

## Privacy - MODEL Facility Policy

POLICY NAME: Limited Data Set and Data Use Agreements

DATE: (facility to insert date here)

NUMBER: (facility to insert number here)

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**Purpose:** To facilitate compliance with the Health Insurance Portability and Accountability Act (HIPAA) Standards for Privacy of Individually Identifiable Health Information (Privacy Standards), 45 CFR Parts 160 and 164, the Health Information Technology for Economic and Clinical Health Act of 2009 (the “HITECH Act”) and any and all other Federal regulations and interpretive guidelines promulgated under the HITECH Act or HIPAA. To establish guidelines for the proper definition and use of a limited data set and provide guidance regarding the requirements for a data use agreement, as required by the HIPAA Privacy Standards.

**Policy:** A Limited Data Set (LDS) may be used or disclosed without patient authorization if the organization enters into a Data Use Agreement (DUA), see attached example, with the LDS recipient; however, such use or disclosure of a LDS may only be for the purposes of research, public health or health care operations. A facility may use protected health information (PHI) to create a LDS, or disclose PHI to a Business Associate for such purpose, whether or not the LDS is to be used by the organization.

**Procedure:**

1. An LDS may be used or disclosed only if the facility obtains satisfactory assurance, in the form of a DUA, that the LDS recipient will only use or disclose the PHI for the limited purposes of research, public health or health care operations.
2. A DUA between the facility and the LDS recipient must:
  - a. Establish that the permitted uses and disclosures of the LDS are limited to the purposes of research, public health or health care operations;
  - b. Establish who is permitted to use or receive the LDS; and
  - c. Provide that the LDS recipient will:
    - (1) Not use or further disclose the information other than as permitted by the agreement or as otherwise required by law;
    - (2) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the agreement;
    - (3) Report to the <facility name’s> facility privacy official any use or disclosure of the information not provided for by the agreement of which it becomes aware;
    - (4) Ensure that any agents, including a subcontractor, to whom it provides the LDS agrees to the same restrictions and conditions that apply to the recipient with respect to such information;
    - (5) Ensure the LDS is not further de-identified, and
    - (6) Not identify the information or contact the individuals.

3. The following identifiers must be excluded from the PHI to create an LDS:
- Names;
  - Street address (town /city, state and zip code **can** be included);
  - Telephone numbers;
  - Fax numbers;
  - Electronic mail addresses;
  - Social security numbers;
  - Medical record numbers;
  - Health plan beneficiary numbers;
  - Account numbers;
  - Certificate/License numbers;
  - Vehicle identifiers and serial numbers, including license plate numbers;
  - Device identifiers and serial numbers;
  - Web universal resource locators (URLs);
  - Internet protocol (IP) address numbers;
  - Biometric identifiers, including finger and voice points; and
  - Full face photographic images and any comparable images.

**References:**

Health Information Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information 45 CFR Part 164, Section: 164.514(e)  
American Recovery and Reinvestment Act of 2009, Title XIII, Subtitle D  
Patient Privacy Program Requirements Policy, IP.PRI.001  
Determination of, and Uses and Disclosures of, De-Identified Information Policy

## DATA USE AGREEMENT

This Agreement is entered into as of the \_\_[date]\_\_\_\_\_, by and between \_\_\_\_\_, a \_\_\_\_\_ corporation (“Covered Entity”), and \_\_\_\_\_ [*name of Limited Data Set recipient*], (“User”), and shall be effective as of the date set forth in Section 6 below.

**WHEREAS**, User is a \_\_\_\_\_ [*identify the User, e.g., local hospital association, disease registry, etc.*]; and

**WHEREAS**, the U.S. Department of Health and Human Services (“HHS”) has issued regulations, pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act of 2009 (the “HITECH Act”), governing the privacy of individually identifiable health information obtained, created, or maintained by certain entities, including health care providers (the “HIPAA Privacy Rule”); and

**WHEREAS**, the HIPAA Privacy Rule requires that Covered Entity enter into this Agreement with User in order to protect the privacy of certain individually identifiable health information created, obtained or maintained by Covered Entity or by User on Covered Entity’s behalf (“Protected Health Information,” or “PHI”); and

**WHEREAS**, Covered Entity desires to enter into this Agreement with User pursuant to which User will use the data identified on Exhibit A for research, public health, or health care operations, as detailed within Exhibit A and, in accordance with the terms and conditions set forth hereafter (such data hereinafter referred to as the “Data”); and

**WHEREAS**, the Data shall be a Limited Data Set (as defined below) of PHI;

**NOW, THEREFORE**, in consideration of the mutual promises hereinafter recited, the parties hereto agree as follows:

1. **Definitions.**

A. **Limited Data Set.** Limited Data Set shall have the same meaning as the term “limited data set” in 45 C.F.R. §164.514(e)(1), as amended from time to time.

B. **Remaining Terms.** Any remaining terms used, but not otherwise defined, in this Agreement, shall have the same meaning as those terms in the HIPAA Privacy Rule, as amended from time to time.

2. **Permitted Uses and Disclosures.** User agrees to strictly limit the use and disclosure of the Data provided by Covered Entity to the User as set forth in Exhibit A attached hereto and incorporated herein, provided that in no event shall any such use or disclosure be for any purpose other than research, public health, or health care operations, consistent with the HIPAA Privacy Rule and the HITECH Act. No other uses or disclosures of the PHI are authorized or permitted.

3. **Limitation on Use or Receipt of the Limited Data Set.** User agrees to limit the persons or classes of persons who are permitted to use or receive the Data and to identify those persons as further set forth in Exhibit A attached hereto and incorporated herein. User will promptly notify Covered Entity in writing when a change in authorized persons or classes of

persons is necessary to continue to effectively achieve the purpose of this Agreement. Notice shall be provided within 45 days prior to such a change.

4. **Nondisclosure of PHI.** Covered Entity and User acknowledge that PHI under 45 C.F.R. Parts 160 and 164 and the HITECH Act will be disclosed by Covered Entity to User pursuant to this Agreement. However, the PHI disclosed by Covered Entity to User will exclude direct identifiers of the protected individuals, the individual's relatives, employers or household members, as detailed in 45 CFR §164.514(e)(2), as amended from time to time.

To the extent and so long as required by law, User will appropriately safeguard PHI made available to or obtained by it. In implementation of such assurance and without limiting the obligations of User otherwise set forth in this Agreement or imposed by applicable law, User hereby agrees to comply with applicable requirements of law relating to PHI and with respect to any task or other activity User performs on behalf of Covered Entity, to the extent Covered Entity would be required to comply with such requirements. The provisions of this Section 4 shall survive termination of this Agreement.

In furtherance and not in limitation of the foregoing provisions of this Agreement, including this Section, User agrees that it will:

- a. not use or further disclose the Data other than as permitted or required by this Agreement or as otherwise required by law;
- b. use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement;
- c. immediately report to Covered Entity in writing any use or disclosure of such Data not provided for by this Agreement of which User becomes aware;
- d. ensure that any subcontractors, employees, agents, representatives or members of its workforce, whose services may be used to fulfill obligations under this Agreement or to whom User provides PHI received from Covered Entity, are appropriately informed of the terms of this Agreement and are under legal obligation to User, by contract or otherwise, sufficient to enable User to comply fully with all provisions of this Agreement and agree to the same restrictions and conditions that apply to User with respect to such Data;
- e. make available PHI in accordance with applicable law;
- f. incorporate any amendments or corrections to PHI when notified pursuant to applicable law;
- g. not identify or attempt to identify the Data nor contact or attempt to contact the individuals who are the subject of the Data;
- h. make User's internal practices, books and records relating to the use and disclosure of PHI received from, or created or received by User on behalf of Covered Entity available to the Secretary of HHS or its authorized delegate for purposes of determining Covered Entity's compliance with applicable law (in all events, User shall immediately notify Covered Entity upon receipt by User of any such request, and shall provide Covered Entity with copies of any such materials);

i. at termination of this Agreement, return or destroy all PHI received from, or created or received by User on behalf of, Covered Entity, which User still maintains in any form and retain no copies of such information; or if the return or destruction of the PHI is not feasible, extend the protections of this Section to the PHI received from Covered Entity and limit any further uses. This provision shall survive the termination of this Agreement. Fees. *[may or may not be relevant for these types of arrangements, other than to recoup costs of data collection or aggregation]*

5. **Term.** The term of this Agreement shall be for one (1) year commencing on the \_\_\_ day of \_\_\_[date]\_\_\_\_\_, and terminating at 11:59 p.m. on the \_\_\_\_\_[date]\_\_\_\_\_. This Agreement shall be automatically renewed for successive one-year terms.

6. **Termination.**

A. **Termination without Cause.** Either party may terminate this Agreement upon thirty (30) days’ written notice to the other party.

B. **Termination for Cause.** Either party shall have the right to immediately terminate this Agreement upon written notice of such termination to the other party in the event that: (1) either party is in material breach of any provision of this Agreement; (2) the business of either party is terminated or suspended; (3) a petition for bankruptcy is filed by or against either party; (4) a receiver is appointed on account of either party’s insolvency; or (5) if any assignment is made of either party’s business for the benefit of its creditors. In addition, Covered Entity shall have the right to terminate this Agreement: (i) in accordance with Section 16, Effect of Government Regulation; and (ii) without notice in its sole discretion to preserve the quality of patient services and/or to protect the health, safety, or welfare of patients, employees, or other persons, including but not limited to any use or disclosure of PHI by the User that Covered Entity determines is a material breach of Section 4, above.

7. **Notice.** All notices and other communications required or permitted to be given shall be made in writing and shall be considered given and received when (a) personally delivered to the other party, (b) delivered by courier, (c) delivered by facsimile or (d) deposited in the United States mail, postage prepaid, return receipt requested and addressed as set forth below or at such other address such party shall have specified by notice given in accordance with the provisions of this Section:

**If to COVERED ENTITY, to:**

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

**If to USER, to:**

With a copy by regular United States mail, postage prepaid, to:

With a copy by regular United States mail, postage prepaid, to:

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

**8. Independent Contractor Relationship.** None of the provisions of this Agreement are intended to create any relationship between the parties other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this Agreement. Neither of the parties, nor any of their respective officers, directors, employees or agents, shall have the authority to bind the other or shall be deemed or construed to be the agent, employee or representative of the other except as may be specifically provided herein. Neither party, nor any of their employees or agents, shall have any claim under this Agreement or otherwise against the other party for Social Security benefits, workers' compensation, disability benefits, unemployment insurance, vacation, sick pay or any other employee benefits of any kind. *User agrees to comply with and assist Covered Entity in observing federal and state accreditation standards, including, if applicable, standards of the Joint Commission (TJC).*

**9. Effect.** This Agreement shall be binding on Covered Entity and User and on respective successor organizations. The obligations of each party hereto may not be delegated without the other party's prior consent.

**10. Confidentiality.** As noted above, the parties shall maintain the confidentiality of patient medical records and treatment in accordance with state and federal laws. In addition, User acknowledges that information regarding Covered Entity's business operations, including, but not limited to, procedures, programs, formularies and reimbursement schedules are proprietary and confidential, and agrees to hold such information in strict confidence and not to disclose or make available such information to any third party, except as required by law. This provision shall survive termination of this Agreement.

**11. Insurance.** In order to adequately insure their respective personnel for liability arising out of the activities to be performed under this Agreement, User and Covered Entity each agree to obtain and maintain in force and effect liability insurance to insure themselves and their respective personnel for liability arising out of activities to be performed under, or in any manner related to, this Agreement.

Each party agrees to provide general liability insurance for itself, its agents and employees. Each party shall maintain comprehensive general liability insurance in the minimum amount of one million dollars (\$1,000,000.00) per occurrence and three million dollars (\$3,000,000.00) aggregate. Upon request, the parties agree to furnish to the other appropriate certificates of insurance. Both parties agree that such insurance may not be revoked, reduced or changed in a material way without at least thirty (30) days' advance written notice to the other party.

**12. Excluded Provider Warranty.** Each party hereby represents and warrants that it is not now and at no time has been excluded from participation in any federally funded health care program, including Medicare and Medicaid. Each party hereby agrees to immediately notify the other of any threatened, proposed or actual exclusion from any federally funded health care program, including Medicare and Medicaid. Each party further represents and warrants that none of its employees are now and at no time have been excluded from participation in any federally funded health care program, including Medicare and Medicaid. In the event that either party is excluded from participation in any federally funded health care program during the term of this Agreement, or if at any time after the effective date of this Agreement it is determined that either party is in breach of this Section, this Agreement shall, as of the effective date of such exclusion or breach, automatically terminate.

**13. Access to Books and Records.** User shall, until the expiration of four (4) years after the furnishing of services pursuant to this Agreement, make available, upon written request, to the Secretary of HHS or the Comptroller of the United States, or any of their duly authorized representatives, this Agreement, and books, documents and records that are necessary to certify the nature and extent of the cost of services provided pursuant to this Agreement; and if User carries out any of its duties pursuant to this Agreement through a subcontract with a value or cost of \$10,000 or more over a 12-month period with a related organization, such subcontract shall contain a clause placing the same obligations on subcontractor as this clause places on User. User shall immediately notify Covered Entity of its receipt of any such request for this Agreement and any other books, documents and records and shall provide Covered Entity with copies of any such materials. In the event this Agreement is not subject to the provision of 42 U.S.C. §1395x(v)(1)(I) and 42 C.F.R. 420.300 et seq. or relevant regulations, this paragraph shall be null and void.

**14. Effect of Government Regulation.** Covered Entity shall have the right to terminate or unilaterally amend this contract, without liability, to comply with any legal order, ruling, opinion, procedure, policy, or other guidance issued, or proposed to be issued, by any federal or state agency, or to comply with any provision of law, regulation, or any requirement of accreditation, tax-exemption, federally-funded health care program participation or licensure which: (i) invalidates or is inconsistent with the provisions of this contract; (ii) would cause a party to be in violation of the law; or (iii) jeopardizes the good standing status of licensure, accreditation or participation in any federally-funded health care program, including the Medicare and Medicaid programs, of Covered Entity, or any affiliate of Covered Entity; or, *(iv) to the extent applicable, jeopardizes the tax-exempt status of Covered Entity, or any affiliate of Covered Entity; or (v) jeopardizes the tax-exempt status of any bonds issued for the benefit of Covered Entity, or any affiliate of Covered Entity.* If Covered Entity deems it necessary to amend this Agreement as provided in this Section and the amendment is unacceptable to User, User may choose to terminate this Agreement without cause.

**15. Miscellaneous.**

**A. Amendment to Comply with HIPAA.** The parties agree to amend this Agreement as necessary to comply with HIPAA, the HIPAA Privacy Rule, and the HITECH Act, as amended from time to time. The parties further agree to execute such other agreements as may be required by law.

- B. **Headings.** The headings to the various sections of this Agreement have been inserted for convenience only and shall not modify, define, limit, or expand express provisions of this Agreement.
- C. **Recovery of Costs and Fees.** If suit is brought to enforce any of the terms or conditions of this Agreement, the prevailing party shall be entitled to recover such sums as the court may fix as costs and reasonable attorney's fees, in addition to any other relief to which it may be entitled.
- D. **Waiver of Breach or Default.** Waiver of a breach of or default under any term or provision of this Agreement by either party, by course of dealing or otherwise, shall not be deemed a waiver of any other breach of or default under the same or a different provision of this Agreement.
- E. **Entire Agreement.** This Agreement constitutes the entire written agreement of the parties with respect to the subject matter of this Agreement and supersedes any prior written agreements of the parties regarding the subject matter of this Agreement.
- F. **Resolution of Ambiguity/Interpretation of HIPAA or the HITECH Act.** Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with its interpretation of the HIPAA Privacy Rule and the HITECH Act. In addition, the terms of this Agreement shall be construed in light of any applicable interpretation or guidance on HIPAA, the HIPAA Privacy Rule, and/or the HITECH Act issued from time to time by HHS or the Office for Civil Rights of HHS.
- G. **Third Party Beneficiary.** Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities, whatsoever.

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

**[USER]**

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

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

**[COVERED ENTITY]**

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

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



**EXHIBIT A**

I. User is authorized to [use/disclose] the following information:

**[List data here]**

II. The following persons are hereby authorized to use or receive the above-listed information:

**[List persons here]**

The persons or classes of persons who are permitted to use or receive the Limited Data Set from Covered Entity include ***[THE FOLLOWING ARE PROVIDED AS EXAMPLES ONLY; REPLACE TO MEET NEEDS OF COVERED ENTITY/USER]:***

- 1) ***[Current data entry personnel of ABC Disease Registry]***
- 2) ***[Quality Control personnel of ABC Disease Registry]***
- 3) ***[Junior and Senior Researchers of State University, who are associated with ABC Disease Registry]***
- 4) ***[Key contact personnel (list them) at ABC Disease Registry]***

***[NOTE: such persons may be modified pursuant to Section 3 of the Agreement.]***

III. The data listed above is provided to User for the following purposes:

***[THE FOLLOWING ARE PROVIDED AS EXAMPLES ONLY; REPLACE TO MEET NEEDS OF COVERED ENTITY/USER]:***

- 1) ***[Participate in national performance improvement initiatives . . .]***
- 2) ***[Develop benchmarks for the local health care community regarding . . .]***
- 3) ***[Republish aggregated data in a de-identified form to the general health care community]***