111 E. University Dr., Ste. 105–355
Denton, TX 76209
Phone/Fax: (217) 726-7980

LAB-LTM: Epilepsy Monitoring and Critical Care EEG Monitoring

ACCREDITATION APPLICATION

PART 2

Please submit the following items (refer to the LTM Intro & Standards document for additional information, references, and ABRET policies):

1. **Policies and Procedures** in electronic form. Please include a Table of Contents with page numbers for the submitted policies. *Please do not include extraneous/additional information that is not listed below*. Upload the relevant portions of your policies that address the following in the order in which they are listed.
    1) Staffing policies (Job descriptions/Competencies)
    2) Infection prevention
    3) Electrical safety
    4) Patient safety
        - Role of technologists, nurses, house staff
        - Monitoring Environment
        - Out of bed policy (including bathroom safety)
    5) Quality improvement
    6) Continuing education requirements
    7) Emergency coverage
    8) HIPAA:
        - Hospital or departmental patient authorization for usage of identifiable material (audio, video) for patient care.
        - For teaching institutions, provide additional patient authorization for educational usage of identifiable audio-video material within the institution.
    9) Archiving:
        - Data retention policy (storage media, security, duration)
        - Archiving procedure (auto-editing/manual clipping, quality control) for:
            - Epilepsy Monitoring
            - Pediatric Epilepsy Monitoring (if applicable)
            - Critical Care EEG
    10) Procedural Policies**:
        - Epilepsy Monitoring
        - Pediatric Epilepsy Monitoring (if applicable)
        - Critical Care EEG

    **Please address the following elements in each Procedural Policy:
        - Information including patient's name, age, record ID, inpatient or outpatient date, and name of technologist
        - Patient preparation

- Patient history
- Electrode placement and application standards
- Electrode impedance standards
- Recording protocols including calibration, montages, activation, length of record, instrument adjustment and record annotation
- Monitoring for scalp breakdown
- Event annotation, testing, documentation, and notification standards
- Documentation of daily medication changes, changes in clinical status, other diagnostic tests, and monitoring procedures
- Monitoring Protocol: If not already included in the policies, provide a narrative addressing:
    - **Epilepsy Monitoring:** type of personnel, hours and days of coverage, backup monitoring plan during breaks, review of raw data, utilization of seizure and spike detection software, access for physicians to review after hour recordings, response to critical results, standard montages available for review.
    - **Pediatric Epilepsy Monitoring** (if applicable).
    - **Critical Care EEG:** review and report ongoing studies, weekend and overnight coverage, utilization of seizure detection software and quantitative EEG, standards for emergency hookup and reporting, access for physicians to review after hour recordings, response to critical results.
- Use of specialized electrodes
    - Epilepsy Monitoring: For extraoperative recording and mapping
    - Critical Care EEG: Imaging compatible electrodes, needle, subdermal electrodes
- Information Technology:
    - Protocol for equipment and network dysfunction (during and after working hours). Include your contingency plan if remote monitoring is not available.

2. Recordings: Provide the official report (interictal abnormalities, ictal abnormalities) with each submitted record. *It is highly recommended that all recordings align with the Expected Technical Standards for Recordings as defined beginning on page 4*.

For Epilepsy Monitoring:

- Submit 3 records (individual patients, complete 12–24-hour continuous EEG segments including annotations) should be submitted for the Epilepsy Monitoring application. All records must have clinical events, at least 2 should demonstrate clinical and/or electrographic seizures.
- An additional recording will be requested based on a date selected by the LAB-LTM Board. The random file does not need to be continuous or contain audio/video unless there are clinical events.
- **Pediatric Centers applying for Accreditation of Pediatric Program** (separately from Adult Program): One of the three records should be a vEEGs on a patient under the age of 2 years.
- Laboratories performing extraoperative invasive recordings (including all designated level 4 NAEC centers) should submit one additional invasive recording showing clinical and electrographic seizures.

- Clipped and archived records are allowed but the submitted record should be from a 24-hour continuous segment. An invasive map (manual, pictures, or image co-registration) and list of implanted electrodes with names and locations should be included.

For Critical Care EEG Monitoring:

- Two 12–24-hour EEG recordings (individual patients, continuous 12–24-hour EEG segments including annotations and audio/video clips of the clinical events) including electrographic seizures with or without clinical correlate.
- An additional recording will be requested based on a selected date. The random file does not need to be continuous or contain audio/video unless there are clinical events.

Important NOTES:

I. Records should be saved and encrypted according to institutional policies, with reading software and all montages typically used in the laboratory and mailed to the address below. Patient identifying information should be removed. *Send two sets of data*, each on its own drive, to facilitate review.

II. Application materials and records saved on CD, DVD, flash drive, or portable hard drives may be mailed to:

ABRET LAB – LTM
c/o Anna M. Bonner
2054 Kildaire Farm Road, #431
Cary, NC 27518

III. A Business Associate Agreement must be completed to satisfy HIPAA requirements. Either send a signed copy of your institutional agreement form or complete/sign the template below (pages 5–8) and return it to anna@abret.org. Data will only be used for evaluation and destroyed or returned upon completion of the evaluation.

3. Accreditation Fees:

- For one (EMU or Critical Care/CC): $1,500
- For both (EMU & CC): $2,500
- Epilepsy Monitoring with invasive (NAEC Level IV): $2,500
- Epilepsy Monitoring with invasive (NAEC Level IV) & CC: $3,000
- Satellite or related labs may be recognized under the same application for a discounted fee if the staff, medical director, and policies are the same.
- Centers with both Adult and Pediatric programs should submit separate applications (NAEC considers these programs separately).
- Refer to the ABRET website for detailed fee information
- To pay by credit card, use this processing form.
- Checks should be payable to ABRET and mailed to the Executive Office at:

ABRET LAB-LTM
111 E. University Drive, Ste. 105–355
Denton, TX 76209

- Contact anna@abret.org if you require an invoice or W-9 for processing.

EXPECTED TECHNICAL STANDARDS FOR RECORDINGS

1. All recordings must be interpretable (provide ancillary material as needed, e.g., event log, electrode map and montages).
2. All submitted records must have been recorded within twelve months of the application.
3. Every record must contain a minimum of sixteen EEG electrodes for ICU and twenty-one for EMU recordings.
4. Every record must contain an EKG channel.
5. All inter-electrode impedances (not greater than 10,000 ohms) should be balanced and documented at least once a day.
6. Patient Age, Date, Tech Name, or ID.
7. Required documentation on the report: Time of Recording, Time and Description of Symptoms or Events, Behavioral State of Patient, Medication, Summary of Relevant Medical History.
8. If meaningful calibration is not available, ideally the first 30 seconds of the recording should be observed by the technologist using the primary system reference montage.
9. Scalp recording standards:

   Sensitivity of 5-10 μv/mm is required and should be adjusted as needed.

   Low frequency (high-pass) filter 1 Hz or lower (time constant of not <0.16 seconds) is required and should be adjusted as needed.

   High frequency (low-pass) filter greater than or equal to 70 Hz is required and should be adjusted as needed.
10. Intracranial recordings:

    Low frequency (high-pass) filter 0.5 Hz or lower; high frequency (high-pass) filter 70 Hz or higher.
11. The notch filter should not be defaulted to “on”.
12. Any artifacts should be corrected or monitored, as necessary.
13. For epilepsy monitoring:

    If hyperventilation is performed, effort should be noted.

    If photic stimulation is performed, stimulus frequency and effect should be documented.
14. Visual, auditory, somatosensory stimulation or noxious stimulation should be used and documented daily. Clear documentation of the patient’s maximal level of alertness must take place at some time during recording.
15. Before submitting data, verify it is viewable on a generic PC, and not just on your review station. Provide additional information/instructions as to how to use your particular reading software, and if there are any nuances to facilitate the process, such as passwords.

References: American Clinical Neurophysiology Society Guidelines (www.acns.org)

1) Minimal Technical Requirements for Performing Clinical EEG, Guideline 1
2) Recording Clinical EEG on Digital Media, Guideline 4
3) Minimal Technical Standards for Pediatric EEG, Guideline 5
4) Standards for Long Term Monitoring for Epilepsy, Guideline 12
5) Guideline on Continuous EEG Monitoring in Neonates, Guideline 13
6) Standardized Critical Care EEG Terminology, Guideline 14

BUSINESS ASSOCIATE AGREEMENT BETWEEN

COVERED ENTITY AND LAB

This Agreement has been made and entered into effective [MONTH DATE, YEAR] by and between ABRET Neurodiagnostic Credentialing and Accreditation (herein after "Covered Entity") and [NAME OF FACILITY/HOSPITAL].

WHEREAS, the United States Congress anticipated and provided that Personal Health Information (herein after referred to as "PHI") would be used in reviewing the competence or qualifications of health care professionals for the purpose of accreditation (codified at 45 CFR part 164.501).

WHEREAS, Covered Entity is seeking accreditation from ABRET Neurodiagnostic Credentialing and Accreditation (hereinafter referred to as "ABRET"); and

WHEREAS, the Lab intends to remove as much individually identifiable information as possible from the records being used; however, in some circumstances it is impossible to remove all personally identifiable information, and so it becomes necessary to enter into a Business Associate Agreement.

NOW THEREFORE, in consideration of the terms herein contained, the parties hereto agree as follows:

The Covered Entity agrees to disclose certain patient records and information to the Lab to be examined for accreditation in [Electroencephalographic Technology, Long-Term Monitoring, Intraoperative Neurophysiological Monitoring].

I. BACKGROUND AND PURPOSE: In order for the qualifications of the Lab to be evaluated for accreditation, Covered Entity agrees to disclose certain limited PHI to the Lab. Covered Entity agrees in advance that Lab may disclose PHI to ABRET reviewers as part of the accreditation examination as long as ABRET agrees to the same or similar terms and conditions as agreed to by Lab contained herein. Patient records and information shall be reviewed over a five-week period. In the course of receiving such PHI, by this Agreement and as a "Business Associate" under the Health Insurance Portability and Accountability Act (codified at 45 CFR parts 160 and 164, as may be amended from time to time), the Lab agrees to do the following:

(a) Preserve the confidential nature of all data and documents submitted related to the application for accreditation of the Lab, an employee of Covered Entity, including, but not limited to, records that contain patient confidential and/or privileged information and quality review information, to the extent required by state and/or federal law.

(b) Only use, disclose and maintain individually identifiable health information in all forms including but not limited to electronic form, from Covered Entity or any other party as a result of the aforesaid application for accreditation in the performance of Business Associate's obligations hereunder, in compliance with federal and state law, rules and regulations, such obligations being the review of said Lab's performance with respect to the operations of Covered Entity's operations for the purpose of possible accreditation of

Lab.

II. DUTIES AND OBLIGATIONS: Lab agrees to:

A. Request the minimum necessary PHI for any uses or disclosures required by subparagraph (b) above.

B. Use appropriate administrative, physical, and technical safeguards and security measures consistent with the healthcare industry to prevent uses or disclosures of PHI other than those specified hereunder.

C. Report to Covered Entity any use or disclosure of the health information not provided for hereunder.

D. Require and ensure that its agent, including a subcontractor, to whom it provides PHI received from, or created or received by, or on behalf of Covered Entity, maintains the confidentiality of such health information, reports any disclosure or breach of security and/or confidentiality to Business Associate and agrees to be bound by the same restrictions and conditions that apply, to Business Associates with respect to the PHI.

E. In accordance with HIPAA, make any received PHI available if requested by the applicable patient for amendment(s).

F. Make available, if requested by Covered Entity, PHI in order to provide an accounting of all disclosures of PHI. In doing so, Business Associate agrees to implement appropriate procedures and methods to allow it to track and maintain a log of any of its disclosures of PHI that are required to be accounted for pursuant to the Privacy Standards. Within ten (10) business days notice, by Covered Entity to Business Associate that it has received a request for any accounting of disclosures, Business Associate shall make available to Covered Entity such information as is in its possession and is required as to make the accounting required by 45 C.F.R. §164.528.

G. Recognize that nothing herein constitutes a transfer of ownership; provided, however, that the parties agree that Business Associate is hereby granted a license to use information contained in Lab's application(s) for its accreditation activity.

H. Maintain any PHI it receives from Covered Entity in compliance with Covered Entity's policies and procedures and all applicable federal and state laws, rules and regulations and allow Covered Entity access to the PHI it possesses as needed to provide patient care and to comply with all applicable federal and state laws, rules, and regulations.

III. TERMINATION: The following procedures shall govern the termination of this Agreement for breach of confidentiality:

A. Covered Entity may immediately terminate this Agreement for cause upon the knowledge of a material breach of confidentiality by Business Associate.

B. Any for cause termination shall be effective only after Covered Entity has provided reasonable written notice of the potential “cause” to Business Associate of the material breach of any term or condition of this Business Associate Agreement.

C. In the event of the termination of this Agreement, Business Associate agrees to return all PHI and other information in all forms or, upon Covered Entity's request, destroy such information in all forms. If for any reason, such health information cannot be returned or destroyed, then all obligations of Business Associate regarding such information shall survive the termination of this Agreement indefinitely or until such information is returned to the Covered Entity or destroyed. Under no circumstances shall Business Associate be considered owner of the PHI used or disclosed by or to Business Associate.

D. Business Associate understands that Covered Entity may be required to report a breach of any term or condition of this Business Associate Agreement required by HIPAA to the Secretary of Health and Human Services.

IV. THIRD PARTY RIGHTS: The terms of this Business Associate Agreement are not intended, nor should they be construed, to grant any rights to any other parties other than Business Associate and Covered Entity.

V. INDEMNIFICATION: Business Associate shall indemnify Covered Entity for any and all claims, inquiries, costs, or damages, including but not limited to any monetary penalties, incurred by Covered Entity arising from a violation by Business Associate of its obligations under this Business Associate Agreement.

VI. CONTROL OF RESPONSE: In the event that Business Associate receives a subpoena, court or administrative order, or other discovery request or mandate for release of PHI, Covered Entity shall have the right to control Business Associate’s response to such request. Business Associate shall notify Covered Entity within two (2) business days of receipt of such request.

VII. REGULATORY CHANGES: The parties acknowledge and agree that this Agreement is at all times subject to applicable laws, including, but not limited to, the Social Security Act and the rules, regulations, and policies of the U.S. Department of Health and Human Services. In the event legislation is enacted or rules, regulations or interpretations thereof are set forth by a governmental agency or a decision or ruling by any such agency or a court or tribunal of competent jurisdiction, which in the opinion of Covered Entity's or Business Associate's legal counsel affects or may affect the legality of this Agreement or materially and adversely affects the ability of either party to perform its obligations or receive the benefits intended hereunder, then, within ten (10) business days of notice from Covered Entity's or Business Associate's legal counsel, the parties will meet to amend this Agreement to carry out the original intentions of the parties. If the parties cannot reach a mutually agreeable resolution within forty-five (45) days after notice from legal counsel, either party may terminate this Agreement upon an additional thirty (30) days written notice to the other.

VIII. HITECH ACT: Business Associate agrees to comply with all the mandatory privacy and security requirements that apply to business associates under the HITECH Act (42 USC §17921 et seq.) and implementing regulations. In the event that an unauthorized use or disclosure occurs, Business Associate will: (i) provide information regarding the incident to the Covered Entity as required by law and as reasonably requested by the Covered Entity, and (ii) take steps to mitigate, to the extent practicable, any harmful resulting effect that is known to Business Associate.

This Agreement shall govern the Lab's receipt, use and disclosure of PHI.

IN WITNESS WHEREOF, the parties have executed this Business Associate Agreement by their duly authorized representatives effective as of the date of signature by Covered Entity.

LAB:_____

Name: _____

Title: _____

Date: _____

COVERED ENTITY:	WITNESS/ATTEST:
By:_____	By: _____
Name: Anna M. Bonner	Name:
Title: Sr. Director of Operations & Programs	Title:
Date:	Date: