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**BUSINESS ASSOCIATE AGREEMENT**

 This Business Associate Agreement (“Agreement”) is entered into between [INSERT COVERED ENTITY], a [INSERT COMPANY TYPE AND STATE OF INCORPORATION] (“Covered Entity”) and the Arizona Board of Regents for and on behalf of Arizona State University (“ASU”) and its [INSERT DEPARTMENT] (collectively “Business Associate”), with an effective date of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Effective Date”). This Agreement sets out the responsibilities and obligations of Business Associate as a business associate of Covered Entity under the Health Insurance Portability and Accountability Act (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”). This Agreement replaces and supersedes the Business Associate Agreement dated \_\_\_\_\_\_\_\_\_. [INCLUDE PRECEDING SENTENCE ONLY IF THIS AGREEMENT IS REPLACING EARLIER AGREEMENT.]

**RECITALS:**

A. [USE THIS LANGUAGE IF THERE IS AN UNDERLYING WRITTEN AGREEMENT] Business Associate and Covered Entity have entered into a written agreement titled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Written Agreement”), with an effective date of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Business Associate performs the services described in Written Agreement (“Services”).

[ALTERNATIVE LANGUAGE IF THERE IS NO UNDERLYING WRITTEN AGREMENT]: Business Associate provides services (“Services”) to Covered Entity, including but not limited to the following, and as may change from time to time:

1. Collecting of health care data from Covered Entity into a repository to produce useful analyses concerning the provision of health care services;
2. Providing of information to improve the health care operations of covered entities, so that those entities can identify ways to improve services and reduce costs;
3. Conducting of studies on behalf of the Covered Entity and/or other entities on mutually agreed upon topics(s).

B. Covered Entity may make available to Business Associate Protected Health Information of Individuals in conjunction with Services. Business Associate will Use or Disclose such Protected Health Information only in accordance with this Agreement.

**AGREEMENT:**

Business Associate and Covered Entity agree to the terms and conditions of this Agreement in order to comply with the rules on handling of PHI under the HIPAA Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subpart E (“Privacy Standards”), the HIPAA Security Standards, 45 C.F.R. Part 160 and Part 164, Subpart C (“Security Standards”), and the HIPAA Breach Notification Regulations, 45 C.F.R. Part 164, Subpart D (“Breach Notification Regulations”), all as amended from time to time.

1. **DEFINITIONS**
	1. Catch-All Definition. Unless otherwise provided, all capitalized terms in this Agreement will have the same meaning as provided under the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Electronic Protected Health Information, 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.
	2. Specific Definitions.
		1. 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 the Arizona Board of Regents for and on behalf of Arizona State University (“ASU”) and its Center for Health Information & Research.
		2. 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 [Insert Name of Business Associate].
		3. HIPAA Rules. “HIPAA Rules” shall mean the Privacy Standards, the Security Standards, the Breach Notification Regulations, and the Enforcement Rules found in 45 CFR Part 160 and Part 164.
2. **USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION**
	1. Performance of Services. Business Associate will Use or Disclose PHI only for those purposes necessary to perform Services, or as otherwise expressly permitted in this Agreement or required by law, and will not further Use or Disclose such PHI. To the extent Business Associate agrees in writing to carry out the Covered Entity’s obligations under the HIPAA Rules, Business Associate will comply with the requirements applicable to Covered Entity in the performance of those obligations.
	2. Subcontractor Performance of Services. Business Associate agrees that, when one of its subcontractors creates, maintains, transmits or receives PHI on behalf of Business Associate, Business Associate first will enter into a contract or confidentiality agreement with such subcontractor that contains substantially the same terms, conditions, and restrictions on the Use and Disclosure of PHI as contained in this Agreement.
	3. Business Associate Management, Administration and Legal Responsibilities. Business Associate may Use or Disclose PHI for Business Associate’s management and administration, or to carry out Business Associate’s legal responsibilities. Business Associate may Disclose PHI received from Covered Entity to a third party for such purposes only if: (1) the Disclosure is required by law; or (2) Business Associate secures assurance from the receiving party that the receiving party will: (i) hold the PHI confidentially; (ii) Use or Disclose the PHI only as required by law or for the purposes for which it was Disclosed to the recipient; and (iii) notify the Business Associate of any known instances in which the confidentiality of the PHI has been breached.
	4. Data Aggregation. Business Associate may Use PHI to perform data aggregation services as permitted by 45 CFR § 164.504(e)(2)(i)(B). Business Associate may also de-identify PHI in accordance with 45 C.F.R. 164.514.
	5. Permissible Requests by Covered Entity. Covered Entity shall not request Business Associate to Use or Disclose PHI in any manner that would not be permissible under the Privacy Standards if done by Covered Entity.
3. **SAFEGUARDS FOR PROTECTED HEALTH INFORMATION**
	1. Adequate Safeguards. Business Associate will implement and maintain appropriate safeguards to prevent any Use or Disclosure of PHI for purposes other than those permitted by this Agreement, including administrative, physical and technical safeguards to protect the confidentiality, integrity, and availability of any electronic protected health information (“ePHI”), if any, that Business Associate creates, receives, maintains, and transmits on behalf of Covered Entity.
	2. Compliance with HIPAA Security Standards. Business Associate will comply with the requirements of the HIPAA Security Standards applicable to Business Associate.
4. **REPORTS OF IMPROPER USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION, SECURITY INCIDENTS AND BREACHES**
	1. Use or Disclosure Not Permitted by This Agreement. Business Associate will report in writing to Covered Entity any Use or Disclosure of PHI for purposes other than those permitted by this Agreement within fifteen (15) business days of Business Associate’s actual knowledge of such Use or Disclosure.
	2. Security Incidents. Business Associate will report to Covered Entity any Security Incident of which Business Associate becomes aware within fifteen (15) business days of Business Associate’s actual knowledge of such Security Incident.
	3. Breaches of Unsecured PHI. Business Associate will report Breaches of Unsecured PHI, as defined in the Breach Notification Regulations, in compliance with 45 C.F.R. § 164.410. Specifically, Business Associate will report in writing to Covered Entity any Breach of Unsecured Protected Health Information within fifteen (15) business days of the date of Business Associate’s actual knowledge of the incident giving rise to the Breach. Business Associate will provide such information to Covered Entity as required in the Breach Notification Regulations.
5. **ACCESS TO PROTECTED HEALTH INFORMATION**
	1. Covered Entity Access. Within fifteen (15) business days of receipt of a request by Covered Entity, Business Associate will make PHI held in a Designated Record Set, if any, available to Covered Entity in accordance with 45 C.F.R. § 164.524.
	2. Individual Access. If an Individual makes a request for access directly to Business Associate, Business Associate will within fifteen (15) business days forward such request in writing to Covered Entity. Covered Entity will be responsible for making all determinations regarding the grant or denial of an Individual’s request for PHI and Business Associate will make no such determinations. Only Covered Entity will release PHI to an Individual pursuant to such a request.
	3. Form and Format. If Business Associate maintains PHI received from Covered Entity electronically in one or more Designated Record Sets and an Individual requests an electronic copy of such information from either Business Associate or Covered Entity, Business Associate will, within fifteen (15) business days of receipt of request by Covered Entity, provide Covered Entity with an electronic copy of such PHI in the form and format requested by Covered Entity, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by Covered Entity and the Individual.
6. **AMENDMENT OF PROTECTED HEALTH INFORMATION**
	1. Covered Entity Request. Within twenty (20) business days of receiving a request from Covered Entity to amend an Individual’s PHI within an existing Designated Record Set maintained by Business Associate, Business Associate will either provide such Designated Record Set, if any, to Covered Entity for amendment or amend the Designated Record Set, if any, in accordance with Covered Entity’s instructions.
	2. Individual Request. If an Individual makes a request for an amendment directly to Business Associate, Business Associate will within twenty (20) business days forward such request in writing to Covered Entity. Covered Entity will be responsible for making all determinations regarding amendments to PHI and Business Associate will make no such determinations.
7. **ACCOUNTING OF DISCLOSURES OF PROTECTED HEALTH INFORMATION**
	1. Disclosure Records. Business Associate will keep a record of any Disclosure of PHI that Business Associate makes to its subcontractors or other third parties, to enable Covered Entity to fulfill its obligations to provide an accounting of such Disclosures to Individuals in accordance with 45 C.F.R. § 164.528.
8. **ACCESS TO BOOKS AND RECORDS**
	1. Business Associate will make its internal practices, books and records on the Use and Disclosure of PHI available to the Secretary of the Department of Health and Human Services to the extent required for determining compliance with the Privacy Standards, Security Standards, or Breach Notification Regulations. Notwithstanding this provision, no attorney-client, accountant-client, work product protection or other legal privilege will be deemed waived by Business Associate or Covered Entity as a result of this Section.
9. **Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions**
	1. 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.
	2. 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.
	3. 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.
10. **TERMINATION**
	1. Covered Entity or Business Associate may terminate this Agreement upon breach of a material term of this Agreement. The party providing notice of breach will provide the breaching party with written notice of the breach and afford the opportunity to cure the breach to the satisfaction of noticing party within thirty (30) days of the date of such notice. If the breaching party fails to timely cure the breach, the noticing party may terminate this Agreement. In addition, either party may terminate the Agreement, subject to the requirements of Section 11, by providing the other party with sixty (60) days prior written notice of such termination.
11. **RETURN OR DESTRUCTION OF PROTECTED HEALTH INFORMATION**
	1. Following termination of this Agreement, Business Associate will return to Covered Entity all PHI possessed by Business Associate. Alternatively, Business Associate may destroy all such PHI (or destroy part and return the remaining PHI) and provide written documentation of such destruction. If Business Associate believes that returning or destroying PHI at the termination of this Agreement is infeasible, it will extend all protections, limitations and restrictions of this Agreement to Business Associate’s Use or Disclosure of PHI retained after termination of this Agreement, and its agreement will limit further Uses or Disclosures to those purposes that make the return or destruction of the PHI infeasible.
12. **COMPLIANCE WITH HITECH ACT AND REGULATIONS**
	1. Business Associate will comply with the requirements of Title XIII, Subtitle D of the Health Information Technology for Economic and Clinical Health (HITECH) Act, codified at 42 U.S.C. §§ 17921-17954, which are applicable to Business Associate, and will comply with all regulations issued by the Department of Health and Human Services (HHS) to implement these referenced statutes, as of the date by which Business Associate is required to comply with such referenced statutes and HHS regulations.
13. **MISCELLANEOUS PROVISIONS**
	1. Compliance with Laws. The parties are required to comply with federal and state laws. If this Agreement must be amended to secure such compliance, the parties will meet in good faith to agree upon such amendments. If the parties cannot agree upon such amendments, then either party may terminate this Agreement upon ten (10) business days’ written notice to the other party.
	2. Construction of Terms. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.
	3. No Third Party Beneficiaries. Nothing in this Agreement will confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
	4. Notices. All notices required under the Agreement will be given in writing and will be delivered by (1) personal service, (2) first class mail, or (3) messenger or courier. All notices shall be addressed and delivered to the contact designated in the signature block, or other address provided by the party from time to time in writing to the other party. Unless otherwise provided in this Agreement, notices given by mail will be deemed for all purposes to have been given forty-eight hours after deposit with the United States Postal Service. Notices delivered by any other authorized means will be deemed to have been given upon actual delivery.
	5. Entire Agreement. This Agreement constitutes the entire agreement between the parties with regard to the HIPAA Rules. There are no understandings or agreements relating to this Agreement that are not fully expressed in this Agreement and no change, waiver or discharge of obligations arising under this Agreement will be valid unless in writing and executed by the party against whom such change, waiver or discharge is sought to be enforced. Nothing in this Agreement shall be construed to apply to information received by Business Associate from sources other than Covered Entity or its business associates.
	6. Counterparts and Signature. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and when taken together shall constitute one agreement. Facsimile and electronic signatures shall be deemed to be original signatures for all purposes of this Agreement.
	7. Written Agreement. [DELETE THIS SECTION IF THERE IS NO WRITTEN AGREEMENT] This Agreement will be considered an attachment to Written Agreement, if any, and is incorporated as though fully set forth within the Written Agreement. This Agreement will govern in the event of conflict or inconsistency with any provision of Written Agreement.
	8. Governing Law and Venue. This Agreement will be governed by the laws of the State of Arizona without regard to any conflicts of laws principles. Business Associate’s obligations hereunder are subject to the regulations/policies of the Arizona Board of Regents. Any proceeding arising out of or relating to this Agreement will be conducted in Maricopa County, Arizona. Each party waives any objection it may now or hereafter have to venue or to convenience of forum.
	9. Publications. Covered Entity recognizes that under ASU policy, the result of work performed under this Agreement must be publishable. Covered Entity agrees that Business Associate and its employees and students engaged in work under this Agreement shall be free to present methods and results of the work performed under this Agreement at symposia or professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the work performed under this Agreement, subject to compliance with the PHI confidentiality requirements specified in this Agreement. Business Associate shall provide Covered Entity, at least thirty (30) days in advance, copies of proposed manuscripts for Covered Entity to review prior to publishing
14. **ARIZONA STATE PROVISIONS**
	1. Nondiscrimination. The parties will comply with all applicable state and federal laws, rules, regulations, and executive orders governing equal employment opportunity, immigration, and nondiscrimination, including the Americans with Disabilities Act. **If applicable, the parties will abide by the requirements of 41 CFR §§ 60-1.4(a), 60 300.5(a) and 60 741.5(a). These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, and prohibit discrimination against all individuals based on their race, color, religion, sex, or national origin. Moreover, these regulations require that covered prime contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, national origin, protected veteran status or disability.**
	2. Conflict of Interest. If within 3 years after the execution of this Agreement, Covered Entity hires as an employee or agent any ASU representative who was significantly involved in negotiating, securing, drafting, or creating this Agreement, then ASU may cancel this Agreement as provided in Arizona Revised Statutes (ARS) § 38-511. Notice is also given of ARS §§ 41-2517 and 41-753.
	3. Arbitration in Superior Court. The parties agree to arbitrate disputes filed in Arizona Superior Court that are subject to mandatory arbitration pursuant to ARS § 12-133. ARS § 12-1518 requires this provision in all ASU contracts.
	4. Records. To the extent required by [A.R.S. § 35-214](http://www.azleg.state.az.us/FormatDocument.asp?inDoc=/ars/35/00214.htm&Title=35&DocType=ARS), Covered Entity will retain all records relating to this Agreement. Covered Entity will make those records available at all reasonable times for inspection and audit by ASU or the Auditor General of the State of Arizona during the term of this Agreement and for a period of five years after the completion of this Agreement. The records will be provided at Arizona State University, Tempe, Arizona, or another location designated by ASU on reasonable notice to Entity.
	5. Failure of Legislature to Appropriate. In accordance with ARS § 35-154, if ASU’s performance under this Agreement depends on the appropriation of funds by the Arizona Legislature, and if the Legislature fails to appropriate the funds necessary for performance, then ASU may provide written notice of this to Covered Entity and cancel this Agreement without further obligation of ASU. Appropriation is a legislative act and is beyond the control of ASU.
	6. ASU Names and Marks. Covered Entity will not use any names, service marks, trademarks, trade names, logos, or other identifying names, domain names, or identifying marks of Business Associate (the "ASU Marks"), without in each case, first obtaining the prior written consent of Business Associate. Covered Entity’s use of any ASU Marks must comply with Business Associate's requirements including using the ® indication of a registered trademark where applicable.
	7. Confidentiality. Business Associate is a public institution and, as such, is subject to A.R.S. §§ 39 121 through 39 127 regarding public records. Accordingly, notwithstanding any other provision of this Agreement to the contrary, any provision regarding confidentiality is limited to the extent necessary to comply with the provisions of Arizona law.

**Signed by the Authorized Representatives of each Party:**

**BUSINESS ASSOCIATE:**

Arizona Board of Regents for and on behalf of Arizona State University

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Debra Murphy

Director, Research Operations

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**COVERED ENTITY:**

\_\_\_*(entity name)*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Contacts for Notices under this Agreement:**

**For ASU:** **For *Covered Entity*:**

Office for Research and Sponsored Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Projects Administration Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

P.O. Box 876011 Address:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Tempe, AZ 85287-6011

480-965-1427 Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ASU.awards@asu.edu Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**and**

Tameka Sama, Center Administrator

George Runger, Director

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**and**

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ASU HIPPA Privacy Officer

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