



May 6, 2026

Dear NAEC Accredited Level 4 Center Medical Directors:

In March 2026, NAEC provided accredited level 4 centers with an overview/timeline and data dictionary of its Surgical Data Collection Program (the “Surgical Program”). The Surgical Program will expand the data NAEC will collect and analyze as part of its accreditation of all Level 4 centers. I am writing to provide some clarification around the Surgical Program and to respond to questions we received from some centers.

As an accrediting entity, the privacy and protection of patient data is vitally important to NAEC. This is why we designed the Surgical Program to avoid collecting any identifiable patient information. Centers will share with NAEC, as has always been the case, only patient data that is fully de-identified in accordance with HIPAA.

For many years, centers have shared de-identified patient data with NAEC for accreditation purposes. The Surgical Program does not change that. The data shared with NAEC still will be limited to information that is fully de-identified under HIPAA. As explained in the overview document, Brad Malin, a respected HIPAA statistician, has certified that the data requested for the Surgical Program is de-identified under HIPAA. In addition to working with Professor Malin, NAEC also engaged Melissa Levine, JD, a senior partner in the Data, Privacy and Cybersecurity practice at Hogan Lovells, a large global law firm that regularly advises clients on HIPAA to ensure the Surgical Program data collection is compliant.

As you are likely aware, HIPAA rules permit epilepsy centers to share patient information with accreditation entities. If NAEC were collecting or receiving *identifiable* patient information, a business associate agreement or data use agreement may be necessary under HIPAA. However, such agreements are not required or appropriate where only de-identified information is shared. NAEC has not previously required such agreements with centers because NAEC received only de-identified information. The Surgical Program follows the same practice, as centers will continue to share only patient data that has been *fully de-identified* under HIPAA.

Some centers asked whether a non-disclosure or similar agreement would be necessary. These types of agreements also are not needed or appropriate in this context. NAEC will use data collected from centers to support accreditation in accordance with its mission. As part

of its accreditation program, centers can benchmark against other similar (anonymous) accredited centers. The benchmarking data is de-identified as to both patients and contributing centers. NAEC also shares information on which centers are accredited. Accordingly, an NDA or similar agreement is not appropriate as it would unduly restrict or inhibit NAEC's accreditation program. It also is not necessary or typical with accrediting bodies.

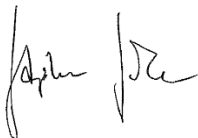
Finally, a few centers asked whether review by an Institutional Review Board (IRB) would be necessary. IRB review is not necessary or relevant here. IRB review is required for human subject research, which involves interaction or intervention with individuals or collection of individually identifiable information, none of which is the case here. The Surgical Program is for purposes of accreditation—not research—and only de-identified data is collected for such purposes. Therefore, the Surgical Program does not constitute human subjects research and IRB review is not warranted or appropriate.

Accrediting epilepsy centers is critical to ensuring quality patient care and NAEC intends to enhance its accreditation of Level 4 centers through the Surgical Program. Although only de-identified data is shared for the Surgical Program, NAEC still protects such data and has policies and guardrails in place to safeguard the data and limit its use appropriately and in accordance with its accreditation and patient care mission.

We hope this clarification helps allay any concerns about your participation in the Surgical Program. If you have any further questions, please contact NAEC at info@naec-epilepsy.org for additional guidance.

Thank you for your continued commitment to excellence in epilepsy care.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stephan Schuele', written in a cursive style.

Stephan Schuele, MD, MPH
President
National Association of Epilepsy Centers (NAEC)