

Loria Pharmaceutical, LLC
POLICY

Policy No.	120
Subject	Business Associate Agreement
Effective Date	03/1/2021

SUMMARY, DESCRIPTION:

Licensor’s Business Associate Agreement.

BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT (“BAA”) is entered into as of the date of the INDEPENDENT LICENSEE AND SERVICE AGREEMENT by and between the parties thereto and is incorporated by reference therein.

The following terms used in this BAA shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

A. Specific definitions

- (a) Business Associate. “Business Associate” shall generally have the same meaning as the term “business associate” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean Licensor.
- (b) Covered Entity. “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean Licensee.
- (c) HIPAA Rules. “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

B. Obligations and Activities of Business Associate

Business Associate agrees to:

- (a) Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law;
- (b) Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of protected health information other than as provided for by the Agreement;

- (c) Report to covered entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware;
- (d) In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information;
- (e) Make available protected health information in a designated record set to the covered entity or its designee as necessary to satisfy covered entity's obligations under 45 CFR 164.524;
- (f) Make any amendment(s) to protected health information in a designated record set as directed or agreed to by the covered entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy covered entity's obligations under 45 CFR 164.526;
- (g) Maintain and make available the information required to provide an accounting of disclosures to the covered entity or its designee as necessary to satisfy covered entity's obligations under 45 CFR 164.528;
- (h) To the extent the business associate is to carry out one or more of covered entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the covered entity in the performance of such obligation(s); and
- (i) Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

C. Permitted Uses and Disclosures by Business Associate

- (a) Business associate may only use or disclose protected health information pursuant to the limitations set forth in the Agreement.
- (b) Business associate may use or disclose protected health information as required by law.
- (c) Business associate agrees to make uses and disclosures and requests for protected health information consistent with and pursuant to covered entity's minimum necessary policies and procedures to perform under the Agreement.
- (d) Business associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by covered entity, except for the specific uses and disclosures set forth below.
- (e) Business associate may use protected health information for the proper management and administration of the business associate or to carry out the legal responsibilities of the business associate.
- (f) Business associate may disclose protected health information for the proper management

and administration of business associate or to carry out the legal responsibilities of the business associate, provided the disclosures are required by law, or business associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(g) Business associate may provide data aggregation services relating to the health care operations of the covered entity.

D. Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions

(a) Covered entity shall notify business associate of any limitation(s) in the notice of privacy practices of covered entity under 45 CFR 164.520, to the extent that such limitation may affect business associate's use or disclosure of protected health information.

(b) Covered entity shall notify business associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her protected health information, to the extent that such changes may affect business associate's use or disclosure of protected health information.

(c) Covered entity shall notify business associate of any restriction on the use or disclosure of protected health information that covered entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect business associate's use or disclosure of protected health information.

E. Permissible Requests by Covered Entity

Covered entity shall not request business associate to use or disclose protected health information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by covered entity, except unless business associate will use or disclose protected health information for data aggregation or management and administration and legal responsibilities of the business associate or the covered entity.

F. Term and Termination

(a) Term. The Term of this Agreement shall be effective as of the effective date of the Agreement, and shall be coterminous therewith or on the date covered entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

(b) Termination for Cause. Business associate authorizes termination of this Agreement by covered entity if covered entity determines business associate has violated a material term of the Agreement and business associate has not cured the breach or ended the violation within the time specified by covered entity in its notice to business associate of the violation.

(c) Obligations of Business Associate Upon Termination. Upon termination of this Agreement for any reason, business associate, with respect to protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, shall:

(i) Retain only that protected health information which is necessary for business associate to continue its proper management and administration or to carry out its legal responsibilities;

(ii) Return to covered entity or destroy the remaining protected health information that the business still maintains in any form;

(iii) Continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information to prevent use or disclosure of the protected health information, other than as provided for in this Section, for as long as business associate retains the protected health information;

(iv) Not use or disclose the protected health information retained by business associate other than for the purposes for which such protected health information was retained and subject to the same conditions set out at herein which applied prior to termination; and

(v) Return to covered entity or destroy the protected health information retained by business associate when it is no longer needed by business associate for its proper management and administration or to carry out its legal responsibilities.

(d) Survival. The obligations of business associate under this Section shall survive the termination of this Agreement.

G. Miscellaneous

(a) Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

(b) Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

(c) Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

[END OF BUSINESS ASSOCIATE AGREEMENT]