# DATA USE AGREEMENT FOR LIMITED DATA SET

This **DATA USE AGREEMENT** (“Agreement”) is between \_ (“User”), and the Arizona Board of Regents for and on behalf of Arizona State University (“ASU”), Center for Health Information & Research (“CHiR”). The Agreement shall be effective as of (“Effective Date”).

##### RECITALS

1. User conducts research, performs public health activities, or performs health care operations using protected health information (“PHI”) in a limited data set as such terms are defined by the HIPAA Privacy Rule regulations at 45 C.F.R. 164.514(e);
2. User wishes to review or receive a Limited Data Set, which includes PHI from CHiR to perform research functions for the following research: (the “Study”). User represents that the statements made in the Study submitted to CHiR are a complete and accurate description of the study to be undertaken;
3. CHiR agrees to provide access to the Limited Data Set to User to perform those research functions;
4. User agrees to pay any applicable fees for the Limited Data Set, including without limitation, CHiR’s costs and expenses for staff time and service time to prepare the Limited Data Set; and
5. CHiR and User recognize this Agreement is required by the Health Insurance Portability and Accountability Act and the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subpart E, as amended from time to time (“HIPAA”), to protect the information included in the Limited Data Set. CHiR shall ensure that the Limited Data Set meets the requirements of a limited data set.

##### AGREEMENT

1. **Definitions.** Unless otherwise provided, all capitalized terms in this Agreement will have the same meaning as provided under HIPAA.

For purposes of this Agreement, “Limited Data Set” means the Protected Health Information provided by CHiR and related to the Study that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; and (xvi) Full face photographic images and any comparable images.

1. **Permitted Uses and Disclosures of Limited Data Set**. User may use and disclose the Limited Data Set only for those purposes related to the research to be conducted in the Study or as required by law. User will not otherwise use or further disclose any information included in the Limited Data Set.
2. **Designation of Personnel.** User designates the following personnel as individuals who will receive, use or disclose the Limited Data Set on User’s behalf:

|  |  |
| --- | --- |
| *Name* | *Name* |
| *Phone number* | *Phone number* |
| *Email address* | *Email address* |

User will require the personnel listed above to comply with the terms of this Agreement. User may reasonably designate other personnel who will receive, use or disclose the Limited Data Set on User’s behalf provided such personnel are required to comply with the terms of this Agreement and are disclosed to CHiR. In addition, User may disclose the Limited Data Set to third parties provided that the applicable requirements of Section 9 are satisfied.

1. **Data Use Site**. User agrees that the physical location(s) specified below will be where the Limited Data Set is accessed and stored according to the terms of Section 7. User agrees that the Limited Data Set must not be physically moved, transmitted or disclosed in any way from the designated site(s) without written approval from CHiR unless such movement, transmission or disclosure is required by law.

|  |
| --- |
| *Company/Organization* |
| *Street Address* |
| *City/State/Zip code* |

1. **Human Subjects Compliance**. User confirms one of the following compliance statements concerning the Limited Data Set.
	1. User has attached the ASU Institutional Review Board (IRB) approval or exemption to this Agreement; or
	2. User has attached a non- ASU IRB or Privacy Board approval or exemption to this Agreement; or
	3. A human subjects research protocol is not required for the following reasons:
		1. The Limited Data Set will be solely used for research on decedent’s information, and the Limited Data Set is necessary for the research purposes. User agrees that if the work preparatory to research leads to a research study, then a human subjects protocol must be reviewed and exempted/approved by the ASU IRB before the Limited Data Set can be used for research.
		2. The Limited Data Set is for health care operations and/or quality improvement purposes.
		3. The Limited Data Set is for a proposal or activity that is preparatory to research.
2. **Applicable Fees**. Prior to sending the Limited Data Set to User, CHiR shall provide User with an invoice of the costs and expenses associated with preparing the Limited Data Set. User shall pay CHiR the invoiced amount prior to receiving the Limited Data Set. In the event of non-payment or late payment, interest shall accrue on any amount owed at 10% per annum.
3. **Safeguards**. User will implement appropriate safeguards to prevent any use or disclosure of the Limited Data Set not otherwise permitted in this Agreement.
4. **Reports of Impermissible Use of Disclosure**. User will report to CHiR any use or disclosure of the Limited Data Set not permitted by this Agreement within five business days of User’s learning of such use or disclosure by telephone at (602) 496-2021 or by email notification to chir@asu.edu. User agrees to cooperate fully in any investigation that may be conducted into the use and disclosure of the Limited Data Set.
5. **Agents and Subcontractors**. If User provides the Limited Data Set to an agent or subcontractor for a purpose authorized under the Agreement, User first will enter into a written contract with the agent or subcontractor that requires the agent or subcontractor to agree to the same restrictions and conditions with respect to the Limited Data Set as contained in this Agreement.
6. **Employees**. User will limit access to the Limited Data Set to only those employees necessary to accomplish the purposes of the Study. Prior to providing any of its employees access to the Limited Data Set, User will require the employees to sign a HIPAA Confidentiality Agreement substantially similar to the form attached as Exhibit A hereto.
7. **Ownership of Data**. CHiR or third parties that have provided the information included in the Limited Data Set own the information. User does not obtain any right, title, or interest in the Limited Data Set other than the ability to use the Limited Data Set for the Study.
8. **Prohibition on Identifying Information and Contracting Individuals.** User agrees that it will not:
	1. Attempt to learn the identity of the individuals whose information is included in the Limited Data Set. If User does learn the identity of the individuals, it agrees not to contact those individuals;
	2. Use the Limited Data Set for any purpose other than for the Study;
	3. Publish or otherwise disclose information that identifies the individuals whose information is included in the Limited Data Set.
9. **Term and Termination**. The Term of this Agreement shall commence as of the Effective Date, and shall terminate under any of the following circumstances:
	1. Termination for Breach of Agreement by User.
		1. CHiR may immediately terminate this Agreement upon written notice to User, if User has breached a material term of this Agreement.
		2. Alternatively, in the event of User material breach, CHiR may elect to provide User with written notice of such breach and afford User the opportunity to cure the breach within a specified cure period. If User fails to timely cure the breach, the Agreement will terminate.
		3. In the event the Agreement is terminated in accordance with this Section, User shall either destroy all of the Limited Data Set, return all of the Limited Data set to CHiR, or if neither return or destruction is feasible, User shall protect the privacy of the Limited Data Set by extending the protections to such Limited Data Set beyond the termination of the Agreement for as long as User possesses such data set or until no longer required by law.
	2. Upon Notice by User. Subject to its payment obligations under Section 6 above, User may terminate the Agreement following written notice to CHiR, effective ten days after such written notice is delivered. Termination under this section is only effective if User demonstrates to CHiR one of the following conditions:
		1. User has destroyed all of the Limited Data Set.
		2. User has returned all of the Limited Data Set to CHiR.
		3. If it is infeasible to return or destroy the Limited Data Set, User protects the privacy of the Limited Data Set by extending the protections to such Limited Data Set beyond the termination of the Agreement for as long as User possesses such data set or until no longer required by law.
10. **Orders.**  User’s obligations relating to the use and disclosure of the Limited Data Set shall not apply if the Limited Data Set is required to be disclosed by User pursuant to a legally enforceable order, subpoena, regulation, statute or other law (“Order”). User agrees to notify CHiR and request a written response from CHiR prior to disclosing the Limited Data Set to comply with a legal Order.
11. **Handling of Study Results**
	1. **Cell Size Suppression**. The User agrees that any use of the Limited Data Set obtained from CHiR or any derivative of the Limited Data Set from CHiR in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the Study listed in this agreement must not display anycell size of 10 or less (e.g. admittances, discharges, patients, services).Also, User agrees that no use of percentages or other mathematical formulas may be used if they result in the display of a cell size of 10 or less.
	2. **Citing Results.** The \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ shall be cited as the source of the data in all tables, graphs, reports, presentations, and other publications. CHiR shall be cited as the source of the calculations, analysis and/or processing of the data.
		1. **Sample Cite.** Data Source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2017. Note: The Center for Health Information & Research is the source for all processing of the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ data.
12. **Non-CHiR Information or Data.**  User’s obligations under this Agreement do not apply to information received from non-CHiR sources.
13. **Marking Requirement.** CHiR shall ensure that the Limited Data Set is conspicuously marked “confidential - limited data set” at the time the Limited Data Set is disclosed to User.
14. **Applicable Law.**  This Agreement shall be construed according to the laws of the State of Arizona, without regard to its conflicts of law provisions.
15. **Counterparts.** This Agreement may be executed in counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement and be effective as of the Effective Date. The parties may evidence execution of this Agreement by faxing or otherwise electronically transmitting a signed counterpart to the other party.
16. **Notices**. Any notices and reports required under this Agreement will be sent to the parties at the following address by first class mail, hand delivery, email or fax:

|  |  |
| --- | --- |
|  If to CHiR: | If to User: |
| 502 E. Monroe Street, Suite C320Phoenix, AZ 85004Fax: 602.496.2020Email: chir@asu.edu |  |
| with copy to:Research.Integrity@asu.edu | with copy to: |

1. **Indemnification by User**. User will indemnify, defend, save and hold harmless the ASU and the State of Arizona, its departments, agencies, boards, commissions, universities, and its and their officials, agents, and employees (collectively, "Indemnitee") for, from, and against any and all claims, actions, liabilities, damages, losses, or expenses (including court costs, attorneys’ fees, and costs of claim processing, investigation, and litigation) for violation of privacy or violation of any applicable law (including HIPAA), but only to the extent caused, or alleged to be caused, by (i) the negligence, acts or omissions of User or any of its owners, officers, directors, members, managers, agents, employees, or subcontractors, or (ii) a breach of this Agreement. User will be responsible for primary loss investigation, defense and judgment costs where this indemnification is applicable. User waives all rights of subrogation against Indemnitee for losses arising from this Agreement.
2. **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.**  In accordance with Arizona Revised Statutes ("A.R.S.") § 38-511, ASU may cancel this Agreement within three years after the execution of this Agreement, without penalty or further obligation, if any person significantly involved in initiating, negotiating, securing, drafting, or creating this Agreement on behalf of ASU, at any time while this Agreement or any extension thereof is in effect, is an employee or agent of any other party to this Agreement in any capacity or a consultant to any other party with respect to the subject matter of this Agreement.
	3. **Notice of Arbitration Statutes.**  In the event of litigation, as required by A.R.S. § 12-1518, the parties agree to make use of arbitration in all contracts that are subject to mandatory arbitration pursuant to rules adopted under A.R.S. § 12-133.
	4. **Failure of Legislature to Appropriate**. In accordance with A.R.S. § 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 User and cancel this Agreement without further obligation of ASU. Appropriation is a legislative act and is beyond the control of ASU.

|  |  |
| --- | --- |
| **Arizona Board of Regents for and on behalf of Arizona State University** | **User** |
| **By:** | **By:** |
| **Printed Name:** | **Printed Name:** |
| **Title:** | **Title:** |
| **Date:** | **Date:** |

**Exhibit A**

**HIPAA CONFIDENTIALITY AGREEMENT**

This HIPAA Confidentiality Agreement (this "Agreement") is between [INSERT EMPLOYER NAME] (“Discloser”), and [ENTER EMPLOYEE NAME] ("Recipient").

Disclosure received certain protected health information (“PHI”) from the Center for Health Information and Research at Arizona State University (“CHIR”), which is subject to the Health Insurance Portability and Accountability Act of 1996 and its subsequent amendments and regulations (“HIPAA”). CHIR entered into a Data Use Agreement (“DUA”) in which Discloser agreed, among other things, not to disclose the PHI and to take reasonable safeguards required by HIPAA, including physical and technical safeguards.

 Subject to the DUA, CHIR has provided to Discloser a limited data set (“LDS”) from the PHI that is intended to be used in [INSERT DESCRIPTION OF THE RESEARCH STUDY].

Discloser will provide Recipient access to the LDS subject to the following terms. Therefore, by signing below, Recipient agrees and acknowledges the following:

1. Recipient will comply with the requirements of HIPAA with respect to the LDS, including only accessing or storing the LDS at the following site: [INSERT DESCRIPTION OF APPROVED STORAGE SITE].
2. Recipient will only use the LDS for the purposes set forth in the approved research study.
3. Recipient will not at any time disclose, reveal, give access to, or disseminate the LDS to any other person, including other employees, unless expressly authorized to do so by CHIR.
4. Recipient will not attempt to learn the identity of the individuals whose information is included in the LDS.
5. Upon completion of the research study or upon other notice, Recipient will destroy the LDS in Recipient’s possession.
6. Recipient will immediately report to Discloser any known or suspected breach of his/her obligations set forth above.

I have read this Agreement and acknowledge my obligations as the Recipient in receiving the confidential information hereunder:

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

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_