

The Janssen Biotech, Inc. Support System HIPAA Business Associate Agreement

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and its implementing regulations in 45 CFR Parts 160 and 164 as amended from time to time, including by the Health Information Technology for Economic and Clinical Health Act (collectively, the "Privacy and Security Rules"), contain requirements for maintaining the privacy and security of a person's protected health information. For purposes of this Agreement, the terms "Protected Health Information" or "PHI" and "Electronic Protected Health Information" or "EPHI" shall have the same meaning as such terms are defined in 45 CFR § 160.103, but limited to such information created, received, maintained, or transmitted by Company in its capacity as a Business Associate of Covered Entity (each as defined below).

The Lash Group, Inc., the administrator of the Janssen Biotech Support Services Program, and Janssen Biotech, Inc., may meet the definition of a "Business Associate," as defined in 45 CFR § 160.103 issued by the Department of Health and Human Services ("HHS"), by providing services to or on behalf of the Covered Entity listed below ("Covered Entity"). Janssen Biotech, Inc., will not meet the definition of a Business Associate except in the event that The Lash Group, Inc. no longer provides Business Associate services as set forth herein and Janssen Biotech, Inc., assumes responsibilities for operating the Janssen Biotech Support Services Program during any resulting transition to a new replacement program administrator. The Lash Group, Inc. and Janssen Biotech, Inc., shall each be referenced individually as "Company" to the extent that each meets the definition of a Business Associate. Covered Entity and Company agree to the following terms and conditions concerning PHI disclosed to Company by Covered Entity (this "Agreement").

Capitalized terms used but not otherwise defined shall have the same meaning as those terms in the Privacy and Security Rules, as such rules are drafted and may be subsequently updated, amended, or revised, and as of the applicable compliance date of such changes. Notwithstanding anything to the contrary in this Agreement, the term "Company" shall refer to each Company separately, and shall not create any joint liability between the Companies. No Company shall be required to perform any obligations under this Agreement except with respect to PHI held by that Company, and no Company shall be responsible for the obligations, acts or omissions of another Company, and nor shall any Company be acting in a Subcontractor or Business Associate capacity to any other Company under this Agreement.

I. Permitted Uses and Disclosures of PHI by Company

- A. Except as otherwise limited in this Agreement, Company may use or disclose PHI as necessary for the purpose of providing services to Covered Entity associated with administering the Janssen Biotech Support Services Program (the "Program"), including but not limited to providing benefits investigations, alternate coverage research and research for prior authorization processes or administrative denial processes, location assistance for infusion sites (as appropriate), personalized care coordination (including benefits explanation to Covered Entity's patients), and patient education materials (providing disease state information and drug administration education); provided that such use or disclosure would not violate the Privacy and Security Rules if done by Covered Entity.
- B. Company may use or disclose PHI for the proper management and administration of Company or to fulfill Company's legal responsibilities, provided that in the case of disclosures: (1) such disclosures are Required By Law; or (2) Company obtains reasonable assurances from the entity to which the PHI is disclosed that: (a) the PHI will remain confidential and will be used or further disclosed only as Required By Law or for the purpose for which Company disclosed PHI to the entity; and (b) the entity will notify Company of any instances of which it is aware in which the confidentiality of the PHI has been breached.
- C. Company may use and disclose PHI for public health, health oversight and for other purposes permitted by and consistent with 45 CFR § 164.512 or to report violations of law to appropriate federal and state authorities consistent with 45 CFR § 164.502(j)(1).
- D. Company may de-identify the PHI in accordance with 45 CFR § 164.514 and use and disclose the de-identified information for any purpose permitted by law.

II. Obligations of Company

- A. Company agrees not to use or further disclose PHI other than as permitted by this Agreement or as permitted by law, including without limitation the Privacy and Security Rules. Company agrees to comply with the applicable requirements of the Privacy and Security Rules.
- B. Company agrees to implement appropriate safeguards and comply, where applicable, with Subpart C of 45 CFR Part 164 with respect to EPHI, to prevent the use or disclosure of PHI other than as provided in this Agreement.
- C. Company agrees to report to Covered Entity any Security Incident involving EPHI by Company of which it becomes aware or any use or disclosure of PHI by Company of which it becomes aware that is not provided for by this Agreement. The parties agree that this Section satisfies any reporting required by Company of attempted but Unsuccessful Security Incidents (as defined below) for which no additional report shall be required. For purposes of this Agreement, "Unsuccessful Security Incidents" include but are not limited to activity such as "pings" and other broadcast attacks on Company's firewall, port scans, unsuccessful log-on attempts, denials of service and any other activities that do not result in unauthorized access, use or disclosure of EPHI.

- D. In the event that Company provides PHI to any Subcontractor to whom Company delegates the performance of services for Covered Entity, Company agrees to ensure that any such Subcontractor agrees to the same restrictions and conditions that apply through this Agreement to Company with respect to such PHI.
- E. Upon written request from Covered Entity, Company agrees to provide Covered Entity with access to PHI contained in Designated Record Sets held by Company, if any, in order to allow Covered Entity to respond to an Individual's request to access and/or copy PHI. Company also agrees to respond directly to an Individual's request for EPHI in a Designated Record Set in electronic format and to send such EPHI to another person as directed by the Individual to the extent required by and in accordance with 45 CFR § 164.524.
- F. Company agrees to amend PHI contained in Designated Record Sets held by Company, if any, as directed in writing by Covered Entity in accordance with 45 CFR § 164.526.
- G. Company agrees to document disclosures of PHI by Company to any third party that are required to be accounted for under 45 CFR § 164.528, and provide such documentation to Covered Entity upon written request, as necessary to enable Covered Entity to respond to an Individual's request for an account of disclosures of PHI under 45 CFR § 164.528.
- H. To assist the Department of Health and Human Services ("HHS") in determining Covered Entity's compliance with the Privacy and Security Rules, Company agrees to make available their internal practices, books, and records relating to the use and disclosure of PHI received from, or created, or received by Company on behalf of Covered Entity, at Company's offices during regular business hours, to HHS, after reasonable written notice and subject to applicable legal privileges.
- I. Upon discovery by Company of a Breach by Company or its Subcontractors involving Unsecured PHI, Company shall notify Covered Entity in writing without unreasonable delay, and in no event longer than thirty (30) days following discovery of such Breach. Such notice shall include, to the extent possible, the identification of each Individual whose Unsecured PHI has been, or is reasonably believed to have been accessed, acquired, used or disclosed, and any other available information that Covered Entity is required to include in its notification to the Individual under 45 CFR § 164.404(c).
- J. To the extent Company agrees to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, Company agrees to comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligations.

III. Obligations of Covered Entity

- A. Covered Entity will notify Company of any limitation in their notice of privacy practices, to the extent that such limitation may affect Company's use or disclosure of PHI.
- B. Covered Entity will notify Company of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Company's use or disclosure of PHI.
- C. Covered Entity will notify Company of any restriction on the use or disclosure of PHI to which Covered Entity has agreed, to the extent that such restriction may affect Company's use or disclosure of PHI.
- D. Covered Entity shall not request Company to use or disclose PHI in any manner that would not be permissible under the Privacy and Security Rules if done by Covered Entity (except as permitted by Section I.B).
- E. Notwithstanding anything to the contrary in Section III.A-D, Covered Entity shall not agree to any limitations or restrictions on the use or disclosure of PHI otherwise permitted or required by this Agreement without the prior written agreement of Company.

IV. Term and Termination

- A. Each party's obligations under this Agreement will remain in effect for as long as Company provides services to Covered Entity that require the use or disclosure of PHI. The provisions of Sections IV.C and V survive the expiration or termination of this Agreement for any reason.
- B. If Covered Entity learns of a material breach of this Agreement by Company, Covered Entity shall provide an opportunity for Company to cure the breach or end the violation. If Company fails to cure the breach or end the violation within a reasonable amount of time, but no less than thirty (30) calendar days, Covered Entity may terminate this Agreement and any services being provided to Covered Entity by Company that require the use or disclosure of PHI. If the parties agree that it is not possible to cure the breach, Covered Entity may immediately terminate the services being provided to Covered Entity by Company that require the use or disclosure of PHI. If neither termination nor cure is feasible, Covered Entity may report the violation to HHS if required to do so.
- C. Upon termination of this Agreement for any reason, Company will return or destroy all PHI received from Covered Entity if it is commercially feasible to do so. However, if it is not commercially feasible to return or destroy the PHI, Company may retain such PHI and will limit further uses and disclosures of the PHI to those purposes that make return or destruction infeasible for as long as Company maintains the PHI. This provision shall apply to PHI that is in the possession of the Company and/or its Subcontractors. Company will require its Subcontractors to extend the same protections to PHI in their possession.

V. Miscellaneous

- A. This Agreement constitutes the entire agreement among the parties with respect to the protection of PHI disclosed by Covered Entity to Company in the course of Company administering the Program. This Agreement supersedes all prior arrangements and understandings between Company and Covered Entity with respect to the matters addressed herein. The terms of any other agreement related to the protection of PHI disclosed by Covered Entity to Company shall not amend, supplement, or modify this Agreement. Any modification of this Agreement must be in writing and signed by authorized representatives of the parties.
- B. The parties agree to enter into negotiations to modify this Agreement to the extent necessary to make it consistent with any new or revised laws, regulations, or judicial decisions governing the use or disclosure of PHI.
- C. Nothing in this Agreement is intended to confer any rights or obligations on any person other than the parties and their respective successors and assigns.
- D. The parties will make efforts to resolve informally any disputes under this Agreement. NO PARTY WILL BE LIABLE TO ANOTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES WITH RESPECT TO THE MATTERS ADDRESSED IN THIS AGREEMENT, REGARDLESS OF THE CAUSE OR LEGAL THEORY AND WHETHER OR NOT FORESEEABLE.
- E. Furthermore, Covered Entity understands that any of its patients may request (through themselves or their representatives or caregivers) that the Program no longer use their PHI at any time by mailing a letter requesting such cancellation to the Janssen Biotech Support Services Program, c/o The Lash Group, Inc., P.O. Box 220829, Charlotte, NC 28222.
- F. All notices, requests, and demands or other communications to be given under this Agreement to a party shall be made by (1) first class mail, registered or certified, (2) overnight courier or personal delivery to such party's address given below, and/or (3) by facsimile to the facsimile number listed below, or to such other address or facsimile number as that party shall designate in writing to the other party.
- G. This Agreement shall be governed by and interpreted in accordance with the laws of Delaware, without regard to its conflict of laws principles, except to extent preempted by the Privacy and Security Rules.
- H. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together will constitute one and the same agreement. Facsimile copies shall be deemed to be originals.

“Covered Entity”

Signed by: _____ Name: _____

Title: _____ Date: _____

Organization: _____

Address: _____

Phone: _____ Fax: _____

“Company”

Janssen Biotech, Inc.
800 Ridgeview Drive
Horsham, PA 19044

The Lash Group, Inc.
3735 Glen Lake Drive
Charlotte, NC 28208

Signed by: 	Signed by: 
Name: Catherine Owen	Name: Kristy Blackwelder
Title: Vice President, Immunology Marketing	Title: Director
Date: _____	Date: _____

**Fax completed form to 1-866-489-5955 or mail to the Janssen Biotech Support Services Program,
P.O. Box 220829, Charlotte, NC 28222.
For additional information, call 1-888-222-3771.**

Janssen Biotech, Inc., Proprietary