Respond in a timely manner to project inquiries
- Contribute to the continuous improvement of group processes, products and outcomes related to this important community resource

Competence

- Deliver multidisciplinary care to patients with bleeding and/or blood clotting disorders through a federally-funded hemophilia treatment center or thrombosis site, OR meet other criteria which may be published by ATHN
- Ensure that data managers are adequately trained in terms of data definitions, data standards and application systems and accurate, timely data submission

Commitment

- Use its best efforts to enroll patients into the ATHNdataset, achieving enrollment and minimum data requirements established by the network
- Maintain accurate and up-to-date core data for enrolled patients
- Designate a Principal Investigator to represent the affiliate organization in votes and to serve as the primary contact for communications. An alternate communications contact may be designated as well.

Compliance

- Deploy ATHN Clinical Manager, Study Manager, ATHNadvoy, or other ATHN endorsed patient management software, which will allow the community to share HIPAA compliant non-identifiable patient data through ATHN.
- Access to an Institutional Review Board (IRB) or willingness to utilize a central IRB adopted by ATHN
- Assure compliance with regulations related to IRB approvals, Patient Informed Consent, HIPAA Privacy and Security Rule.
- Adhere to minimum data standards, quality assurance standards, data utilization guidelines, training requirements, publication guidelines or other criteria which may be recommended by ATHN Affiliates and adopted as ATHN policy.

Appendix D
Designated Contacts and Center Statistics

Principle Investigator

Name:
Title:
Email:
Telephone:

Alternate Contact (if desired)

Name:
Title:
Email:
Telephone:

Medical / Pediatric Director

Name:
Title:
Email:
Telephone:

Senior Administrator (CEO, President, Executive Director, etc.)

Name:
Title:
Email:
Telephone:

TOTAL number of the FTEs (full time equivalents) at the center:

Number of FTEs at the center by type:

- Physicians**
- Nurses**
- Physical Therapists**
- Licensed Social Workers**
- Data Managers**
- Other**