

Critical Care EEG Monitoring Research Consortium

Consortium Bylaws

The Critical Care EEG Monitoring Research Consortium Bylaws encompass the following aspects of consortium governance and activity: data transfer and use, confidentiality, publication and authorship, addition and termination of consortium members, and conflicts of interest.

1. DEFINITIONS.

“CEEG Certification” means the certification given to individuals who have completed the specific training module(s) and passed the CEEG Certification Exam approved by the Executive Committee. Re-certification will be required every 3 years.

“Central Database” means the database developed and managed by the CEEG Consortium that contains the Data.

“Confidential Information” means all information (other than Data) that is disclosed by one party (“the Disclosing Party”) to the other party (“the Receiving Party”) and marked “Confidential.”

“Consortium Member” means Columbia, Institution, or any other academic/non-profit institution who has signed a Data Consortium Agreement with Columbia **“Data”** means all patient data that has been de-identified according to 45 CFR § 164.514 and deposited in the Central Database by a Consortium Member.

“Executive Committee” means the committee comprising the Principal Investigator (or his designee) and the Institution Investigator (or his/her designee) from all other Consortium Members. The Executive Committee will have a chairperson and vice-chairperson, to be elected by the Committee every 2 years. In the event of a tie in an election, the current chairperson will choose the winner. For the first election, the Principal Investigator will choose the winner in the event of a tie vote.

2. DATA TRANSFER AND USE.

a. Consortium Members shall deposit Data into the Central Database.

(i) Consortium Member represents to the best of its knowledge that it has de-identified all Data that it has deposited in the Central Database in compliance with 45 CFR § 164.514 and agrees to notify Columbia in writing if it discovers that any of the Data which it deposits has not been so de-identified.

(ii) All Data comprising EEG interpretations shall be entered into the Central Database by Consortium Member personnel who possess a current CEEG Certification.

(iii) All Data entered into the Central Database shall bear a code identifying the depositing Consortium Member in a format specified by the Executive Committee. The depositing Consortium Member warrants that it will maintain the key to said codes at its individual institution in confidence and further warrants that it will not distribute the key to said code to any party outside of its institution or any other information that identifies or could be used to de-code the Data. Thus, Data will be

de-identified from the standpoint of the Consortium and all the other consortium members, but coded from the standpoint of the depositing consortium member.

- (iv) All such Data remains the property of the respective depositing Consortium Member. The depositing Consortium Member remains free to use, disclose, and publish its own Data, provided however, that any such use, disclosure, or publication concerns research conducted outside the specific aims of ongoing CEEG Consortium research projects or concerns research initiated prior to the Effective Date of this Agreement.
- b. The Data will be available to Consortium Members through the Central Database which will be accessible via a secure internet site.
- c. Consortium Members warrant that they shall not try to ascertain the identities of any patients associated with Data deposited by other Consortium Members in the Central Database. With respect to Data deposited by other Consortium Members in the Central Database, Consortium Members warrant that they shall not have or seek access to any identifiable information (such as the key to the code) under any circumstances. Consortium Members depositing Data warrant that they shall not provide access to any identifiable information (such as the key to the code) to other Consortium Members under any circumstances.
- d. Except as provided in Section 2.a.(iv) and Section 2.f. herein, Consortium Members shall only use the Data for academic research and teaching purposes. To avoid duplication of efforts and resources, Consortium Members shall submit proposed projects in advance to the Executive Committee for approval.
- e. Except as provided in Section 2.f. herein, the Data shall not be used for Commercial Purposes of any kind. "Commercial Purposes" means:
 - (i) the sale, lease, license, or other transfer of the Data to any for-profit organization,
 - (ii) the use of the Data by any Consortium Member to perform contract research,
 - (iii) the use of the Data to produce or manufacture products for general sale, or
 - (iv) the use of the Data to conduct research activities that result in any sale, lease, license or transfer of the Data to a for-profit organization.

However, industrially sponsored academic and/or non-profit research shall not be considered a use of the Data for Commercial Purposes *per se*, unless any of the above conditions of this definition are met.

- f. The Data may not be used for Commercial Purposes unless prior written permission is obtained from the depositing Consortium Member(s) whose Data are to be used for such Commercial Purposes. Requests to use the Data for Commercial Purposes shall be submitted to the Executive Committee, who will forward such requests to the relevant depositing Consortium Member(s). It is understood that the depositing Consortium Member shall have no obligation to grant permission to use their Data for Commercial Purposes, and may grant such permission to others, including any third parties, or otherwise dispose of their Data, subject only to applicable laws and regulations, as well as the depositing Consortium Member's own institutional policies and procedures.

- g. Consortium Members shall not disclose, transfer, or share the Data with any other person or organization, except the following:
 - (i) those scientists affiliated with and working within the Institution under the supervision of Institution Investigator who have been advised of the terms of this Agreement,
 - (ii) other Consortium Members, and
 - (iii) third-party contractors whose participation on specific EEG Consortium projects has been approved in advance by the Executive Committee and who have agreed in writing to be bound by equivalent obligations of confidentiality and restricted Data use as set forth in this Agreement.

Notwithstanding the foregoing, the Data may be disclosed in a publication, pursuant to the process set forth in Section 4 herein.

- 3. **CONFIDENTIALITY**. The Receiving Party agrees not to disclose Confidential Information to any third party and agrees that it will use all Confidential Information solely for the purpose of this Agreement. However, the aforementioned obligations of confidentiality and restricted use will not apply to information which:
 - a. was already known to the Receiving Party prior to the time of first disclosure, as demonstrated by written documentation; or
 - b. at the time of disclosure, is in the public domain; or
 - c. after the date of the disclosure, lawfully becomes a part of the public domain other than through breach of this Agreement by the Receiving Party; or
 - d. is received without any obligation of confidentiality from a third party having a legal right to disclose the same; or
 - e. is independently developed by the Receiving Party by individuals without access to such information, as demonstrated by contemporaneous written documentation; or
 - f. is required to be disclosed by the Receiving Party pursuant to a legally enforceable order, direction or other regulation ("Order"), provided however, that the Receiving Party promptly notifies the Disclosing Party in advance of such disclosure and discloses only that information necessary to comply with said Order.

The obligations of this Section pertaining to confidentiality and limited use will survive the termination of this Agreement for an additional five (5) years.

- 4. **PUBLICATION**.
 - a. **Pre-Publication Review.**
 - (i) All parties agree that any proposed publication and/or public disclosures reporting the results of research using the Data will be submitted to the Executive Committee at least thirty (30) days prior to submission for publication or other disclosure. The Executive Committee shall provide a copy of each proposed publication to each Consortium Member Investigator (one per institution) to review. All parties agree that any Confidential Information will be deleted from the manuscript prior to submission for publication or other disclosure.
 - (ii) No one will be permitted to use the name of the Consortium or to make any statement implying the Consortium's involvement or endorsement of any particular research

result or publication without the prior, written permission of the Executive Committee.

b. Authorship.

Authorship on publications and/or disclosure will follow the guidelines set forth by the New England Journal of Medicine statement on Authorship and Acknowledgements (Volume 325, Number 21, November 21, 1991).

- (i) In order to qualify for authorship, individuals must have made substantial contributions to:

conception and design of the Protocol or analysis and interpretation of the generated data;

AND

writing the publication or revising it critically.

- (ii) In addition, individuals who are named as authors on publications generated from the use of the Data must review and provide written comments regarding the final version of the manuscript. Determination by the Executive Committee that an individual has failed to meet these requirements will result in the individual's name being removed from the author list.
- (iii) For the sake of clarification, merely depositing Data to the Central Database without meeting the requirements of Section 4.b.(i) and (ii) above shall not form sufficient basis for authorship.
- (iv) In case of a dispute, the Executive Committee will make the decision regarding authorship on such publications, including the order of authors. All publications will include a list of named authors. In addition, a list of Consortium Member Investigators and their designated sub-investigators (maximum of 10 per Consortium Member) will be included in the acknowledgments as contributors to the CEEG Consortium. Those named in this listing must meet the guidelines for acknowledgment as discussed in the aforementioned New England Journal of Medicine article.

- c. Attribution.** The support of the American Epilepsy Society will be acknowledged in all publications or public disclosures reporting the use of the Data as follows: *"The Continuous EEG Research Consortium is supported by the American Epilepsy Society and the Epilepsy Foundation,"* for as long as funding is continuing and for 2 years thereafter.

5. ADDITION OF NEW CONSORTIUM MEMBERS.

- a. Any institution and their respective investigator(s) may apply to be a Consortium Member. All such requests shall be considered by the Executive Committee. All centers must possess the following attributes and be approved by a 2/3 majority of the Executive Committee:
- (i) A continuous EEG monitoring program that averages recording of at least 5 patients per month and includes networking for remote review, digital video, and review at least twice per day for patients being monitored. This excludes patients admitted electively to an epilepsy monitoring unit.
- (ii) An involved member who is a certified clinical neurophysiologist, either via the American Board of Clinical Neurophysiology ("ABCN") or via added qualifications

in clinical neurophysiology by the American Board of Psychiatry and Neurology (“ABPN”) if the Institution is located within the United States, or an involved member who is a certified clinical neurophysiologist via equivalent training boards if the Institution is located outside the United States.

(iii) An involved member who is a registered EEG technologist certified by the American Board of Registration of Electroencephalographic and Evoked Potential Technologists (“ABRET”) if the Institution is located within the United States, or an involved member who is a certified EEG technologist via equivalent training boards if the Institution is located outside the United States.

(iv) Ability to obtain IRB approval.

b. The above requirements do not apply to the following founding Consortium Members:

Columbia Comprehensive Epilepsy Center, New York, NY

Barrow Neurological Institute, Phoenix, AZ

Beth Israel Deaconess Medical Center, Boston, MA

Cleveland Clinic Epilepsy Center, Cleveland, OH

Duke University Medical Center, Durham, NC

Emory Epilepsy Program, Emory University School of Medicine, Atlanta, GA

Penn Epilepsy Center, University of Pennsylvania, Philadelphia, PA

University of Calgary, Calgary, AB (Canada)

University of Virginia School of Medicine, Charlottesville, VA

6. TERMINATION.

a. Institution reserves the right to terminate this Agreement at any time by giving 45 days prior written notice to Columbia. In the event of such termination, all Data collected to that point will remain in the Central Database for use in academic research and teaching by Consortium Members.

b. Upon 30 days prior written notice either party may terminate this Agreement for a material breach of the Agreement by the other party if such breach has not been cured within 30 days after written notice of the breach has been given. Upon receipt of notice of termination, the Institution agrees to promptly dispose of any Data obtained from the Central Database and certify in writing to Columbia that such Data has been destroyed.

c. Columbia reserves the right to terminate this Agreement if the Executive Committee votes to terminate the Institution with a 2/3 majority for any reason, including, but not limited to instances where any one of the following conditions is not remedied by the Institution within sixty (60) days of notification:

(i) IRB approval is not obtained and maintained.

(ii) No Data is entered by the Institution for more than 1 year.

(iii) The Institution has not participated in consortium activities for more than 1 year.

(iv) Requests for review or submission of information required for maintaining the Consortium are not completed within 30 days on more than 1 occasion.

d. Within 60 days of termination under this Section 8, the CEEG Consortium will supply the Institution with a copy of all Data deposited by said Institution.

7. CONFLICT OF INTEREST. Columbia, Principal Investigator, Institution, and Institution Investigator each certify that they will disclose any real or apparent material conflict of interest with respect to financial holdings in companies which may benefit from the activities or results of this Consortium. The parties are cognizant that full disclosure of all ties to such companies is required. The parties certify that they currently have a policy in place to manage, reduce or eliminate actual or proposed conflicts of interest and will develop mechanism(s) to resolve such conflict.