

NEUROGLEE THERAPEUTICS INC

BUSINESS ASSOCIATE AGREEMENT SCHEDULE

This Business Associate Agreement (this “**BAA**”) is made as of _____, 2022 (the “**Effective Date**”), by and between Neuroglee Therapeutics Inc, a Delaware corporation (“**Business Associate**”) and _____ (“**Covered Entity**”) (individually a “**Party**” and collectively the “**Parties**”).

RECITALS

WHEREAS, the Parties desire to enter into this Agreement in order to comply with the privacy regulations (45 C.F.R. Part 160, subpart A and C, and Part 164, subparts A and E) (the “**Privacy Rule**”) and security regulations (45 C.F.R. Part 160, subpart A and C, and Part 164, subparts A and C) (the “**Security Rule**”) adopted by the U.S. Department of Health and Human Services (“**HHS**”), as promulgated by HHS in accordance with the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”); the Health Information Technology for Economic and Clinical Health Act of 2009 (“**HITECH**”); and any other regulations promulgated by HHS in accordance with HIPAA and/or HITECH (from time to time hereinafter, such regulations and Acts collectively referred to as the “**HIPAA Regulations**”);

WHEREAS, Covered Entity and Business Associate have entered into or will enter into one or more agreements (the “**Agreements**”) under which Business Associate provides or will provide services to Covered Entity (“**Services**”);

WHEREAS, in connection with these Services, Business Associate meets the definition of a “business associate” as defined by 45 C.F.R. Section 160.103; and

WHEREAS, the Parties desire to enter into this BAA in order to ensure the Covered Entity receives adequate and satisfactory assurances from Business Associate that Business Associate and its subcontractors will comply with all applicable obligations under the HIPAA Regulations;

NOW THEREFORE, in consideration of the mutual promises and covenants herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and incorporating the recitals above, the Parties agree as follows:

1. DEFINITIONS.

Unless otherwise provided in this BAA, all capitalized terms in the BAA will have the meaning set forth in the HIPAA Regulations. References to Protected Health Information (hereinafter “**PHI**”) shall be construed to include Electronic Protected Health Information, and references to PHI shall mean only the PHI that Business Associate uses, discloses, creates, receives, maintains and/or transmits for or on behalf of Covered Entity to perform the Services. For purposes of this BAA, capitalized words shall have the definitions given or used by the HIPAA Regulations as of the compliance deadline established by such requirements.

2. **OBLIGATIONS OF BUSINESS ASSOCIATE.**

A. **Compliance with Laws.** Business Associate acknowledges and agrees it meets the definition of a “business associate” as defined at 45 C.F.R. §160.103. Business Associate shall only create, receive, use, disclose, maintain, and/or transmit PHI in compliance with this BAA and the HIPAA Regulations. Business Associate agrees to comply with applicable federal and state privacy laws, including but not limited to the HIPAA Regulations.

B. **Business Associate Agreements with Subcontractors.** If Business Associate subcontracts any portion of the Services to any agent or subcontractor as those terms are defined or otherwise used in the HIPAA Regulations (hereinafter referred to individually as a “**Subcontractor**” or collectively as “**Subcontractors**”), prior to any Subcontractor accessing, creating, using, disclosing, maintaining, transmitting or receiving any PHI Business Associate shall require such Subcontractor to agree in writing to the same business associate agreement restrictions and conditions set forth in the HIPAA Regulations, including but not limited to the implementation specifications of 45 C.F.R. §§164.314, 164.410, 164.502, and 164.504(e); provided further, such agreement shall require the Subcontractor to comply with the Security Rule.

C. **Use of PHI.** Except as otherwise permitted by law and this BAA, Business Associate shall only create, receive, use, disclose, maintain, and/or transmit PHI in compliance with the Agreements, this BAA and the HIPAA Regulations, whichever is more protective of patient confidentiality and patient rights. In accordance with the foregoing, Business Associate shall use PHI (i) to perform the Services, and (ii) as necessary for the proper management and administration of the Business Associate or to carry out Business Associate’s legal responsibilities, provided that such uses are permitted under federal and applicable state law. Additionally, Business Associate may use and disclose PHI for Data Aggregation purposes relating to the health care operations of the Covered Entity.

D. **Disclosure of PHI.** Business Associate may disclose PHI if required to do so by law. In addition to the requirements of Section 2.B. of this BAA regarding Business Associate Agreements with Subcontractors, Business Associate may disclose PHI to a third party, including any Subcontractor, as necessary for such third party to assist Business Associate in performance of the Services; provided, however, that prior to any such disclosure Business Associate: (a) obtains reasonable written assurances from the third party, including any Subcontractor, to whom the PHI is disclosed that the third party will hold such PHI confidentially and will use or disclose such PHI only as Required by Law or for the purpose(s) for which the PHI was disclosed to the third party; and (b) requires the third party, including any Subcontractor, to agree to notify the Business Associate promptly following any instance of which such third party is aware that PHI has been used or disclosed for a purpose that is not permitted by this BAA or the HIPAA Regulations. Business Associate further agrees that any disclosures of PHI made by Business Associate to any third party, including Subcontractors, shall comply with the HIPAA Regulations, including but not limited to the Security Rule.

E. **Report of Misuses and/or Inappropriate Disclosures of PHI.**
Business

Associate shall: (1) report to the Covered Entity any use or disclosure of PHI not permitted by this BAA or the HIPAA Regulations, such report to be made within ten (10) business days of the Business Associate becoming aware of such misuse or inappropriate disclosure; and (2) mitigate,

to the extent practical, any harmful effect that is known or reasonably foreseeable to Business Associate and is the result of a use or disclosure of PHI by Business Associate or any Subcontractor in violation of the BAA, the HIPAA Regulations or other applicable law.

F. **De-identification and Limited Data Sets.** Subject to any restrictions in the HIPAA Regulations, Business Associate shall have full discretion and authority to create deidentified information from PHI as described under 45 CFR §164.514, or perform Data Aggregation activities with PHI.

G. **Safeguards by Business Associate and Subcontractors.** Business Associate represents and warrants that it has adopted, implemented and shall continue to maintain, for so long as Business Associate has access to, maintains, uses or discloses Data, as defined below, adequate and appropriate safeguards to: (i) protect the confidentiality and security of PHI and other individually identifiable information obtained from, or created on behalf of, Covered Entity (for purposes of this Section 2.G, "Data"), and (ii) prevent the use or disclosure of Data other than as provided for by this BAA, the HIPAA Regulations and other applicable law. Business Associate's administrative, physical and technical safeguards protecting Data shall comply with applicable law, and the HIPAA Security Rule.

H. **Minimum Necessary.** Business Associate shall limit its uses and disclosures of PHI to the "Minimum Necessary," that is, Business Associate shall only use and further disclose PHI as permitted by this BAA and the HIPAA Regulations (including but not limited to the minimum necessary standard set forth at 45 C.F.R. Section 164.502(b)), to accomplish the intended purpose of such use, disclosure, or request to use or disclose.

3. **INDIVIDUAL RIGHTS.** Business Associate agrees as follows:

A. **Individual Right to Copy or Append PHI in the Designated Record Set.** In the event Business Associate maintains a Designated Record Set on behalf of Covered Entity, Business Associate shall promptly take all actions necessary for Covered Entity to comply with 45 C.F.R. Sections 164.524 and 164.526. Business Associate shall provide any request it (or its Subcontractors) receives from an Individual for access or amendment under such regulations to Covered Entity within five (5) business days of receipt. Business Associate agrees that only Covered Entity shall respond to requests received by Business Associate (or its Subcontractors) from Individuals.

B. **Accounting of Disclosures.** Business Associate agrees to maintain documentation of the information required to provide an Accounting of Disclosures of PHI in accordance with 45 C.F.R. § 164.528, and to make this information available to Covered Entity within ten (10) business days of Covered Entity's request, in order to allow Covered Entity to respond to an Individual's request for Accounting of Disclosures. Such accounting is limited to disclosures that were made in the six (6) years prior to the request (not including disclosures prior to the compliance date of the Privacy Rule) and shall be provided for as long as Business Associate maintains the PHI. If an Individual requests an Accounting of Disclosures directly from Business Associate, Business Associate will forward the request and its Disclosure record to Covered Entity within ten (10) business days of Business Associate's receipt of the Individual's request. Covered Entity will be responsible for preparing and delivering the Accounting to the Individual. Business Associate will not provide an Accounting of its Disclosures directly to any Individual.

4. **INTERNAL PRACTICES, POLICIES AND PROCEDURES.** Except as otherwise specified herein, Business Associate shall make available information regarding Covered Entity's and Business Associate's internal practices, policies and procedures relating to the use and disclosure of PHI to HHS or its authorized agents for the purpose of determining Covered Entity's and/or Business Associate's compliance with the HIPAA Regulations. Records requested that are not protected by an applicable legal privilege will be made available in the time and manner specified by HHS or its authorized agents. To the extent permitted by law, Business Associate shall promptly notify Covered Entity in writing regarding any requests for such information received from HHS or its authorized agents.

5. **WITHDRAWAL OF AUTHORIZATION.** If the use or disclosure of PHI in this BAA is based upon an Individual's specific authorization for the use or disclosure of his or her PHI, and the Individual revokes such authorization, the effective date of such authorization has expired, or such authorization is found to be defective in any manner that renders it invalid, Business Associate shall, if it has notice of such revocation, expiration, or invalidity, cease the use and disclosure of the Individual's PHI except to the extent it has relied on such use or disclosure, or if an exception under the HIPAA Regulations expressly applies.

6. **SECURITY INCIDENTS.** Business Associate agrees to report to the Covered Entity any Security Incident of which Business Associate becomes aware, as follows:

A. Attempted incidents, i.e., those incidents that are unsuccessful and neither penetrate the information systems nor cause any threat of harm to such systems, shall be reported to the Covered Entity within sixty (60) days of the Covered Entity's written request. The Covered Entity will not make such a request more frequently than annually.

B. Successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operation shall be reported to the Covered Entity within ten (10) business days after verification of the security incident by Business Associate.

7. **BREACHES OF UNSECURED PHI.** Business Associate will report in writing to Covered Entity any Breach of Unsecured Protected Health Information, as defined in the Breach Notification Regulations, 45 C.F.R. Section 164.400 *et seq.* (each a "**HIPAA Breach**"), within ten (10) business days of the date Business Associate after verification of the Breach, and shall provide Covered Entity with all information required by 45 C.F.R. Section 164.410 that Business Associate has or may obtain without unreasonable difficulty. Business Associate will provide such information to Covered Entity in the manner required by the Breach Notification Regulations and its Breach Notification Policy, and as promptly as is possible.

8. **DATA BREACH NOTIFICATION AND MITIGATION UNDER STATE LAWS.** Business Associate agrees to implement reasonable systems for the discovery and prompt reporting of any breach of individually identifiable information accessed, maintained, created, transmitted, used or disclosed on behalf of Covered Entity (including, but not limited to, PHI and referred to in this Section 8 as "Individually Identifiable Information") that, if misused, disclosed, lost or stolen, would trigger an obligation under one or more State data breach notification laws (each a "**State Breach**") to notify the individuals who are the subject of the information.

9. **OBLIGATIONS OF COVERED ENTITY.**

A. **Notice of Privacy Practices.** Upon written request by Business Associate, Covered Entity shall provide Business Associate with Covered Entity's then current Notice of Privacy Practices.

B. **Revocation of Permitted Use or Disclosure of PHI.** Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by a patient to use or disclose PHI of Covered Entity, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

C. **Restrictions on Use or Disclosure of PHI.** Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

D. **Requested Uses or Disclosures of PHI.** Except for Data Aggregation or management and administrative activities of Business Associate, Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA Regulations if done by Covered Entity.

E. **Account Management.** The Covered Entity shall ensure that only authorized individuals have access to the account(s) and application(s). Covered Entity shall promptly remove access to terminated accounts. Covered Entity shall notify Business Associate of terminated accounts that are managed by Business Associate, ensuring that appropriate access privileges to the account(s) and application(s) are revoked in a timely manner.

10. **TERM AND TERMINATION.**

A. **Term.** This BAA shall be effective as of the Effective Date and shall be terminated concurrently with the termination of the last Agreement in effect, or as otherwise provided in this BAA.

B. **Termination for Breach.** Either Party may terminate this BAA (the "**Terminating Party**") upon written notice to the other Party (the "**Terminated Party**") if the Terminating Party determines that the Terminated Party has breached a material term of this BAA. The Terminating Party will provide the Terminated Party with written notice of the breach of this BAA and afford the Terminated Party the opportunity to cure the breach to the satisfaction of the Terminating Party within thirty (30) days of the date of such notice. If the Terminated Party fails to timely cure the breach, as determined by the Terminating Party in its sole discretion, the Terminated Party may terminate this BAA.

C. **Effect of Termination.** Upon termination of this BAA for any reason, Business Associate agrees to return or destroy all PHI received from, or accessed, maintained, used, disclosed and/or transmitted for or on behalf of, Covered Entity by Business Associate (or its Subcontractors). If Business Associate reasonably determines that the return or destruction of PHI is not feasible, Business Associate shall inform Covered Entity in writing of the reason thereof, and shall agree to extend the protections of this BAA to such PHI and limit further uses and disclosures of the PHI to those purposes that make the return or destruction of the PHI not feasible for so long as Business Associate retains the PHI.

11. **MITIGATION.** If Business Associate violates this BAA, Business Associate shall take commercially reasonable efforts to mitigate any damage caused by such violation or breach.

12. **MISCELLANEOUS.**

A. **Survival.** The respective rights and obligations of Business Associate under this BAA shall survive the termination of this BAA and shall continue for so long as Business Associate, its Subcontractors or agents maintain PHI.

B. **Notices.** Any notices pertaining to this BAA shall be given in writing and shall be deemed duly given when personally delivered to a Party or a Party's authorized representative as listed below or sent by means of a reputable overnight carrier, or sent by means of certified mail, return receipt requested, postage prepaid. A notice sent by certified mail shall be deemed given on the date of receipt or refusal of receipt. All notices shall be addressed to the appropriate Party as follows:

If to Covered Entity:

Attn: _____

If to Business Associate:

Attn: _____

C. **Amendments.** This BAA may not be changed or modified in any manner except by an instrument in writing signed by a duly authorized officer of each of the Parties hereto. The Parties, however, agree to amend this BAA from time to time as necessary to comply with the HIPAA Regulations.

D. **Choice Of Law.** This BAA and the rights and the obligations of the Parties hereunder shall be governed by and construed under the laws of the [State of Massachusetts] without regard to applicable conflict of laws principles.

E. **Assignment Of Rights And Delegation Of Duties.** This BAA is binding upon and inures to the benefit of the Parties hereto and their respective successors and permitted assigns. Neither Party may assign any of its rights or delegate any of its obligations under this BAA without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Notwithstanding any provisions to the contrary, however, Business Associate retains the right to assign or delegate any of its rights or obligations hereunder to any of its wholly owned subsidiaries, affiliates or successor companies. Assignments made in violation of this provision are null and void.

F. **Nature Of BAA.** Nothing in this BAA shall be construed to create (i) a partnership, joint venture or other joint business relationship between the Parties or any of their affiliates, (ii) any fiduciary duty owed by one Party to another Party or any of its affiliates, or (iii) a relationship of employer and employee between the Parties. The Parties explicitly agree that Business Associate is an independent contractor of Covered Entity, and not an agent of Covered Entity.

G. **No Waiver.** Failure or delay on the part of either Party to exercise any right, power, privilege or remedy hereunder shall not constitute a waiver thereof. No provision of this BAA may be waived by either Party except by a writing signed by an authorized representative of the Party making the waiver.

H. **Severability.** The provisions of this BAA shall be severable, and if any provision of this BAA shall be held or declared to be illegal, invalid or unenforceable, the remainder of this BAA shall continue in full force and effect as though such illegal, invalid or unenforceable provision had not been contained herein.

I. **No Third Party Beneficiaries.** Nothing in this BAA shall be considered or construed as conferring any right or benefit on a person not party to this BAA nor imposing any obligations on either Party hereto to persons not a party to this BAA.

J. **Headings.** The descriptive headings of the articles, sections, subsections, exhibits and schedules of this BAA are inserted for convenience only, do not constitute a part of this BAA and shall not affect in any way the meaning or interpretation of this BAA.

K. **Entire BAA.** This BAA, together with all Exhibits, Riders and amendments, if applicable, which are fully completed and signed by authorized persons on behalf of both Parties from time to time while this BAA is in effect, constitutes the entire BAA between the Parties hereto with respect to the subject matter hereof and supersedes all previous written or oral understandings, BAAs, negotiations, commitments, and any other writing and communication by or between the Parties with respect to the subject matter hereof. In the event of any inconsistency or conflict between any provisions of this BAA in any provisions of the Agreements, Exhibits, Riders, or amendments, the provisions of this BAA shall control.

L. **Regulatory References.** A citation in this BAA to the Code of Federal Regulations shall mean the cited section as that section may be amended from time to time.

M. **Counterparts.** This BAA may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document. In making proof of this BAA, it shall not be necessary to produce or account for more than one such counterpart executed by the party against whom enforcement of this BAA is sought. Signatures to this BAA transmitted by facsimile transmission, by electronic mail in portable document format (“.pdf”) form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same force and effect as physical execution and delivery of the paper document bearing the original signature.

[Signatures on Next Page]

IN WITNESS WHEREOF, the parties hereto have caused this Business Associate Agreement to be executed and delivered as of the day and year first above written.

BUSINESS ASSOCIATE

COVERED ENTITY

By:

By:

Name:

Name:

Title:

Title:

[Signature Page to Business Associate Agreement]