

BUSINESS ASSOCIATE AGREEMENT

Note: This Agreement should be used by a covered entity entering into a new business relationship with a business associate. Section 4(b) addresses particular "incident" reporting obligations that apply not only under HIPAA but also under the FTC Red Flag Rules and applicable state laws concerned with privacy or security breach involving personal information.

This **BUSINESS ASSOCIATE AGREEMENT** ("Agreement") is made and entered into by and between Orthopaedic Research Foundation, Inc. (hereinafter collectively referred to as "PROVIDERS") and _____ ("BUSINESS ASSOCIATE").

RECITALS

- A. PROVIDERS and BUSINESS ASSOCIATE is entering into one or more underlying contracts or purchase orders ("Underlying Contracts") that require BUSINESS ASSOCIATE to perform, or assist in the performance of a function or activity, or otherwise provide services of a type for PROVIDERS which qualifies BUSINESS ASSOCIATE as a "Business Associate" as that term is defined by the Health Information Portability and Accountability Act of 1996 and all such regulations promulgated thereunder ("HIPAA").
- B. PROVIDERS and BUSINESS ASSOCIATE desire to enter into this Agreement in order to provide satisfactory assurances to PROVIDERS that BUSINESS ASSOCIATE shall maintain appropriate Administrative, Physical and Technical Safeguards to protect the Confidentiality, Integrity and Availability of any and all Protected Health Information that is the property of PROVIDERS and which BUSINESS ASSOCIATE requires in order to perform, or assist in the performance of a function or activity on behalf of PROVIDERS hereunder ("PHI"), all in accordance with HIPAA as amended, including but not limited to the statutory Agreements to HIPAA that were enacted under Title XIII of the American Recovery and Reinvestment Act of 2009 ("ARRA") which is entitled the Health Information Technology for Economic and Clinical Health ("HITECH") Act (hereinafter collectively referred to as "HIPAA") and other applicable requirements discussed herein. Except as supplemented, the terms of the Underlying Contracts shall continue unchanged and shall apply with full force and effect as to the matters addressed therein.

NOW THEREFORE, PROVIDERS and BUSINESS ASSOCIATE agree as follows:

1. **Definitions.** All capitalized terms and phrases in this Agreement shall have the same meanings as defined by HIPAA and if not otherwise defined therein, shall have their ordinary and customary meaning:
2. **Restriction on Use and Disclosure of Protected Health Information.** BUSINESS ASSOCIATE shall not Use or Disclose PHI except as permitted or required by an Underlying Contract, this Agreement, or HIPAA.
3. **Authorized Uses and Disclosures.** BUSINESS ASSOCIATE is hereby authorized to Use and Disclose PHI on a "Need to Know" basis, but only in connection with the performance of the particular functions, activities or services set forth in the Underlying Contracts or as otherwise required by PROVIDERS, in writing, from time to time. BUSINESS ASSOCIATE may also Use and Disclose PHI for the proper management and administration of BUSINESS ASSOCIATE or to carry out the legal responsibilities of BUSINESS ASSOCIATE; provided (a) the Disclosure is Required by Law; or (b) BUSINESS ASSOCIATE obtains reasonable assurances from the third party to whom the PHI is Disclosed that the PHI will be held confidential and will be Used or further Disclosed only for authorized purposes of as otherwise Required by Law, and the third party agrees to immediately notify the BUSINESS ASSOCIATE if there is any reason to believe the confidentiality of the PHI has been breached.
4. **BUSINESS ASSOCIATE Obligations.**
 - (a) **Compliance; Safeguards.** BUSINESS ASSOCIATE represents and warrants that BUSINESS ASSOCIATE complies with HIPAA to the extent applicable to BUSINESS ASSOCIATE.

BUSINESS ASSOCIATE shall implement and document appropriate Administrative, Physical and Technical Safeguards in order to preserve the Confidentiality, Integrity and Availability of all PHI and to prevent any unauthorized Use or Disclosure of PHI, or any Breach or Security Incident, or other material breach or violation of an Underlying Contract, this Agreement or HIPAA involving said PHI (hereinafter collectively referred to as "Incident").

- (b) **Reporting.** BUSINESS ASSOCIATE shall report to PROVIDERS any Incident involving PHI or other nonpublic personal information protected by law (hereinafter collectively referred to as "PHI" for purposes of this Section 4(b)) not more than twenty-four (24) hours after BUSINESS ASSOCIATE learns of the Incident. Said report shall identify: (i) the known facts and circumstances related to the Incident; (ii) the PHI that is known to be the subject of the Incident; (iii) the persons who are known to have information about the Incident; and (iv) the corrective action that BUSINESS ASSOCIATE took or will take to mitigate any deleterious effects of the Incident and to prevent future Incidents. BUSINESS ASSOCIATE shall submit a written report to PROVIDERS for review upon request. Additionally, BUSINESS ASSOCIATE, in its capacity as a "service PROVIDERS" to PROVIDERS under the FTC Red Flags Rule set forth at 16 CFR part 681, as amended, shall report to PROVIDERS any suspicious circumstances or "red flags" indicative of actual or possible identity theft or deception as required therein.
- (c) **Agents, Contractors, and Subcontractors.** BUSINESS ASSOCIATE shall ensure that any agent, contractor, or subcontractor, to whom it provides Protected Health Information, agrees, in writing, to the same restrictions and conditions that apply to BUSINESS ASSOCIATE under this Agreement.
- (d) **Patient's Access to PHI.** BUSINESS ASSOCIATE shall act in a manner that permits PROVIDERS to permit Patient Access to PHI in accordance with HIPAA, as amended.
- (e) **Agreement of PHI.** BUSINESS ASSOCIATE shall act in a manner that permits PROVIDERS to make Agreements to PHI in accordance with HIPAA, as amended.
- (f) **Accounting of Disclosures.** BUSINESS ASSOCIATE shall act in a manner that permits PROVIDERS to provide an accounting of Disclosures to Patients in accordance with HIPAA, as amended.
- (g) **Practices, Books and Records.** BUSINESS ASSOCIATE shall make its internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by BUSINESS ASSOCIATE on behalf of PROVIDERS, available to the Secretary for the purpose of determining PROVIDERS'S compliance with the HIPAA, subject to the BUSINESS ASSOCIATE'S professional obligations with respect to such practices, books and records.
- (h) **Cure of Noncompliance.** If PROVIDERS notifies BUSINESS ASSOCIATE of any Incident under Section 4(b) herein, or alternatively, if BUSINESS ASSOCIATE notifies PROVIDERS of an Incident under Section 6(c) herein, BUSINESS ASSOCIATE shall immediately take all steps necessary to cure any such Incident immediately, notwithstanding PROVIDERS's right to terminate the Underlying Contract(s) and this Agreement under Section 6(a) herein.
- (i) **Mitigation.** Business Associate shall take reasonable steps to mitigate, to the extent practicable, any harmful effect to PHI that is known to BUSINESS ASSOCIATE or communicated to BUSINESS ASSOCIATE by PROVIDERS that is the result of any Incident; provided, however, that this provision shall not be deemed to permit or excuse any such violation.
- (j) **Legal Obligations.** In the event BUSINESS ASSOCIATE believes it has a legal obligation to further Disclose any PHI in BUSINESS ASSOCIATE'S possession, including, but not limited to obligations that arise from the issuance of a third party discovery request, subpoena or court order, BUSINESS ASSOCIATE shall notify PROVIDERS as soon as reasonably practical after it learns of such obligation, and in any event within a time sufficiently in advance of the proposed release

date such that PROVIDERS'S rights and interests would not be prejudiced, as to the legal requirement pursuant to which BUSINESS ASSOCIATE believes the PHI must be released. If PROVIDERS objects to the release of such PHI, BUSINESS ASSOCIATE shall allow PROVIDERS to exercise any legal rights or remedies which either PROVIDERS or BUSINESS ASSOCIATE might have with respect to the further Disclosure of PHI.

- (k) **Return or Destruction of the PHI.** Upon the termination of the business relationship between PROVIDERS and BUSINESS ASSOCIATE, BUSINESS ASSOCIATE shall return to PROVIDERS, or, at PROVIDERS'S direction, destroy, all PHI that BUSINESS ASSOCIATE has created or received and maintained or stored in any medium or storage system, pursuant to the Underlying Contracts, subject to any professional responsibilities of BUSINESS ASSOCIATE to maintain such information, in which event BUSINESS ASSOCIATE shall maintain all such PHI in accordance with its custom and practice with respect thereto. BUSINESS ASSOCIATE shall complete such return or destruction of PHI (if applicable) as promptly as possible, but not later than thirty (30) after the effective date of the termination, cancellation, expiration or other conclusion of the Underlying Contracts. BUSINESS ASSOCIATE shall identify any recorded PHI of PROVIDERS that is in BUSINESS ASSOCIATE'S possession and which cannot feasibly be returned or destroyed to PROVIDERS, and BUSINESS ASSOCIATE shall limit any further Use of that PHI to those purposes that make return or destruction of said PHI infeasible. Within said thirty (30) days, BUSINESS ASSOCIATE shall certify to PROVIDERS, in writing and under oath, (i) that the return of all PHI has been completed; and (ii) that any PHI not returned will be Used or Disclosed by BUSINESS ASSOCIATE only for those purposes which make return of the PHI infeasible or not required. BUSINESS ASSOCIATE shall remain bound by the provisions of this Agreement, even after termination of any Underlying Contracts, until such time as all PHI has been (i) returned to PROVIDERS; (ii) De-Identified; or (iii) otherwise destroyed as provided in this Section; provided that the parties understand and agree that certain unrecorded information can not be returned, destroyed, or De-Identified, so the BUSINESS ASSOCIATE shall remain bound by the provisions of this Agreement so long as BUSINESS ASSOCIATE possesses the PHI.

5. **Term of this Agreement.** This Agreement shall be effective when executed on behalf of both of the parties hereto and shall continue in full force and effect until the effective date of the termination, cancellation, expiration or other conclusion of all Underlying Contracts executed by and between the parties hereto.

6. **Remedies.**

- (a) **Termination.** PROVIDERS shall have the right to terminate the business relationship between PROVIDERS and BUSINESS ASSOCIATE, including any Underlying Contracts, agreements, arrangements or understandings, whether or not in writing, upon which the business relationship is based and such other agreements, arrangements or understandings are hereby amended to permit such termination, if PROVIDERS determines that BUSINESS ASSOCIATE has violated a material term of this Agreement or HIPAA that cannot otherwise be cured by BUSINESS ASSOCIATE under Section 4(h) herein. Termination of the business relationship by PROVIDERS shall be in addition to and not in place of any other remedies that may be available to PROVIDERS.

- (b) **Injunction.** Notwithstanding any other rights or remedies provided for in this Agreement, the parties agree that PROVIDERS may seek injunctive relief to prevent or stop any Incident by BUSINESS ASSOCIATE, or any agent, subcontractor or other third party that received PHI from BUSINESS ASSOCIATE, without the necessity of proving actual damages or the occurrence of the Incident.

7. **Indemnification.** BUSINESS ASSOCIATE shall indemnify and hold PROVIDERS and each of its officers, employees, directors, agents and representatives ("Indemnified Persons") harmless from and against any and all claims, losses, costs, damages, or expenses, including reasonable attorneys' fees, that arise out of any actions or omissions by BUSINESS ASSOCIATE, or any of its officers, employees,

directors, agents or representatives which result in an Incident caused by BUSINESS ASSOCIATE as that term is defined herein, and without limiting the foregoing, PROVIDERS shall give BUSINESS ASSOCIATE prompt written notice of such claim, suit, or proceeding.

8. **Conflicting Laws and Obligations.** If BUSINESS ASSOCIATE believes that it is unable to comply with any of its obligations under this Agreement due to any conflicting laws, regulations, pronouncements, or ethical obligations, it may seek a determination, or judgment, from a court of competent jurisdiction regarding its ability to comply with such obligations, so long as such actions will not cause PROVIDERS to be in violation of HIPAA.
9. **Notices.** Any notices required or permitted to be given under this Agreement shall be in writing and shall be personally delivered or sent by certified or registered mail, first class postage prepaid, return receipt requested, or by prepaid overnight delivery service such that proof of delivery will be obtained, and shall be addressed as set forth below or to such other address as may be specified in a prior written notice to the other party:

If to PROVIDERS:
Orthopaedic Research Foundation, Inc
8450 Northwest Boulevard
Indianapolis, IN 46278

IF to BUSINESS ASSOCIATE:

Such notice shall be deemed to be given on the date it is deposited in the mail as stated above, on the date it is given to the overnight delivery service, or the date it is given personally to the party to whom it is directed. A notice shall be deemed to have been given personally to a party if it is handed to the representative of the party to whom the notice must be addressed or if left at his or her office located at the street address to which a notice would be mailed.

10. **Agreement.** This Agreement may not be changed, modified, or amended except by a written agreement executed by an authorized representative acting on behalf of each of the parties.
11. **No Waiver.** No waiver of one or more of the provisions of this Agreement or the failure to enforce any provision of this Agreement by either party shall be construed as a waiver of any subsequent breach of this Agreement, or a waiver of the right at any time thereafter to require strict compliance with all of its terms.
12. **Entire Agreement.** This Agreement sets forth the entire agreement and understanding between the parties as to the matters contained in it, and supersedes all prior discussions, agreements, and understandings of every kind and nature between them.
13. **Headings.** The headings placed before the various paragraphs and subparagraphs of this Agreement are inserted for each of reference only, do not constitute a part of this Agreement, and shall not be used in any way whatsoever in the construction or interpretation of this Agreement.
14. **Governing Law.** This Agreement shall be construed and enforced in accordance with, and governed by, the laws of the state of Indiana without reference to the choice of laws principles thereof.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives on the dates set forth below.

“PROVIDERS”

Orthopaedic Research Foundation, Inc

BY: Melanie Glover
PRINTED: Melanie Glover, MD
ITS: Research Director
DATED: 11/17/2020

“BUSINESS ASSOCIATE”

BY: _____
PRINTED: _____
ITS: _____
DATED: _____