

Contents of the ATHN Data Sharing and Use Agreement

This document is provided for your review. You do not have to sign and return this document. You will be asked to sign an official agreement if you are selected for an award.

The American Thrombosis and Hemostasis Network (ATHN) is committed to providing ATHN Affiliates, academic, and other investigators an opportunity to use data collected as part of the ATHNdataset for purposes that are consistent with ATHN's mission and patients' authorization for data use. In allowing investigators and entities to use the data, ATHN is bound by its responsibility to guard the confidentiality of patient participants and ensure that data are used for a legitimate purpose. Toward that end, ATHN is required to obtain assurances from Requestor that Requestor will only use or disclose data as permitted herein. The provisions of this Agreement are intended to meet the Data Use Agreement requirements of HIPAA.

The data covered under this agreement are the data that were generated from the ATHNdataset. This project will be conducted by _____. The purpose of the project is: _____.

The data set is a restricted access data set. That is, it is not available for unrestricted public use. Requestor agrees to use the ATHNdataset exactly as proposed in the research proposal, dated _____, and accepted by ATHN. This proposal is attached to this agreement as Exhibit A, incorporated herein by reference. Requestor understands that the authorized period of data use begins at 12:00 am (EST) on _____ and ends at 11:59 pm (EST) on _____. Requestor agrees not to use or access the ATHNdataset outside of the authorized period of use.

Obligations and Activities of Requestor:

In accepting this agreement, Requestor also agrees to the following terms and conditions of data use:

1. Requestor will not use, nor permit others outside of <Requestor organization> to use, the data in any manner except that explicitly stated in Exhibit A.
2. Requestor will notify others outside of <Requestor Organization> that want to use the data to contact ATHN.
3. Requestor will not attempt any linkage or combination of the ATHNdataset data to any other dataset for any purpose.
4. Requestor will not re-release, share, provide access to, or otherwise make the ATHNdataset available to any other party for any reason whatsoever. Requestor agrees to refer all requests for access to the data to the ATHN Research Committee.
5. Requestor understands that ATHN has de-identified the ATHNdataset to the best of its ability, in accordance with standards for de-identification set forth in the Family Educational Rights and Privacy Act (FERPA, 20 U.S.C. § 1232g) and the Health Insurance Portability and Accountability Act (HIPAA, 45 C.F.R. Parts 160 and 164). Requestor agrees that it will not attempt, in any way, to re-identify any person included in these data.
6. Requestor agrees to make no disclosure or use of the identity of a person discovered inadvertently, for research, marketing, fundraising or other purposes, and will advise the ATHN Research Committee of any such discovery in writing within two (2) business days of the date of discovery. If such a discovery is made, the information that would identify the individual will be safeguarded or destroyed by Requestor, as requested by ATHN.

7. Requestor also agrees to the following security procedures:
 - i. It will password protect any permanent analysis files, such as those produced by SAS or other statistical analysis package.
 - ii. It will treat all ATHNdataset as confidential materials and not give other persons access to it.
 - iii. It will keep all hard copies of analysis and data runs containing small cells, defined herein as five (5) or fewer cases per cell, locked in a secure location when they are no longer necessary to perform the analysis. In addition, for public reporting of results of my analysis on the ATHNdataset, the requestor agrees not to report information on any small cells, without authorization of ATHN.
 - iv. It is responsible for obtaining IRB review of proposed research where appropriate.
8. If applicable, within seven (7) business days from the ending date of the authorized period of data use, defined above, Requestor agrees to destroy any data files extracted from the ATHNdataset and to notify the ATHN Research Committee that this file(s) has been destroyed, except that Requestor shall be permitted to retain one copy (1) of the extracted data files solely for the purposes of complying with its obligations under this Agreement.
9. Requestor agrees to notify the ATHN Research Committee, in writing, if Principal Investigator will be leaving the organization. Principal Investigator agrees not to take copies of the data or data analysis, printouts, runs, graphs, etc. when leaving the Requestor organization or if changing to an unrelated position within the Requestor organization without the approval of the Requestor and ATHN.
10. Requestor agrees not to imply or state, in either written or oral form, that interpretations based on the data are those of the original data sources (i.e., the Hemophilia Treatment Centers) or of ATHN.
11. Requestor agree to acknowledge, in all reports on these data, the original source of the data at determined by the ATHN Research Committee.
12. Requestor agrees to provide to ATHN, within one month of publication, a courtesy copy of any publications or other public disseminations of the findings of my analysis.
13. Requestor agrees to indemnify and hold ATHN, its employees, agents, assigns, and contractors (and their subcontractors and vendors) harmless for any damages, actual or consequential, that arise directly from the use of the ATHNdataset under this Agreement, except that such damages arise from ATHN's gross negligence or willful misconduct.
14. Requestor agrees that ATHN has the right to conduct on-site audits, at reasonable and mutually agreeable times, of the use of the ATHNdataset to verify compliance with the terms and conditions of this Agreement. Requestor agrees to provide any information deemed reasonably relevant to these audits to ATHN personnel. All such visits by ATHN shall be subject to applicable Requestor's policies concerning identification, on-premises behavior, and related matters.
15. Requestor understands that the following federal laws may pertain to this data; that these laws allow for criminal and civil penalties for disclosure and violation of confidentiality; that Requestor is solely responsible for compliance with these and other applicable federal laws; and that Requestor will also investigate and comply with any relevant state laws that might pertain to this data. The applicable laws include but are not limited to:
 - i. Human subjects common rule - 45 CFR § 46
 - ii. Assurances of Confidentiality - Section 308(d) of the Public Health Service Act 42 USC 242 m(d)
 - iii. Privacy Act - 5 USC § 552a; 45 CFR § 5b