

#### Registry Program Improving Orthopaedic Care Through Data

#### PARTICIPANT INFORMATION AND INSTRUCTION SHEET

#### **Participant Information:**

Name	
State of Organization	
Participant Type	☐ Private Physician Practice ☐ Single Hospital ☐ Health System (parent, on behalf of itself and its Affiliates) ☐ Ambulatory Surgery Center (ASC)
Primary Contact Name	
<b>Primary Contact Title</b>	
Primary Contact Telephone	
Primary Contact E-mail	
Primary Address	
Invoice Contact Name	
Invoice Contact Telephone	
Invoice Contact Email	
Selected Registries	☐ American Joint Replacement Registry (AJRR)
	☐ Shoulder and Elbow Registry (SER)
	☐Musculoskeletal Tumor Registry (MsTR)
	☐ American Spine Registry* (ASR)
	□ Fracture & Trauma Registry (FTR)
	= Tractate & Tradina Region (1 TR)

#### **MASTER REGISTRY PARTICIPATION AGREEMENT**

#### **AAOS REGISTRY PROGRAM**

THIS AGREEMENT is entered into and made effective the day of,	20
("Effective Date"), by and between (a) THE AMERICAN ACADEMY OF ORTHOPA	EDIC
SURGEONS, an Illinois not-for-profit corporation, with its principal place of business	at 9400
West Higgins Road, Rosemont, Illinois 60018 ("AAOS"); and (b)	entity
known as ("Participant").	_

WHEREAS, AAOS owns certain computerized databases containing information relating to patient treatment, the practice of medicine, and third parties submitting data to these databases pursuant to AAOS rules (said databases collectively referred to herein as the "the Registry"); and

WHEREAS, Participant has expressed an interest in participating in the Registry in accordance with AAOS requirements;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants contained herein, and for other good and valuable consideration, the parties hereto agree as follows:

#### 1. Participation in AAOS Registry Program

- 1.1 Participant agrees to participate in the Registry by transmitting data through a web-based portal or other means designated by AAOS, either directly or via a third-party vendor designated by Participant ("the Vendor") for the collection and submission of data pertaining to the practice of orthopaedics.
- 1.2 Participant will participate in the data harvests conducted by the Registry by submitting Participant's data to the AAOS through the web-based portal, and otherwise complying with the rules and harvest schedules reasonably established by AAOS in connection therewith.
  - 1.2.1 Participant hereby warrants, to the best of its knowledge, that all data submitted for inclusion in the Registry will be accurate and complete, and acknowledges that such data may be subject to independent audit in accordance with terms and conditions mutually agreed upon by the parties. Participant will use its best efforts to address any data or related deficiencies identified by AAOS, and agrees to cooperate with and assist AAOS and its designees in connection with the performance of any independent audit.
  - 1.2.2 Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the Registry.

- 1.2.3 Participant agrees to assist and cooperate with AAOS in its efforts to conduct the Registry.
- 1.2.4 If applicable, Participant takes full responsibility for the acts and omissions of the Vendor in Participant's participation in the Registry. For purposes of this Agreement, any submission of data by Participant through the Vendor shall be treated as if such data were submitted directly by Participant. Participant will immediately notify AAOS of any changes to the agreement with Participant and the Vendor. The Vendor must also complete an Authorized Vendor Agreement and enter into a business associate agreement with Participant in order to act on the Participant's behalf and Participant acknowledges that Vendor will not be authorized to Participate in the Registry on Participant's behalf until such agreements are completed.
- 1.3 Participant agrees and acknowledges that its (or Vendor's) failure to submit data to the Registry, or its (or Vendor's) submission of data to the Registry that does not comply with AAOS requirements, may result in Participant's failure to receive one or more reports generated by the Registry (see Section 2).
- 1.4 Participant agrees and acknowledges that the data captured by the Registry will include certain entity and physician-identifying information (which shall be encrypted during transfer and at rest in the AAOS software system). Participant agrees that it is Participant's responsibility to obtain any permissions required in order to submit such data for inclusion in the Registry, and specifically agrees to indemnify, defend, and hold harmless AAOS from and against all claims and liabilities associated therewith to the extent permitted by applicable law.
- 2. <u>AAOS Reports.</u> Provided that Participant participates in the Registry in accordance with AAOS requirements (including but not limited to Participant's payment of all applicable fees), Participant will be entitled to receive reports and graphical dashboards, all of which will include both aggregated data from the Registry and Participant-specific information; and such other reports as AAOS or its independent service providers may prepare for Participants. All such reports shall be structured to reflect data of the Participant, as directed by Participant in a written request. Additional reports may be created for Participant in consideration for the fees required by AAOS in order to provide them. The aggregated data included in any and all reports provided hereunder constitute "AAOS Intellectual Property" (as defined herein) and, as such, may not be reproduced, further disseminated or otherwise used except as provided in Section 6.4 of this Agreement or as otherwise permitted by AAOS policies and procedures (which shall be made available to Participant).
- 3. Participant Ad Hoc Queries. Participant may submit to AAOS for analysis such requests for ad hoc queries (requiring access to and analysis of aggregate data from the Registry) as Participant may desire. All such requests for ad hoc queries shall be subject to prior approval by AAOS, in accordance with such procedures and other requirements as it may reasonably establish, before efforts are undertaken to respond thereto. In its response to each of Participant's ad hoc queries, AAOS shall give due consideration to scientific merit, the funds and other resources available to address ad hoc queries and other pertinent factors; provided, however, that AAOS may condition its approval of a request for an ad hoc query upon

Participant's agreement to pay the fees required by the AAOS and any other service providers required in order to appropriately address Participant's ad hoc query. As a part of its efforts to promote the use of the Registry as a tool for the development of beneficial scientific information, AAOS will provide reasonable assistance to Participant in refining Participant's requests for ad hoc queries so as to enhance their potential for approval in light of the pertinent factors noted above.

- 4. <u>Fees</u>. Fees payable by Participant to AAOS pursuant to the Agreement are described in Addendum 2(a)-(d), as applicable, and as follows:
- 4.1 Any additional fees payable to address data submitted to the Registry that fails to conform with AAOS requirements.
  - 4.2 Any additional report-related fees required pursuant to Section 2.
  - 4.3 Any additional ad hoc query fees required pursuant to Section 3.
- 4.4 The subscription fees set forth in Addendum 2(a)-(d) provide the Participant (or affiliate detailed in Addendum 2(a)-(d)) with a user license ("User License"), allowing for electronic access to a set of reports and electronic dashboards on demand via the user account RegistryInsights<sup>TM</sup>. The terms and conditions of such access are set forth in Section 7 herein.
- 5. <u>Confidentiality</u>. AAOS acknowledges that the data submitted to the Registry by Participant are deemed confidential. Accordingly, and if applicable, AAOS agrees and acknowledges that it will require any data warehouse service providers to treat such information as confidential pursuant to an appropriate and material term within its written data warehouse service contract for the AAOS. The parties hereby agree to comply with all applicable statutes 1 and regulations, under federal and state laws, including but not limited to the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and any other applicable statutes or regulations concerning patient privacy and data security. To that end, it is agreed and acknowledged that they are executing the Business Associate Contract and Data Use Agreement ("BAC/DUA") attached hereto as Addendum 1 in conjunction with their execution of this Agreement, which is incorporated herein by reference and made part of this Agreement.

#### 6. <u>Intellectual Property</u>.

- 6.1 It is agreed and acknowledged that all data submitted for inclusion in the Registry by or on behalf of Participant are and shall remain Participant's proprietary information, and may be used by AAOS and its designees only in accordance with the terms of this Agreement and any subsequent instruction from Participant with respect thereto (*e.g.*, in connection with data collection efforts of geographically based groups of physicians).
- 6.2 Participant hereby agrees that all data submitted by or on behalf of Participant to AAOS or AAOS's designee for purposes of inclusion in the Registry may be used by AAOS as a part of the Registry and any subset thereof that AAOS may choose to create and use as it sees fit

for the purposes of promoting Participant's and other Registry participants' health care operations, for medical research (as defined by HIPAA regulations) by AAOS and others authorized by AAOS, and the other interests of the Registry (including, without limitation, publication of such data); provided, however, that no such data shall be used and disclosed in such a way as to identify Participant or any individual physician or physician group, unless and until Participant advises AAOS in writing that it has authorized and/or secured appropriate consent for such disclosure. AAOS will not share PHI with third-parties except as otherwise authorized under this Agreement, the BAC/DUA in Addendum 1, and HIPAA.

- 6.3 Participant acknowledges that AAOS is and shall be deemed the owner of all rights to the Registry including but not limited to the aggregate data contained therein and subsets thereof; all data fields, data elements, datasets, databases, and data dictionaires developed by and for the Registry; any and all reports based on Registry data, and all information derived therefrom (including, without limitation, all risk algorithms and associated Beta coefficients and Y intercepts); and all trademarks (including, without limitation, AAOS, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, AJRR, AMERICAN JOINT REPLACEMENT REGISTRY and all variations thereon and graphic representations thereof), trade secrets and all other intellectual property arising from or reflected in the Registry, with the exception of Participant's data (collectively, "AAOS Intellectual Property").
- 6.4 Participant may not use AAOS Intellectual Property without first obtaining the express written consent of AAOS, provided that Participant may use aggregated data from the Registry that have been included in reports to Participant or previously released to the public by AAOS (*e.g.*, in published reports and slide sets) without first obtaining such written consent so long as Participant does not make any statements about such data that are false or misleading.
- 6.5 Neither party shall use the name, trademark, or logo of the other party or its employees for promotional purposes without prior written consent of the other party, except that AAOS may list Participant as a participating entity on its website and in other materials listing its participating entities for noncommercial purposes.
- 7. <u>Access to AAOS RegistryInsights<sup>TM</sup> Platform.</u> During the term of the Agreement, Participant shall have a User License to access the AAOS RegistryInsights<sup>TM</sup> Platform, which includes a predefined list of electronic reports and dashboards tailored to the Participant's data, (the "Service") subject to the following terms and conditions:
- 7.1 Participant may access the AAOS RegistryInsights<sup>TM</sup> solely for Participant's own internal business operations consistent with this Agreement. Participant may not allow third parties to access the Service.
- 7.2 Participant understands and agrees that the access provided to the Service herein conveys no rights or ownership interest in the Service.
- 7.3 Participant acknowledges and agrees that AAOS is not responsible in any way and bears no liability whatsoever for the development or performance of the Service and makes

no representations, warranties, or guarantees and provides no indemnities with respect to the Service.

- 7.4 Participant agrees to pay the subscription fees set forth in Addendum 2.
- 7.5 This User License Will be valid for the term of the Agreement, which is set forth in Section 10.1.
- 7.6 Participant understands and agrees that login credentials for the Service may not be shared with third parties.
- 7.7 Participant understands and agrees that it must immediately notify AAOS of any staffing changes involving authorized users so that AAOS can timely terminate access to the Service for such users. Such changes may include, but are not limited to, termination of employment of an authorized user, or change of employment such that the authorized user's new role does not include a need to access the Service.
- 8. <u>Indemnification; Limitation of Liability</u>. AAOS agrees to indemnify, defend, and hold harmless Participant from and against any and all third-party claims, costs and expenses (including attorneys' fees and expenses), demands, actions and liabilities of every kind and character whatsoever arising or resulting in any way from AAOS's breach of its obligations under this Agreement, absent the gross negligence or willful misconduct of Participant. All of the foregoing rights of indemnification shall apply to any expenses incurred by Participant in defending itself against claims of gross negligence or willful misconduct unless a court of competent jurisdiction concludes in a final judgment that such party seeking indemnification has committed gross negligence or willful misconduct.

Participant agrees to indemnify, defend, and hold harmless AAOS and its data warehouse service provider (if any) or cloud-based service provider (if any) from and against any and all third-party claims, costs and expenses (including attorneys' fees and expenses), demands, actions and liabilities of every kind and character whatsoever arising or resulting in any way from Participant's breach of its obligations under this Agreement, absent the gross negligence or willful misconduct of AAOS. All of the foregoing rights of indemnification shall apply to any expenses incurred by AAOS and any independent data warehouse service provider in defending themselves, respectively, against claims of gross negligence or willful misconduct unless a court of competent jurisdiction concludes in a final judgment that such party seeking indemnification has committed gross negligence or willful misconduct.

Under no circumstances will either party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

9. <u>Insurance</u>. At all times during the term of this Agreement, Participant and AAOS shall maintain insurance with coverage and limits reasonably sufficient to cover their respective obligations hereunder and shall provide proof of such insurance upon the other party's request.

Participant may satisfy the foregoing requirement through an appropriate self-insurance program, but must provide proof of such insurance upon AAOS's request.

#### 10. Term and Termination.

- 10.1 Subject to the terms of Section 10.2, this Agreement shall be effective through December 31, 2023, and shall be automatically renewed on an annual basis at the prevailing rate thereafter unless any party provides the other(s) with a written notice of termination on or before December 1, 2023, or December 1 of any subsequent renewal year.
- 10.2 Either party may terminate this Agreement upon sixty (60) days written notice to the other party. This Agreement may be terminated prior to December 31, 2023 (or December 31 of any subsequent renewal year) upon any party's material breach of this Agreement and any other party's provision of written notice thereof; provided, however, that if said breach is cured to the non-breaching party's(ies') satisfaction (as reflected in written notice thereof) within thirty (30) days after the provision of such notice, said termination notice shall of no further force or effect and this Agreement shall be fully reinstated.
- 11. <u>Equitable Relief</u>. The parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this Agreement, and that emergency injunctive relief shall be available as a potential remedy for any such breach by any other party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this Agreement, but shall be in addition to all other remedies at law or in equity to the non-breaching party (ies).
- 12. <u>Independent Contractors</u>. The relationship of the parties to this Agreement is that of independent contractors, and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.
- 13. <u>Notices</u>. All notices and demands of any kind or nature which any party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States mail, by facsimile transmission or by overnight courier (e.g., Federal Express or DHL) to the following addressees:

If to Participant:	
	Tel:(fax #)
	Attn:
If to AAOS:	American Academy of Orthopaedic Surgeons 9400 West Higgins Rd.
	Rosemont, IL 60018
	Tel: (847) 384-4050
	Fax: (847) 268-9550
	Attn: Office of General Counsel

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Without limiting the generality of the foregoing, if notice is given by facsimile transmission, such notice shall be deemed to be provided upon confirmation of the receipt of the transmission. Any party hereto may, from time to time, by notice in writing served upon the other party(ies) as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

- 14. <u>Headings</u>. The headings of the various sections hereof are intended solely for the convenience of reference and are not intended for any purpose whatsoever to explain, modify or place any construction upon any of the provisions of this Agreement.
- 15. <u>Assignment</u>. This Agreement may not be assigned by any party without the prior express written approval of the other party(ies), except that either party may assign this Agreement to an affiliate, successor entity, or subsidiary without the written approval of the other party.
- 16. <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.
- 17. <u>Waiver</u>. A waiver by any party to this Agreement of any of its terms or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.
- 18. <u>Choice of Law and Forum</u>. All disputes regarding the meaning, effect, force or validity of this Agreement shall be determined according to federal law and the law of the State of Illinois. The parties expressly agree that the federal and state courts located in the State of Illinois are the most reasonable and convenient forums for resolutions of any such disputes, and designate said courts as the exclusive forums in which all such disputes shall be litigated. Accordingly, the parties consent to the jurisdiction and venue of, and service of process by, said courts. Each party agrees that the provisions of this Section 18 are specifically enforceable, and that it shall pay all expenses, damages, and costs (including attorneys' fees and expense) of any

other party if said other party commences, prosecutes, or permits to continue any actions in any other forum.

- 19. <u>Severability</u>. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.
- 20. <u>Survival</u>. The provisions of Sections 5, 6, 8, 9, 11, 18 and all other terms within this Agreement that are necessary or appropriate to give meaning thereto shall survive any termination of this Agreement.
- 21. <u>Entire Agreement</u>. This Agreement, and its exhibits, appendices, and addenda (which are attached hereto and incorporated by reference), (a) constitutes the entire agreement between the parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the party against whom enforcement is sought.

# ADDENDUM 1 TO MASTER REGISTRY PARTICIPATION AGREEMENT: BUSINESS ASSOCIATE CONTRACT AND DATA USE AGREEMENT

**WHEREAS**, the Participation Agreement permits and provides for the Participant, acting as a Covered Entity, to submit data to the Registry, and for AAOS, acting as a Business Associate, to conduct of data analyses that relate to the Participant's Health Care Operations, including but not limited to Data Aggregation, quality assessment, and peer review functions;

**WHEREAS**, the Participation Agreement may from time to time require the receipt, Use, and/or Disclosure of Protected Health Information ("PHI");

**WHEREAS**, the Participation Agreement may from time to time require the Disclosure of PHI in the form of a Limited Data Set ("Limited Data Set Information") for AAOS to provide services to Participant related to its Health Care Operations and for Research purposes; and

WHEREAS, the Parties desire to allocate responsibility for the Use and Disclosure of PHI, including Limited Data Set Information, and to comply with applicable requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and the regulations promulgated thereunder by the United States Department of Health and Human Services ("HHS") codified at 45 CFR Parts 160 and 164, (commonly known as the Privacy and Security Rules) as amended by the Privacy and Security provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public law 111-5 ("HITECH Act"), (collectively referred to herein as the "HIPAA Regulations"), as they pertain to Business Associates and Limited Data Sets;

**NOW THEREFORE**, in consideration of the mutual promises and conditions contained herein, and for other good and valuable consideration, the Parties agree as follows:

### SECTION 1 DEFINITIONS

Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning ascribed to them in the HIPAA Regulations or the Participation Agreement, as the case may be. Except as otherwise specified herein, the term "Agreement" refers to this Business Associate Contract and Data Use Agreement and not the Participation Agreement. PHI will have the meaning ascribed to it in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Participant to AAOS or a Subcontractor of AAOS, or created by AAOS or its Subcontractor on behalf of Participant. PHI will include PHI in electronic form ("Electronic PHI") unless specifically stated otherwise. Limited Data Set Information will have the meaning ascribed to "Limited Data Sets" in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to Limited Data Set Information transmitted from or on behalf of Participant to AAOS or a Subcontractor of AAOS, or created by AAOS or its Subcontractor on behalf of Participant. "Subcontractor" shall have the meaning ascribed to it by the HIPAA Regulations, and shall include any agent or other person who acts on behalf of an entity, provided that AAOS is not acting as an agent of Participant in its role as an independent contractor herein. Unless otherwise specified, the use of the term PHI will be interpreted to include Limited Data Set Information.

#### SECTION 2 EFFECT AND INTERPRETATION

The provisions of this Agreement shall apply with respect to the Use or Disclosure of any PHI by the Parties under the Participation Agreement. In the event of any conflict or inconsistency between the Participation Agreement and this Agreement concerning the Use or Disclosure of PHI, the terms of this Agreement will prevail unless the Parties mutually agree that the applicable terms of the Participation Agreement would be more protective of PHI. The provisions of this Agreement are intended in their totality to implement 45 CFR 164.504(e) and 45 CFR 164.314(a) as they concern Business Associate Contracts and 45 CFR 164.514(e) as it concerns Data Use Agreements. The provisions of the Participation Agreement will remain in full force and effect and are amended by this Agreement only to the extent necessary to effectuate the provisions set forth herein.

### SECTION 3 GENERAL OBLIGATIONS OF AAOS

#### Section 3.1. Business Associate Contract Obligations.

The obligations set out in this Subsection 3.1 apply with respect to AAOS's Use or Disclosure of PHI, other than Limited Data Set Information.

(a) AAOS agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law and agrees to maintain the security and privacy of all PHI in a manner consistent with all applicable laws; provided that Participant will inform AAOS of any specific state laws that it believes are applicable to PHI submitted by Participant and would require AAOS to take compliance steps beyond those required under the HIPAA regulations.

- (b) AAOS agrees to use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI, to prevent Use or Disclosure of PHI other than as provided for by this Agreement. Without limiting the generality of the foregoing, AAOS further agrees to:
- (i) implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.308, 164.310, and 164.312;
- (ii) ensure that any Subcontractor, to whom it provides such PHI agrees to implement reasonable and appropriate safeguards to protect the PHI and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI; and
- (iii) report promptly, but in no case later than five (5) business days after Discovery, to the Participant any Security Incident or Breach of Unsecured PHI that is known to or reasonably should be known to AAOS and shall mitigate, to the extent practicable, any harmful effects of said Security Incident or Breach; provided however, that the Parties acknowledge and agree that this Section 3.1 b(iii) constitutes notice by AAOS to Participant of the ongoing existence and occurrence or attempts of Unsuccessful Security Incidents for which no additional notice to Participant shall be required. "Unsuccessful Security Incidents" means, without limitation, pings and other broadcast attacks on firewalls, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, use or disclosure of PHI.
- (c) AAOS agrees to report promptly, but in no case later than five (5) business days after Discovery, to Participant any Use or Disclosure of PHI which is not authorized by this Agreement of which AAOS becomes aware.
- (d) AAOS agrees to ensure that any Subcontractor that creates, receives, maintains, or transmits PHI, on behalf of AAOS, will agree in writing to comply with the same restrictions and conditions with respect to such information that apply through this Agreement to AAOS, to the extent the restrictions, conditions, and requirements are required under HIPAA. For the purposes of this Agreement, all PHI provided at AAOS's direction to a Subcontractor of AAOS will be deemed to have been provided to AAOS.
- (e) If PHI provided to AAOS, or to which AAOS otherwise has access, constitutes a Designated Record Set, AAOS agrees to provide Participant with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Participant's request, to provide an Individual with access to his or her PHI in order to meet the requirements under 45 CFR 164.524 concerning access of Individuals to Protected Health Information. In the event an Individual contacts AAOS or its Subcontractor directly about gaining access to his or her PHI, AAOS will not provide such access but rather will forward such request to Participant within three (3) business days of such contact, unless otherwise required by law.
- (f) If PHI provided to AAOS, or to which AAOS otherwise has access, constitutes a Designated Record Set, AAOS agrees to make timely amendment(s) to such PHI as

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Participant may direct or agree to pursuant to 45 CFR 164.526. In the event an Individual contacts AAOS or its Subcontractor directly about making amendments to his or her PHI, AAOS will not make such amendments, but rather will promptly forward such request to Participant, unless otherwise required by law.

- (g) AAOS agrees to make internal practices, books and records relating to the Use and Disclosure of PHI available to the Secretary of the United States Department of Health and Human Services, during regular business hours, for purposes of the Secretary's determining compliance with the HIPAA Regulations.
- (h) AAOS agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. In addition, AAOS agrees to provide promptly to Participant or an Individual, upon Participant's reasonable request, information collected in accordance with this Subsection 3.1(h) in order to permit Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. Notwithstanding the foregoing, this Subsection 3.1(h) will not apply with respect to Disclosures made to carry out Participant's Health Care Operations or the Disclosure of Limited Data Set Information, in accordance with the exceptions to 45 CFR 164.528 as set forth in the HIPAA Regulations, provided that this exception shall not apply to Disclosures of PHI through an electronic health record.
- (i) AAOS shall mitigate, to the extent practicable, any adverse effects from any improper Use and/or Disclosure of Protected Health Information by AAOS that are known to AAOS.

#### Section 3.2. Data Use Agreement Obligations.

The obligations set out in this Subsection 3.2 apply only with respect to AAOS's Use or Disclosure of Limited Data Set Information.

- (a) AAOS agrees to not Use or further Disclose Limited Data Set Information other than as permitted by Section 4(d) of this Agreement, or as otherwise Required By Law.
- (b) AAOS agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by Section 4(d) of this Agreement.
- (c) AAOS will report promptly, but in no case later than five (5) business days after Discovery, to Participant any Use or Disclosure of the Limited Data Set Information not permitted by Section 4(d) of this Agreement of which AAOS becomes aware.
- (d) AAOS will not attempt to identify the Individuals to whom the Limited Data Set Information pertains, or attempt to contact such Individuals, provided that this restriction will not be interpreted to prevent AAOS from conducting such activities under the Business Associate Contract provisions of this Agreement. Under no circumstances will AAOS attempt to contact Individuals except with Participant's prior written consent.

- (e) AAOS agrees to require that any Subcontractor to whom it, directly or indirectly, provides Limited Data Set Information will agree in writing to comply with the same restrictions and conditions that apply through this Section 3.2 to AAOS.
- (f) AAOS agrees to enter into a written agreement with each third party to which it Discloses Limited Data Set Information that includes the terms and provisions required by the HIPAA Regulations for such Disclosures.

### SECTION 4 PERMITTED USES AND DISCLOSURES BY AAOS

(a) General Business Associate Contract Use and Disclosure Provisions.

Except as otherwise limited in this Agreement, AAOS may Use or Disclose PHI on behalf of, or in order to provide services to, Participant to the extent such Use or Disclosure is reasonably necessary to facilitate Participant's participation in The Registry, consistent with the Participation Agreement, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant. In providing these services, AAOS will be acting as an independent contractor and not as an employee or agent of Participant. AAOS shall have no authority, express or implied, to commit or obligate Participant in any manner whatsoever.

(b) Specific Business Associate Contract Use and Disclosure Provisions.

The permitted Uses and Disclosures set out in this Subsection 4(b) apply only with respect to AAOS's Use or Disclosure of PHI other than Limited Data Set Information.

- (i) Except as otherwise limited in this Agreement or the Participation Agreement, AAOS may *Use* PHI for the proper management and administration of AAOS or to carry out the legal responsibilities of AAOS.
- (ii) Except as otherwise limited in this Agreement or the Participation Agreement, AAOS may *Disclose* PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or AAOS otherwise obtains reasonable assurances from the person to whom it Discloses the PHI that such person will a) protect the Confidentiality of the PHI; b) Use or further Disclose the PHI only as Required By Law or for the purpose for which it was Disclosed to the person; and c) promptly notify AAOS of any instances of which the person is aware that the Confidentiality of the PHI has been Breached.
- (iii) Except as otherwise limited in this Agreement or the Participation Agreement, AAOS may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).
- (iv) AAOS may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR 164.514(b), including without limitation any documentation requirements. AAOS may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this Agreement; provided that such Use or Disclosure is consistent with the Participation Agreement and applicable law.

- (v) AAOS may partially de-identify any PHI to create a Limited Data Set, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2).
- (c) The Parties agree that the permissible Uses and Disclosures of Protected Health Information set forth in the Participation Agreement and this Agreement are consistent with Participant's minimum necessary policies and procedures.

#### (d) Uses and Disclosures Under Data Use Agreement Provisions.

Notwithstanding Subsection 4(b) above, AAOS may, consistent with this Agreement, Use or Disclose PHI that consists solely of Limited Data Set Information to a third party for Research, Public Health, or Health Care Operations in accordance with the provisions of the HIPAA Regulations concerning Limited Data Sets, provided that such Use or Disclosure is (i) limited to the minimum information necessary to facilitate Participant's participation in The Registry or for AAOS's Research purposes; (ii) is consistent with the Participation Agreement; and (iii) would not violate the HIPAA Regulations if done by Participant. The term Health Care Operations as used herein includes Data Aggregation.

### SECTION 5 GENERAL OBLIGATIONS OF PARTICIPANT

- (a) Participant's Notice of Privacy Practices, Permissions, and Restrictions.
- (i) Participant acknowledges and agrees that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and any other applicable provisions of the HIPAA Regulations. Participant will provide AAOS with a copy of its Notice of Privacy Practices upon request.
- (ii) Participant will provide AAOS with any changes in, or revocation of, the permission by an Individual to Use or Disclose PHI, if such changes affect AAOS's permitted or required Uses and Disclosures.
- (iii) Participant will ensure on a continuing basis that all Disclosures of PHI made to AAOS are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual's PHI to AAOS impermissible. Participant will notify AAOS of any specific or general restrictions on the Use or Disclosure of PHI submitted to AAOS that Participant has agreed to in accordance with 45 CFR 164.522, if such restrictions affect AAOS's permitted or required Uses or Disclosures.
- (b) <u>Permissible Requests by Participant</u>. Participant will not ask AAOS to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by Participant, provided that Participant may, as otherwise permitted under this Agreement, request that AAOS Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of AAOS, as provided for in 45 CFR 164.504(e)(4).

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#### SECTION 6 TERM AND TERMINATION

- (a) <u>Term</u>. This Agreement will commence as of the Effective Date and will remain in effect for a period that is coterminous with the Participation Agreement, unless (i) this Agreement is terminated sooner in accordance with either Subsection (b) or (c) of this Section; or (ii) the Participation Agreement is amended by written agreement of the Parties in a manner that the Parties mutually agree renders the provisions of this Agreement unnecessary.
- (b) <u>Termination for Material Breach</u>. Either Party may terminate this Agreement based upon a material breach of this Agreement by the other Party, provided that the non-breaching Party gives the breaching Party thirty (30) days written notice and the opportunity to cure such breach, and the breach is not cured during the notice period. In the event such material breach is not cured, the non-breaching Party may terminate this Agreement immediately upon the expiration of the notice period. In the event it is not possible to cure such material breach, the non-breaching Party may terminate this Agreement immediately and without any notice.
- (c) <u>Termination Permitted Due to Change in Law</u>. Either Party may terminate this Agreement as permitted in accordance with Section 8(b) of this Agreement upon a change in an applicable law that causes performance in compliance with this Agreement to violate the law. Except as otherwise specified herein, this Agreement shall terminate immediately upon the termination of the Participation Agreement.

#### (d) Effect of Termination.

- (i) Except as provided in paragraph (ii) of this Subsection and except with respect to Limited Data Set Information, upon termination of this Agreement for any reason, AAOS will return or destroy all PHI received from Participant, or created or received by AAOS on behalf of Participant. AAOS will retain no copies of the PHI, except as provided in paragraph (ii) of this Subsection or to the extent that the PHI constitutes Limited Data Set Information.
- (ii) In the event that AAOS reasonably determines that returning or destroying the PHI is infeasible due to inclusion of such PHI in a Database or for other reason, AAOS will not return or destroy the PHI, may retain copies of the PHI to the extent it has been entered into a Database, and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, AAOS will extend the protections of this Agreement to such PHI and limit any further Use or Disclosure of such PHI to those purposes that make the return or destruction infeasible, for so long as AAOS maintains such PHI.
- (iii) The Parties acknowledge and agree that the provision of any PHI to AAOS in accordance with the Participation Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the Parties agree that Participant will refrain from submitting PHI to AAOS, and AAOS will refrain from accepting PHI from Participant. In the event of a termination under either Subsection (b) or (c) of this Section 6, either Party may also elect to terminate the Participation

Agreement. In the event the Parties engage in negotiations undertaken in accordance with Subsection 8(b) of this Agreement, the Parties will suspend during such period of negotiation any provision of the Participation Agreement requiring or obligating either Party to Use or Disclose PHI in a manner that either Party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations.

(iv) The obligations of this Subsection 6(d) will survive any expiration or termination of this Agreement.

#### SECTION 7 INDEMNIFICATION; BREACH NOTIFICATION

(a) Indemnification. AAOS agrees to indemnify and hold harmless Participant from direct losses and damages relating to third-party claims suffered by Participant as a result of AAOS's breach of its obligations under this Agreement. Participant agrees to indemnify and hold harmless AAOS from direct losses and damages relating to third-party claims suffered by AAOS as a result of Participant's breach of its obligations under this Agreement. Under no circumstances, however, will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement. The Parties' obligations under this Section 7 regarding indemnification will survive any expiration or termination of this Agreement.

[IF PARTICIPANT IS A GOVERNMENT INSTITUTION THAT IS NOT ABLE TO PROVIDE INDEMNIFICATION, THE FOLLOWING ALTERNATIVE PROVISION MAY BE SUBSTITUTED FOR THE ABOVE SECTION 7:

#### **7.**Responsibilities of the Parties

Each Party to this Agreement agrees that it will be responsible for its own acts and omissions and the results thereof; and, shall not be responsible for the acts and omissions of the other Party and the results thereof. Each Party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees under this Agreement. Under no circumstances will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

(b) <u>Breach Notification</u>. Participant and AAOS agree that if either fails to adhere to any of the provisions set forth in this Agreement or the Participation Agreement and, as a result, PHI or other confidential information is unlawfully accessed, used, or disclosed, the Party or Parties responsible for the Breach agree to pay all (or their proportionate share of) costs associated with any notification to affected individuals that is required by law, and the Party or Parties responsible will also pay any and all (or their proportionate share of) fines and/or administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting. Unless otherwise agreed upon by the

Parties, if AAOS notifies Participant of a Breach of Unsecured PHI, Participant shall be responsible for providing notification to comply with Breach Notification requirements set forth in the HIPAA regulations. Such notification shall not identify AAOS unless agreed upon by AAOS in writing.

#### SECTION 8 MISCELLANEOUS

- (a) <u>Regulatory References</u>. A reference in this Agreement to a section in the HIPAA Regulations means the section as in effect or as amended from time to time and for which compliance is required.
- (b) Amendment. This Agreement may not be amended except by the mutual written agreement of the Parties. Notwithstanding the foregoing, the Parties agree to work together in good faith to take such action as is necessary to make technical amendments to this Agreement from time to time if necessary for Participant and/or AAOS to comply with the requirements of HIPAA, the HIPAA Regulations, or any applicable provisions of any other federal or state law, as such laws or regulations may be amended from time to time. However, should any state or federal law or regulation now existing or enacted after the Effective Date of this Agreement, including without limitation HIPAA or the HIPAA Regulations, be amended or interpreted by judicial decision or a regulatory body in such a manner that either Party reasonably determines renders any provision of this Agreement in violation of such law or regulation or adversely affects the Parties' abilities to perform their obligations under this Agreement, the Parties agree to negotiate in good faith to amend this Agreement so as to comply with such law or regulation and to preserve the viability of this Agreement. If, after negotiating in good faith, the Parties are unable to reach agreement as to any necessary amendments, either Party may terminate this Agreement without penalty.
- (c) <u>Assignment</u>. Neither this Agreement nor either Parties' rights and obligations in this Agreement may be assigned to a third party without the prior written consent of the non-assigning Party.
- (d) <u>Interpretation</u>. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participant and AAOS to comply with the HIPAA Regulations or applicable state patient privacy laws or regulations. Where provisions of this Agreement are different from those mandated in the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this Agreement will control.
- (e) <u>Third Party Beneficiaries</u>. AAOS and Participant agree that Individuals whose PHI is Used or Disclosed to AAOS or its Subcontractors under this Agreement are not third-party beneficiaries of this Agreement or the Participation Agreement.
- (f) <u>Waiver</u>. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving Party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

(g) <u>Correspondence</u>. The Parties will send any reports or notices required under this Agreement to the addresses set forth in the notice provision of the Participation Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement, as of the date and year first written above.

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS	PARTICIPANT
By:	By:
Name:	Name:
Title:	Title:
Date:	Date:

## ADDENDUM 2(a) TO MASTER REGISTRY PARTICIPATION AGREEMENT $\frac{(AJRR)}{}$

Subscription Fees entitle the Participant(s) listed below to access the AAOS RegistryInsights <sup>TM</sup> Platform_as described in section 7 of the Participation Agreement.		
Site Name(s):		
Selected Registry	☐ American Joint Replacement Registry (AJRR)	

Annual per-site Participation Fee	Number of sites	Term of participation	Total subscription fee
\$4,250.00	1	Annually	\$4,250.00
One time configuration fee	Number of sites	N/A	Total configuration fee
\$750.00	1	N/A	\$750.00
		TOTAL	\$5,000.00

Notes:

## ADDENDUM 2(b) TO MASTER REGISTRY PARTICIPATION AGREEMENT $\underbrace{(SER)}$

Subscription Fees entitle the Participant(s) listed below to access the AAOS RegistryInsights<sup>TM</sup> Platform\_as described in section 7 of the Participation Agreement.

Site Name(s):		
		-
Selected Registry	☐Shoulder and Elbow Registry (SER)	

Annual per-site Participation Fee	Number of sites	x (Term of participation)	Total subscription fee
\$3,500.00	1	Annually	\$3,500.00
One time configuration fee	Number of sites	N/A	Total configuration fee
\$750.00	1	N/A	\$750.00
		TOTAL	\$4,250.00

Notes:

## ADDENDUM 2(c) TO MASTER REGISTRY PARTICIPATION AGREEMENT $\underline{(MsTR)}$

Subscription Fees entitle the Participant(s) listed below to access the AAOS RegistryInsights<sup>TM</sup> Platform as described in section 7 of the Participation Agreement.

Site Name(s):		
		<del></del>
Calcated Designary		1
Selected Registry	☐Musculoskeletal Tumor Registry (MsTR)	

Annual per-site Participation Fee	Number of sites	Term of participation	Total subscription fee
\$3,500.00	1	Annually	\$3,500.00
One time configuration fee	Number of sites	N/A	Total configuration fee
\$750.00	1	N/A	\$750.00
	TOTAL		\$4,250.00

Notes:

## ADDENDUM 2(d) TO MASTER REGISTRY PARTICIPATION AGREEMENT

(ASR)

Subscription Fees entitle the Participant(s) listed below to access the AAOS RegistryInsights<sup>TM</sup> Platform as described in section 7 of the Participation Agreement.

Site Name(s):		
Selected Registry	☐American Spine Registry* (ASR)	

Annual per-site	Number of sites	Term of	Total subscription fee
Participation Fee		participation	
\$5,000.00	1	Annually	\$5,000.00
One time configuration fee	Numbe of sites	N/A	Total configuration fee
\$750.00	1	N/A	\$750.00
		TOTAL	\$5,750.00

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<sup>\*</sup>American Spine Registry (ASR) is a partnership of the American Association of Neurological Surgeons/NeuroPoint Alliance and the American Academy of Orthopaedic Surgeons. The ASR expands the reach of the Quality Outcomes Database (QOD) Spine registry to facilitate the participation of all North American spine surgeons in a shared, quality data-collection platform.

## ADDENDUM 2(e) TO MASTER REGISTRY PARTICIPATION AGREEMENT (FTR)

Subscription Fees entitle the Participant(s) listed below to access the AAOS RegistryInsights<sup>TM</sup> Platform\_as described in section 7 of the Participation Agreement.

Site Name(s):		
		-
Selected Registry	☐ Fracture & Trauma Registry (FTR)	

Annual per-site	Number of sites	Term of	Total subscription fee
Participation Fee		participation	
\$3,500.00	1	Annually	\$3,500.00
One time	Numbe of sites	N/A	Total configuration fee
configuration fee			
\$750.00	1	N/A	\$750.00
		TOTAL	\$4,250.00

#### Notes:

### MASTER REGISTRY PARTICIPATION AGREEMENT REGISTRY ACCESS TO ORTHOPAEDIC SURGEONS

**WHEREAS**, the AAOS Registries contain clinical information that may be relevant to support the individual medical care by provided by physicians ("Physicians");

**WHEREAS**, the undersigned hospital or amubulatory surgery center participates in one or more AAOS Registries through its parent or affiliated entity ("Registry Participant");

**WHEREAS,** the AAOS is willing, at the request of Participant, to make limited access to one or more AAOS Registries available to Physicians through their active membership on the medical staff of Participant; and

**WHEREAS,** such Physicians may not, individually or as a part of a group practice, participate in an AAOS Registry or Registries.

**NOW, THEREFORE**, the AAOS and the undersigned Participant agree as follows:

- 1. The Physicians listed on Addendum 3-Exhibit A-D shall have access to the information listed to the AAOS Registries listed on Addendum 3-Exhibit A but only the information expressly identified. Such access is conditioned on the Physician maintaining active membership on the medical staff of the Participant. Participant is responsible for informing AAOS of any change in the employment status of the Physician.
- 2 Participant warrants that each Physician will be bound by the obligations set forth in this Addendum and, to the extent applicable, in the Master Registry Participation Agreement. Participant is responsible for compliance of the Physician with the foregoing requirements.
- 3. The information obtained from an AAOS Registry will be used by the Physician only for purposes of individual patient Treatment or for Quality Improvement as a part of Health Care Operations. It is not for use in Research, nor shall it be published, aggregated, de-identified or Sold. The capitalized terms in this Section have the meaning ascribed to them in HIPAA.
- 4. Subject to compliance with the terms herein, this Addendum 3 does not require additional fees from Participant or Site or fees from the Physician. The Physician shall, however, be a member in good standing of the AAOS, except that Physicians granted access to the American Spine Registry may be a member in good standing of either AAOS or the American Association of Neurological Surgeons.
- 5. This Addendum does not grant the Physicians any contractual or other rights against the AAOS under the Participation Agreement ("Participation Agreement") or under any other agreement between the AAOS and the Participant. The Physician is not a third party beneficiary of the Participation Agreement or any other AAOS/Participant/ Agreement.
- 6. The Participant and each Physician are Covered Entities under HIPAA. The AAOS is a Business Associate of the Participant. As a Covered Entity, the Participant hereby instructs AAOS to make the information (including Protected Health Information) available through

AAOS Registries specified in this Addendum available to designated Physicians, in its capacity as the Hospital's Business Associate. Participant acknowledges and agrees that once the information leaves AAOS systems, it shall have no further obligation or liability for the information.

- 7. The AAOS makes no representation or warranty as to the ongoing availability, completeness, accuracy, or substance of information obtainable from an AAOS Registry. The information is provided entirely "as-is" and "as-available" and AAOS disclaims all warranties, express or implied, with regard to the information. The Physician is solely responsible for the Physician's clinical decision making. Participant and Physician waive any and all claims, now known or later discovered, that they may have against AAOS relating in any way to the information.
- 8. Participant agrees that it is responsible for any damages or claims against the AAOS arising from the Physician's access to an AAOS Registry, including a HIPAA Breach of PHI or a state breach of Personal information under the indemnification provisions of the master Registry Participation Agreement.

Participant	American Academy Of Orthopaedic Surgeons
By:	By:
Name:	Name:
Title:	_Title:
Date:	Date:

## Addendum 3 - Exhibit A American Joint Replacement Regisitry (AJRR) Authorized AJRR Surgeons

Surgeon Name (First, Last)	<b>Email Address</b>	NPI
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#### Addendum 3 - Exhibit B Shoulder and Elbow Registry (SER) Authorized SER Surgeons

Surgeon Name (First, Last)	<b>Email Address</b>	NPI
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#### Addendum 3 - Exhibit C Musculoskeletal Tumor Registry (MsTR) Authorized MsTR Surgeons

Surgeon Name (First, Last)	Email Address	NPI
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#### Addendum 3 - Exhibit D American Spine Registry (ASR) Authorized ASR Surgeons

Surgeon Name (First, Last) Email Address	NPI
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#### Addendum 3 - Exhibit E Fracture & Trauma Registry (FTR) Authorized FTR Surgeons

Surgeon Name (First, Last) Email Address	NPI
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