Axon Registry Data Governance Policy

1. Introduction

The Axon Registry’s clinical data registry focuses on quality improvement developed by the American Academy of Neurology’s (“AAN”) 501c3 subsidiary, the American Academy of Neurology Institute (“AANI”) (collectively, “Academy”). It is a centralized data warehouse that collects relevant patient data and performs statistical analysis to improve the quality of neurologic care and patient outcomes by facilitating implementation of quality improvement at a practice and specialty level. Once data is collected for these Health Care Operations purposes, Axon Registry data may be utilized for the secondary purposes of informing quality measures and clinical practice guidelines, assisting AAN members in meeting reporting and certification requirements, and for informing research to advance scientific developments in neurology.

The Academy is committed to transparent, compliant, secure, and responsible governance of the Axon Registry. The Academy and its registry vendor (FIGmd) comply with the laws and regulations applicable to the Axon Registry and have adopted HIPAA Privacy Policies and Procedures. To further describe the collection, use, disclosure, and stewardship of Axon Registry data, the Academy adopted this Data Governance Policy.

2. Glossary

a. **Analytic Reports**: A Report provided in response to an approved query of Redacted Data within the Axon Registry, not intended for use in abstract presentations, manuscripts in peer-reviewed publications, or other publicly released information.

b. **Collected Data**: Health Information (including PHI and De-Identified Data) and Provider Data collected by the Axon Registry from Participants to provide Health Care Operations services. The Axon Registry requests and collects only the minimum necessary PHI from Participants, in addition to collection of certain Provider Data. With respect to the ongoing provision of Health Care Operations services to Participants, the Academy has determined that the minimum necessary PHI is the complete electronic health record. In addition, at the time a Participant enrolls in the Axon Registry, the Registry may collect a certain amount of historic data from the Participant that is necessary to enable the Axon Registry to provide Health Care Operations services to the Participant. The Axon Registry may also collect PROs for the Health Care Operations purposes described in this Policy. In the future, the Axon Registry may also collect claims data, etc., which the use and disclosure of would be subject to applicable laws, regulations, and Academy policies.

c. **Covered Entity**: A health plan, healthcare clearinghouse, or healthcare provider that transmits any health information in electronic form in connection with a transaction covered by Title 45 of the Code of Federal Regulations Subchapter C.
d. **De-Identified Data**: Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. This de-identified information is not Individually Identifiable Health Information.

e. **Fully-Identifiable PHI**: PHI that contains any one or more direct identifiers such that the PHI does not constitute Limited Data Set Information or De-Identified Data.

f. **Health Care Operations**: Certain administrative, financial, legal, and quality improvement activities of a Covered Entity that are necessary to run its business and to support the core functions of treatment and payment, which are listed in the definition of “health care operations” at 45 CFR 164.501.

g. **Health Information**: Any information, whether oral or recorded in any form or medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school, university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

h. **HIPAA**: Collectively, the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations as amended from time to time.

i. **Individually Identifiable Health Information**: Health Information that either identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

j. **Limited Data Set Information**: PHI that does not include any of the following direct identifiers of the individual or of relatives, employers, or household members of the individual: Names; Postal address information, other than town or city, state, and zip code; Telephone numbers; Fax numbers; Electronic mail addresses; Social Security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; and Full face photographic images and any comparable images.

Limited Data Set Information may include the following non-exhaustive list of identifiers: Dates relating to an individual, including birth date, death date, date of admission, date of discharge, dates of service; Age (including age 90 and over);
City, State, and/or five-digit ZIP code; and Any other unique identifying number, characteristic, or code, such as study ID numbers and accession numbers.

Limited Data Set Information may be used or disclosed, for purposes of Research, Public Health Activities or Health Care Operations, with a Data Use Agreement specifying that the Limited Data Set Information recipient must only use or disclose the PHI for limited purposes.

k. Participant: An entity or practice (on behalf of their Participant User(s)) that enters into a Participation Agreement, Business Associate Agreement and Data Use Agreement with AANI in order to provide data to the Axon Registry and receive Health Care Operations services from AANI.

l. Participant Reports: A Report that Participant has access to as a part of their participation in the Axon Registry, that is developed through analysis of Collected Data for the purpose of Health Care Operations. Participants may request additional custom or ad hoc Reports, which will be reviewed following established Academy procedures.

m. Participant User: Participant’s AAN members who are enrolled in the Axon Registry through the Participant.


o. Protected Health Information (“PHI”): Individually Identifiable Health Information that is transmitted by or maintained in electronic media, or is transmitted or maintained in any other form or medium. PHI does not include Individually Identifiable Health Information contained in education records or employment records.

p. Provider Data: Certain entity and physician-identifying information provided by the Participant.

q. Public Health Activities: Activities described in 45 C.F.R. § 164.512(b).

r. Quality Development: Activities that relate to general efforts to improve quality of care, including trend analysis, hypothesis generation, and the development or refinement of quality measures or clinical practice guidelines.

s. Recipient: Individuals or entities who have their requests approved for receipt of Reports. Any individual or entity may request and be eligible to receive Reports,
including Participants, Academy boards, committees, and sections, AAN members, academic institutions, volunteer health organizations, other medical specialty societies, pharmaceutical and medical device companies, and other health care related companies.

t. **Redacted Data**: De-Identified Data and Limited Data Set Information, collectively, in the Axon Registry.

u. **Report**: A document or dashboard that provides information and analysis gleaned from the Axon Registry. The Academy will offer several types of Reports, including Participant Reports, Research Reports, and Analytic Reports.

v. **Research**: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

w. **Research Reports**: A Report provided in response to an approved hypothesis-driven study based upon secondary analysis of Redacted Data within the Axon Registry, with the intent to develop manuscripts suitable for peer-reviewed publication or inform scientific presentations.

3. **Data Governance**

   a. The AANI Registry Committee (operating under a charter approved by the AANI Board of Directors), is responsible for the development of policies and procedures regarding the ethical and secure use of Axon Registry data, selection and refinement of quality measures and PROs in the Axon Registry, ensuring the quality of Axon Registry data, and approving requests for new data elements.

   b. The Registry Analytics Subcommittee of the Registry Committee is responsible for reviewing and approving requests for use of Axon Registry data, recommending Academy publications from registry data, and ensuring registry data are presented accurately in publications.

4. **Data Collection**

   a. The Axon Registry collects data for the Health Care Operations activities it is designed to support.

   b. In accordance with the Academy’s HIPAA Privacy Policies and Procedures and this Data Governance Policy, the Axon Registry requests and collects only the minimum necessary PHI from Participants, in addition to collection of certain Provider Data. With respect to the ongoing provision of Health Care Operations services to Participants, the Academy has determined that the minimum necessary PHI is the complete electronic health record. In addition, at the time a Participant enrolls in the Axon Registry, the Registry may collect a certain amount of historic data from the Participant that is necessary to enable the Axon Registry to provide
Health Care Operations services to the Participant. The Axon Registry may also collect PROs for the Health Care Operations purposes described in this Policy.

c. Because PHI is submitted to the Axon Registry for providing Health Care Operations services to Participants, individual patient authorization is not required under HIPAA. However, certain state laws may require Participants to obtain patient authorization or consent prior to disclosing certain patient medical information (as defined by state law) to the Axon Registry.

d. Practices contemplating participation in the Axon Registry are encouraged to consider whether unique state law requirements apply to their disclosure of patient medical information, including certain sensitive information. Some states have privacy and breach notification laws that impose more stringent privacy and security protections than HIPAA related to the use or disclosure of patient medical information. Also, some states have privacy laws pertaining to certain types of sensitive information, including genetic, mental health, communicable disease, or substance abuse information. If a Participant is required to obtain patient authorization, consent, or permission for the uses of Collected Data described in this Data Governance Policy and the Participation, Business Associate, and Data Use Agreements with AANI, it is the Participant’s responsibility to obtain lawful authorization or consent prior to disclosing the applicable information to the Axon Registry.

e. Participant warrants that it has full rights and authority to submit the Collected Data to the Axon Registry and has obtained any necessary patient authorization, consent, or permission as required by law for the uses of Collected Data described in this Data Governance Policy and the Participation, Business Associate, and Data Use Agreements with AANI.

f. Participant must have and make available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520, any other applicable provisions of HIPAA, and applicable state law. The Academy will provide language describing the Axon Registry to Participants as needed to inform appropriate notices.

5. Use and Disclosure of Health Information

Fully-Identifiable PHI:

a. Collected Data that constitutes Fully-Identifiable PHI is only used for Health Care Operations, including quality improvement and care coordination, as well as creating Redacted Data sets.

b. Only FIGmd, the vendor contracted by the Academy to provide services in support of the development, operation and maintenance of the Axon Registry, has access to Fully-Identifiable PHI within the Collected Data. FIGmd’s access is only as necessary to perform their specific services and responsibilities and must
be done in accordance with FIGmd’s HIPAA Privacy Policies and Procedures, and applicable laws, regulations, and Academy policies.

c. Academy employees and volunteers, data analytics centers the Academy contracts with, and Recipients do not have access to Collected Data that constitutes Fully-Identifiable PHI.

d. Academy employees or volunteers, or data analytics centers the Academy contracts with, who may have access to the Redacted Data for the purpose of engaging in Research, Quality Development, generation of Reports, or any other activity for which the use of Fully-Identifiable PHI is prohibited under applicable law or Academy policies, must not access, use, or disclose Fully-Identifiable PHI or any key to a code that links the Fully-Identifiable PHI and the Redacted Data.

e. Participant User has access to Fully-Identifiable PHI only where the Fully-Identifiable PHI relates to a patient with whom that Participant User has a treatment relationship, unless the Participant opts to allow Participant Users within Participant’s practice to access Fully-Identifiable PHI related to patients with whom other Participant Users within the same practice have a treatment relationship with.

Redacted Data

f. In its capacity as a Business Associate of Participants, AANI has contracted with FIGmd (acting as a Sub-Business Associate) to have FIGmd create two types of redacted data from the Fully-Identifiable PHI in the Collected Data:
   i. De-Identified Data and
   ii. Limited Data Set Information.

g. The Redacted Data enables the Academy to provide Health Care Operations services and conduct Quality Development, using the minimum necessary PHI (or no PHI) whenever possible.

h. The Redacted Data may also be used for Research, Public Health Activities, and other purposes as permitted by applicable law, the Participation Agreement, Business Associate Agreement and Data Use Agreement, and as set forth in this Policy.

i. A firewall segregates the Fully-Identifiable PHI and the Redacted Data and prohibits access to Fully-Identifiable PHI by persons who may access the Redacted Data for the purpose of engaging in Research, Quality Development, generation of Reports, or any other activity for which the use of Fully-Identifiable PHI is prohibited under applicable law or Axon Registry policies.
j. Academy employees and volunteers, data analytics centers the Academy contracts with, Participants, and Recipients are prohibited from re-identifying Redacted Data.

k. Limited Data Set Information may be used for Health Care Operations services, Quality Development, Research and Public Health Activities.

l. In all cases, only the minimum necessary amount of PHI within Limited Data Set Information is used and disclosed.

6. Use and Disclosure of Provider Data

a. The Axon Registry contains Provider Data (for example, quality improvement reports that describe provider performance compared to a clinical guideline or aggregate measure). Provider Data may describe professional or practice characteristics of a Participant User or characteristics of a Participant through the aggregate reporting of the Participant Users in a participating practice.

b. Any type of Provider Data, to the extent that it includes PHI, is subject to and protected under HIPAA and any other applicable law.

c. Analytic and Research Reports do not contain Provider Data that can identify a Participant or a Participant User and contain only analysis of such data.

d. Participant Users have access to the aggregate practice-level Participant Reports for their Participant practice (for example, a report describing the performance of all Participant Users in the Participant practice in the aggregate for a specific quality measure in such a way that does not directly identify scores associated with an individual Participant User).

e. At the Academy’s discretion, Participant Users may have access to certain aggregate, national-level Participant Reports (for example, a report describing the performance of Participant User in comparison to aggregate, national benchmarking for a specific quality measure in such a way that does not directly identify scores associated with an individual Participant User).

f. A Participant and its Participant Users are not able to access the Participant Reports of another Participant or its respective Participant Users.

g. As a default setting, Participants have access to only their own Participant-level Reports. The Participant, if authorized to do so, may designate certain others associated with the Participant to have access to the Participant User-level reports for all Participant Users at the Participant.

h. The Academy does not make Participant-level or Participant User-level Reports available outside of the Participant’s practice without an opt-in by the Participant.
or Participant User, respectively. For example, (given the Axon Registry is approved as a qualified clinical data registry under the Physician Quality Reporting System) a Participant User who permits the Academy to submit his/her quality data to the Centers for Medicare and Medicaid Services may opt-in to such reporting by the Academy.

i. As a courtesy, if the Participant User is a diplomate of the American Board of Psychiatry and Neurology ("ABPN"), the Academy sends Participant User’s Axon Registry participation start date to the ABPN for maintenance of certification purposes, unless the Participant User opts-out.

j. The Academy may list Participant on its website and in other materials listing its Participants, for noncommercial purposes.

k. The Academy does not use Provider Data outside of the uses described in this Policy unless Participant advises in writing that it has authorized such disclosure or that it has secured appropriate consent for such disclosure.

7. Research and Data Analytics

a. All requests for Research Reports or Analytic Reports must be reviewed by the Registry Analytics Subcommittee.

b. Individuals requesting Research Reports or Analytic Reports are required to complete a Relationship Disclosure Form.

c. The Registry Analytics Subcommittee *may* consider the following criteria for all Research Report requests:
   i. Goal of the study and its alignment with the Academy’s mission, vision and values;
   ii. Overlap with existing knowledge and current studies;
   iii. Significance of the study to original scholarship;
   iv. Potential conflicts of interest;
   v. Feasibility of study based on available data elements required and the time line; and
   vi. Accurate representation of the Axon Registry data, including methodology used to conduct the analysis in the context of the hypothesis.

d. The Registry Analytics Subcommittee *may* consider the following criteria for all Analytic Report requests:
   i. Purpose of the request and its alignment with the Academy’s mission, vision, and values;
   ii. Overlap with current analytic report requests;
   iii. Potential conflicts of interest; and
   iv. Feasibility of the request based on available data elements required and the time line.
e. Recipients are prohibited from using or disclosing any Report for a purpose not specified in the approved Report request or as otherwise described in this Policy.

f. Participants and Participant Users are prohibited from sharing Participant Reports with anyone outside of their practice without written permission from the Academy, except for purposes related to financial/legal advising, insurance reimbursement, or to provide evidence of quality improvement as permitted by this Policy.

g. Participants are prohibited from attempting to identify any other Participants whose information is included in Participant Reports.

h. Recipients of Analytic Reports are prohibited from sharing the Analytic Reports with anyone outside of their practice, organization, or company without written permission from the Academy.

i. If Reports are shared externally, the following requirements are strictly enforced:
   i. Reports must not be used to suggest an endorsement or accreditation by the Academy or the Axon Registry.
   ii. Participants and Recipients are prohibited from advertising their quality or achievements compared to those of other practices (such as declaring a practice “better” or “best”) based on Reports.
   iii. Disclaimers or legal notices, as required by the Academy, must not be removed or obscured from the Reports.
   iv. Reports must not be altered in any fashion.

j. Participant retains ownership of all individual data submitted for inclusion in the Axon Registry by or on behalf of Participant and grants to AANI a license to use the data as described in, or consistent with, the Participation Agreement, the Business Associate Agreement, the Data Use Agreement, HIPAA, and Academy policies.

k. Once Collected Data has been submitted to the Axon Registry, the Academy retains the intellectual property rights in the organization of the Collected Data, aggregated data, and any analytics or Reports produced by the Academy, as described in the Participation Agreement.

l. Reports, including the display of content contained in such Reports, is the intellectual property of the Academy and must not be sold, reproduced, or shared without approval by the Academy.

Policy History: Approved by AAN and AANI Board of Directors - August 3, 2017.