



## Data Use and Business Associate Agreement

This Data Use and Business Associate Agreement (“Agreement”), effective as of \_\_\_\_\_, supplements and is made part of any other agreements by and between the American Thrombosis and Hemostasis Network (hereafter, “ATHN”) and \_\_\_\_\_ (hereafter, “Affiliate”).

WHEREAS, ATHN and Affiliate have entered into an agreement through which Affiliate has agreed to collect and store data through a secure national web-based information infrastructure managed by ATHN and to provide ATHN a Limited Data Set so that ATHN may carry out its mission of advancing and improving the care of individuals affected by bleeding, thrombotic, and other disorders (the “Services”);

WHEREAS, ATHN acting as Business Associate to Affiliate will provide stewardship and oversee the national information infrastructure and provide support services including training, technical assistance and support for research, public health surveillance and outcomes improvement to Affiliate in connection with use of the national information infrastructure, whereby ATHN or an ATHN business partner may have access or receive Protected Health Information (“PHI”) from Affiliate, who is a Covered Entity;

WHEREAS, ATHN intends to maintain an electronically created Limited Data Set with data submitted by the Affiliate, for research into the specific causes, prevention, treatment and social and economic impact of bleeding, thrombotic, and other genetic disorders.

WHEREAS, ATHN and Affiliate seek to comply with all requirements of HIPAA and the Privacy Rule which permit a covered entity to use or disclose PHI if the information is released in the form of a “limited data set” stripped of all sixteen (16) patient identifiers as defined in the Privacy Rule, section 164.514(e)(2).

WHEREAS, ATHN and Affiliate also seek to enter into a business associate agreement so that ATHN may host the electronic infrastructure containing Affiliate data and provide training and technical assistance to Affiliate in connection with the use of the national information infrastructure.

NOW THEREFORE, ATHN and Affiliate agree to be bound by the following terms and conditions.

## 1. Definitions

- a. “HIPAA” shall mean the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
- b. “HIPAA Regulations” shall mean the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 CFR Parts 160, 162 and 164 as in effect or as amended from time to time.
- c. “Limited Data Set” means a data set that contains protected health information, but is stripped of certain direct identifiers that are specified in the HIPAA Privacy Rule.
- d. “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.
- e. “Security Rule” means the requirements of the HIPAA Regulations pertaining to the standards for the security of electronic Protected Health Information.
- f. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Rule.

## 2. Obligations and Activities of ATHN as Business Associate

- a. Limited Use. ATHN shall not use or further disclose PHI obtained from Affiliate in discharging its duties as steward and manager of the national information infrastructure and providing support services including training, technical assistance, other than as expressly permitted or required by this Agreement or as required by law. ATHN shall not use or disclose PHI received from Affiliate in any manner that would constitute a violation of the Privacy Rule if done by Affiliate.
- b. Reasonable Precautions. ATHN shall use appropriate safeguards designed to prevent use or disclosure of the PHI other than as provided for by this Agreement.
- c. Security Regulations Compliance. ATHN shall implement Administrative, Physical and Technical Safeguards designed to reasonably and appropriately protect the Confidentiality, Integrity and Availability of electronic PHI, including any Limited Data Sets, that it receives, maintains, creates, or transmits to or on behalf of Affiliate. ATHN shall cause any agent, including a subcontractor, to whom it provides electronic PHI, including any Limited Data Sets, to implement reasonable and appropriate safeguards designed to protect such information.
- d. Reporting Violations.
  - i. Generally. ATHN shall, upon becoming aware of any use or disclosure of PHI, including any Limited Data Sets, in violation of this Agreement or any Security Incident, promptly report any such use or disclosure to Affiliate.
  - ii. Breaches of Unsecured PHI. With the exception of law enforcement delays that satisfy the requirements under 45 C.F.R. § 164.412 or as otherwise required by applicable State law, ATHN shall notify Affiliate promptly in writing without unreasonable delay and in no case later than sixty (60) calendar days upon the Discovery of a Breach of Unsecured PHI. Such notice must include, to the extent possible, the name of each Individual whose Unsecured PHI has been, or is reasonably believed by ATHN to have been, accessed, acquired, or disclosed

during such Breach. ATHN shall also provide, to the extent possible, Affiliate with any other available information that Affiliate is required to include in its notification to Individuals under 45 C.F.R. § 164.404(c) at the time of ATHN's notification to Affiliate or promptly thereafter as such information becomes available. Notice shall include: (a) a brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known; (b) a description of the types of Unsecured Protected Health Information that were involved in the breach; (c) a brief description of what ATHN is doing to investigate the breach, to mitigate harm to individuals, and to protect against further breaches.

- iii. Such reports can be made to the following representative at the Affiliate institution:

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Phone: \_\_\_\_\_

e-mail: \_\_\_\_\_

e. Agents and Subcontractors.

- i. ATHN shall limit the use and receipt of the PHI received from Affiliate to only those ATHN personnel and / or ATHN business partners for which use or receipt is necessary to carry out the purposes of the national information infrastructure, including but not limited to technical personnel and information technology vendors that support the national information infrastructure, and supporting research, public health surveillance and outcomes improvement.
  - ii. ATHN shall obtain and maintain an agreement with each agent or subcontractor that has or will have access to the PHI, which is received from, or created or received by ATHN on behalf of Affiliate, pursuant to which such agent or subcontractor agrees to be bound by the same restrictions, terms, and conditions which apply to ATHN pursuant to this Agreement with respect to such PHI, including but not limited to the requirement that the agent or subcontractor implement reasonable and appropriate safeguards to protect any electronic PHI that is disclosed to it by ATHN.
- f. Requests for Access. Following a request by Affiliate for access to PHI about an Individual contained in a Designated Record Set of Affiliate, ATHN shall promptly make available to Affiliate such PHI. If any Individual requests access to PHI directly from ATHN, ATHN shall refer such Individual to his or her providers.
- g. Requests for Amendment. Following a request from Affiliate for the amendment of an Individual's PHI contained in a Designated Record Set of Affiliate, ATHN shall promptly provide such information to Affiliate for amendment and incorporate any such amendments in the PHI as required by 45 C.F.R. § 164.526.
- h. Requests for Accounting of Disclosures. Following notice by Affiliate to ATHN that it has received a request for an accounting of disclosures of PHI, ATHN shall make available such information as is in ATHN's possession to Affiliate in order for Affiliate

to make an accounting in accordance with 45 C.F.R. § 164.528. If the request for an accounting is delivered directly to ATHN, ATHN shall promptly forward such request to Affiliate.

- i. Access to Books and Records. At Affiliate's request, and consistent with its legal and ethical obligations, ATHN shall make its internal practices, books and records relating to the use and disclosure of PHI received from or created or received by ATHN on behalf of Affiliate available to the HHS Secretary for purposes of determining Affiliate's compliance with the Privacy Regulations.
- j. Use of Minimum Necessary Data Sets by ATHN. ATHN shall limit, to the extent practicable and except as permitted by 45 C.F.R. § 164.502(b)(2), its use, disclosure, and requests of PHI under the Agreement to the minimum necessary PHI to accomplish the intended purpose of such use, disclosure or request.
- k. Delegation of Affiliate Obligation. To the extent ATHN is engaged by Affiliate to carry out one or more of Affiliate's obligation(s) under the Privacy Regulations, ATHN shall comply with the requirements of the Privacy Regulations that apply to Affiliate in the performance of such obligation(s).
- l. Prohibition on Identification. ATHN will not identify or attempt to identify or contact the individuals whose information is contained in the Limited Data Set based on the PHI provided to ATHN.
- m. Prohibition on Sale of PHI. ATHN agrees that it will not receive remuneration directly or indirectly in exchange for PHI without authorization unless an exception under 42 U.S.C. § 17935(d) applies.
- n. Prohibition on Marketing. Business Associate agrees that it will not receive remuneration for certain communications that fall within the exceptions to the definition of Marketing under 45 C.F.R. § 164.501 unless permitted by 42 U.S.C. § 17936.
- o. Prohibition on Use of Genetic Information for Underwriting Purposes. Business Associate agrees that it will not use or disclose genetic information for underwriting purposes, as that term is defined by 45 C.F.R. § 164.502.

### **3. Permitted Uses and Disclosures By ATHN**

- a. Generally Permitted Uses and Disclosures. ATHN may use and disclose PHI, including the Limited Data Set, only as required to satisfy its obligations to perform the Services as permitted herein, as permitted under Section 3(c) of this Agreement, or as Required By Law. ATHN shall use appropriate safeguards designed to prevent use or disclosure of the Limited Data Set other than as provided for by this Agreement.
- b. Other Permitted Uses and Disclosures. Unless otherwise limited herein, ATHN may:
  - i. Use PHI for its proper management and administration, including but not limited to administration of the national information infrastructure, or to carry out its legal responsibilities;
  - ii. Disclose PHI for its proper management and administration, including but not limited to administration of the national information infrastructure, or to carry out its legal responsibilities, provided that (i) disclosures are Required By Law,

- or (ii) ATHN obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and be used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies ATHN of any instances of which the person is aware in which the confidentiality of the information has been breached;
  - iii. Use PHI to provide data aggregation services relating to the health care operations of Affiliate; and
  - iv. Use PHI to create de-identified information consistent with the standards set forth at 45 C.F.R. § 164.514.
- c. Limited Data Set. ATHN shall have the right to create and use the Limited Data Set and make it accessible to approved researchers for research into the specific causes, prevention, treatment and social and economic impact of bleeding, thrombotic and other genetic disorders. ATHN shall ensure that any researchers to whom it provides the Limited Data Set agree to the same restrictions and conditions that apply to ATHN with respect to the Limited Data Set.

#### **4. Obligations of Affiliate as Covered Entity.**

- a. Notification of Limitations. Affiliate shall notify ATHN in writing of any limitation(s) in its notice of privacy practices in accordance with 45 C.F.R. § 164.520, to the extent that such limitation may affect ATHN's use or disclosure of PHI, and any restriction(s) to the use or disclosure of PHI that Affiliate has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect ATHN's use or disclosure of PHI.
- b. Affiliate Requests. Affiliate shall not request that ATHN use or disclose PHI in any manner that would not be permissible under the Privacy or Security Regulations, HITECH, or its implementing regulations if done by Affiliate.
- c. Use of Minimum Necessary Data by Affiliate. Affiliate shall limit, to the extent practicable and except as permitted by 45 C.F.R. § 164.502(b)(2), its disclosure of PHI under the Agreement to the minimum necessary PHI to accomplish the intended purpose of such use, disclosure or request.

#### **5. Term and Termination.**

- a. Term. This Agreement shall be effective as of the Effective Date and shall continue unless or until terminated by ATHN or Affiliate or the underlying Affiliate agreement is terminated.
- b. Termination. Affiliate may terminate this Agreement and any disclosures of PHI pursuant hereto, upon 10 days written notice to ATHN, if ATHN violates or breaches any material term or condition of this Agreement. ATHN may terminate this Agreement without cause upon 30 days written notice.
- c. Return or Destroy. Upon termination of this Agreement, ATHN shall either return or destroy all PHI received from Affiliate or created or received by ATHN on behalf of Affiliate that ATHN still maintains in any form, and shall cause subcontractors and agents to do the same. Notwithstanding the foregoing, to the extent that it is not feasible

to return or destroy such PHI, as is the case with the Limited Data Set, the protections of this Agreement and applicable HIPAA privacy Standards shall survive termination of this Agreement and such PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of such PHI.

## **6. Miscellaneous.**

- a. Amendment. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary to comply with the requirements of the Privacy Rule, Security Rule, and any other applicable HIPAA requirements.
- b. Governing Law. Governing law shall be in the State of Illinois without regard to its conflicts of law rules.
- c. No Third Party Beneficiaries. This Agreement is not intended to benefit any person or entity not a party to this Agreement.
- d. No Assignment. No party may assign this Agreement or its rights hereunder or delegate any obligation hereunder without the prior written consent of the other party.
- e. Independent Contractors. None of the provisions of this Agreement are intended to create, nor will be deemed to create, any relationship between the parties other than that of independent contracting parties with each other solely for the purposes of affecting the provisions of this Agreement and any other agreements between the parties evidencing their business relationship.
- f. Integration. This Agreement embodies and constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof and supersedes all prior contracts, oral or written agreements, commitments, and understandings pertaining to the subject matter hereof.
- g. Severability. If any one or more of the provisions of this Agreement are for any reason held to be invalid, illegal or unenforceable by a court of competent jurisdiction, the remaining provisions of this Agreement shall be unimpaired and shall remain in full force and effect, and the invalid, illegal or unenforceable provision shall be replaced by a valid, legal and enforceable provision that comes closest to the intent of the parties underlying the invalid, illegal or unenforceable provision.
- h. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument.
- i. Notices. All notices, demands, solicitations of consent or approval and other communications hereunder required or permitted shall be in writing and shall be hand delivered or given by certified or registered mail to the representatives at the addresses set forth below.

Affiliate Representative:  
[NAME]  
[TITLE]  
[ADDRESS]  
[CITY, STATE ZIPCODE]  
[EMAIL]

ATHN Representative: Linda Magliocco, Director of Finance and Administration  
Copy to: Diane J. Aschman, President and CEO  
Address: 72 Treasure Lane, Riverwoods, IL. 60015  
E-mail: lmagliocco@athn.org; daschman@athn.org

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the Effective Date.

**AMERICAN THROMBOSIS AND HEMOSTASIS NETWORK**

Diane J. Aschman, President and CEO  
72 Treasure Lane  
Riverwoods, Illinois 60015  
P: 847.607.9479  
F: 847.572.0967  
[www.athn.org](http://www.athn.org)  
[daschman@athn.org](mailto:daschman@athn.org)

\_\_\_\_\_  
Signature Date

**ATHN AFFILIATE**

\_\_\_\_\_  
Affiliate Institution / HTC Name HTC ID Number

\_\_\_\_\_  
Name and Title of Affiliate Representative

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Person to contact about this Agreement

\_\_\_\_\_  
Phone for contact e-mail for contact