



Data Use and Business Associate Agreement (DUBAA)

This Data Use and Business Associate Agreement (“Agreement”), effective as of _____ (enter effective date), supplements and is made part of any other agreements by and between the American Thrombosis and Hemostasis Network (hereafter, ATHN) and _____ (enter Affiliate Name, 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 through ATHN and to provide ATHN a limited data set consistent with ATHN’s vision of advancing and improving the care of individuals affected by bleeding and thrombotic disorders;

WHEREAS, ATHN will provide stewardship of the national information infrastructure and support services including training and technical assistance;

WHEREAS, ATHN intends to maintain an electronically created Limited Data Set on behalf of the HTC Affiliates, for research into the specific causes, prevention, treatment and social and economic impact of blood disorders.

WHEREAS, ATHN and Affiliate seek to comply with all requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), *Standards for Privacy of Individually Identifiable Health Information* (hereafter, “Privacy Rule”), which permit a covered entity to use or disclose Protected Health Information (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), with a data use agreement executed prior to the use or disclosure of protected health information for the purpose of research.

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. “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.
- d. “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.

- 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. ATHN Obligations and Assurances in Providing Stewardship of the National Information Infrastructure

- a. ATHN agrees not to use or further disclose Protected Health Information In discharging its duties as steward of the national information infrastructure, other than as expressly permitted or required by this Data Use Agreement or as required by law.
- b. With respect to any PHI in electronic form, in accordance with the requirements of the Security Rule, ATHN shall (i) implement Administrative, Physical and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity and Availability of electronic PHI that it creates, receives, maintains or transmits on behalf of Affiliate.
- c. Should any PHI be disclosed to ATHN or any of its employees or agents, other than the Limited Data Set, ATHN agrees to return or destroy the PHI when it is no longer needed for the purposes for which it was used or disclosed.
- d. ATHN agrees to report to Affiliate any use or disclosure of the information contained in the Limited Data Set that is not permitted by this Data Use Agreement of which it becomes aware. Such reports can be made to the following representative at the Affiliate institution:

Name: _____

Title: _____

Phone: _____ e-mail: _____

- e. ATHN agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from Affiliate and received by ATHN, agrees to the same restrictions and conditions that apply through this Agreement to ATHN with respect to such information.

3. Permitted Uses and Disclosures by ATHN for the Limited Data Set

- a. ATHN will 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 blood disorders.
- b. All direct identifiers will be stripped from the health information as required by the HIPAA Privacy Rule.
- c. 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.

4. Term and Termination.

- a. 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. Affiliate may terminate this Agreement and any disclosures of PHI pursuant hereto, upon 10 days 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. Upon termination, ATHN shall retain the data already provided to ATHN and will continue the protections required under this Agreement for the Limited Data Set consistent with the requirements of this Agreement and applicable HIPAA privacy standards.

5. **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 and any other requirements of the Health Insurance and Portability and Accountability Act
6. **Governing Law.** Governing law shall be the State of Georgia.

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

AMERICAN THROMBOSIS AND HEMOSTASIS NETWORK

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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 and e-mail for contact