



**Participation Agreement** 

# **Participation Agreement**

South Dakota Health Link (SDHL) is a public-private partnership between the South Dakota Department of Health (SDDOH) and participating member organizations to provide Health Information Exchange (HIE) Services. This "PARTICIPATION AGREEMENT" is made by and between SDHL and \_\_\_\_\_\_\_\_\_ "PARTICIPANT". The effective date for this participation agreement is \_\_\_\_\_\_\_\_ "EFFECTIVE DATE".

This Participation Agreement sets forth the terms and conditions under which the participant joins with other SDHL member organizations to form the "NETWORK". The network includes health care organizations, payers, government agencies, HIEs and "OTHER PARTICIPANTS" that contribute, access, and utilize the HIE as defined by this Participation Agreement. By signing this participation agreement, it replaces any previous agreements signed by the Participant and SDHL.

The Participation Agreement includes and incorporates for reference the following exhibits:

Exhibit A: Definitions Exhibit B: Terms and Conditions Exhibit C: Business Associate Agreement

All policies and standards found in the Policy & System Operation Manual - SD Health Link.

| Name of Participant Organization  | )             |                  |       |          |  |  |  |
|---|---------------|------------------|-------|----------|--|--|--|
| Name of CEO or Individual Authorized to Sign on Behalf of Participant Title |               |                  |       |          |  |  |  |
| Address   | City          |                  | State | Zip Code |  |  |  |
| Email Address   | Tele          | Telephone Number |       |          |  |  |  |
| Signature of CEO or Individual Authorized to Sign on Behalf                 | of Participan | nt Date          |       |          |  |  |  |
|   |               |                  |       |          |  |  |  |

| SOUTH DAKOTA HEALTH LINK                       |       |       |                           |       |          |
|--|-------|-------|---------------------------|-------|----------|
| Name of Authorized Representative              |       |       | Title                     | 6     |          |
| Address  | City  | City  |                           | State | Zip Code |
| 820 N Washington Ave                           | Madis | lison |                           | SD    | 57042    |
| Email Address                                  |       |       | ohone Numbe<br>) 800-1678 | er    |          |
| Signature of South Dakota Health Link Official |       |       | Date                      |       |          |

# **Exhibit A: Definitions**

The following terms apply unless otherwise indicated in this Agreement:

- (a) "Affiliate" means a subsidiary or affiliate of Covered Entity that is, or has been, considered a covered entity, as defined by HIPAA.
- (b) "Agreement" means this document and any exhibits or appendices attached hereto and incorporated herein.
- (c) "Authorized User" means an individual authorized by Participant or Other Participant and SDHL to access data for a permitted use.
- (d) "Breach" means the acquisition, access, use, or disclosure of EHI in a manner not permitted under the Privacy Rule which compromises the security or privacy of the EHI, as defined in 45 CFR §164.402.
- (e) "Breach Notification Rule" means the portion of HIPAA set forth in Subpart D of 45 CFR Part 164.
- (f) "Data" means patient record elements relevant to the scope of work of SDHL and includes all written or electronic patient information relating to patient's identity, medical history, diagnosis, treatment, tests or prognosis which is accessible to Participant through SDHL. Such information may also include, but not be limited to, any medical or laboratory services or prescription medications.
- (g) "Designated Record Set" has the meaning given to such term under the Privacy Rule, including 45 CFR §164.501.B.
- (h) "De-Identify" means to alter the EHI such that the resulting information meets the requirements described in 45 CFR §§164.514(a) and (b).
- (i) "Electronic Health Record System" and the abbreviation "EHR" mean an electronic data system that stores current and historical information about patient diagnosis and treatment, including test results, provider notes, treatment notes, medication history, problem lists and other information related to care of the patient such as billing, scheduling, and registration data.
- (j) "Electronic Health Information" or "EHI" means any EHI maintained in or transmitted by electronic media as defined in 45 CFR §160.103 and contained in the Designated Record Set
- (k) "Health Care Operations" shall have the definition assigned to it by the HIPAA Privacy and Security Regulations at 45 C.F.R. § 164.501.
- (I) "HIPAA Privacy and Security Regulations" means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR. Parts 160 and 164 and the Security Standards for the Protection of Electronic Protected Health Information at 45 C.F.R. Parts 160 and 164, as amended by the Health Information Technology for Economic and Clinical Health Act §§ 13400-13424, 42 U.S.C. §§ 17921-17954 (2009).
- (m) "Individual" has the same meaning given to that term in 45 CFR §§164.501 and 160.130 and includes a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).
- (n) "Network" means the full list of SDHL participants and other participants that contribute to the HIE, or benefit from HIE services as defined in the participation agreement.
- (o) "Other Participant" means non-health care providers, such as State Agencies and their related programs, payers, or participants engaged in quality improvement, care management or

population health, on a case-by-case basis as determined by SDHL personnel. "Other Participant" may also be a HIPAA non-covered entity.

- (p) "Participant" means an entity that fully executes the SDHL Participation Agreement on behalf of one or more facilities, providers, or organizations.
- (q) "Permitted Use" means the use of any Data available for query on SDHL only as allowed by the state or federal law pursuant to the Policies and Procedures of SDHL.
- (r) "Privacy Rule" means that portion of HIPAA set forth in 45 CFR Part 160 and Part 164, Subparts A and E.
- (s) "Protected Health Information" or "PHI" and the abbreviation "EHI" shall have the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the individually identifiable health information created or received by, from or on behalf of a Participant. Such term shall also include Electronic Protected Health Information.
- (t) "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.
- (u) "Security Rule" means the Security Standards for the Protection of Electronic Health Information provided in 45 CFR Part 160 & Part 164, Subparts A and C.
- (v) "Treatment" shall have the definition assigned to it by the HIPAA Privacy and Security Regulations at 45 C.F.R. § 164.501, namely the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party, consultation between health care providers relating to a patient, or the referral of a patient for health care from one health care provider to another.
- (w) "Unsecured EHI" means any "protected health information" as defined in 45 CFR §§164.501 and 160.103 that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the HHS Secretary in the guidance issued pursuant to the HITECH Act and codified at 42 USC §17932(h).
- (x) "Use Case" means a data sharing scenario that requires EHI to be shared for a specific purpose in accordance with HIPAA and in compliance with the 21<sup>st</sup> Century Cures Act or other applicable scenario. Examples may include analytics, immunization data sharing with schools, and community-based organizations for referral and care coordination.
- (y) "Vendor" means the technology vendor(s) with whom SDHL has subcontracted to assist it in meeting its obligations under this Agreement.

### [END OF DEFINITIONS]

## **Exhibit B: Terms and Conditions**

### 1. System Availability

- (a) During the term, SDHL grants to each Participant, including Other Participants, a nonexclusive, nontransferable, license to use the software solely for participation in SDHL, subject to the limitations described in this Agreement.
- (b) Such access and use are subject to Participant's compliance with all applicable laws and regulations, the terms and conditions set forth in this Participation Agreement and the HIE Policies. Participant shall obtain no rights to SDHL except for the limited rights to use SDHL expressly granted by this Participation Agreement.
- (c) SDHL will make reasonable efforts to make SDHL available to Participants 24 hours a day, 7 days a week, and 365 days a year. SDHL availability may be temporarily suspended for maintenance or unscheduled disruptions. SDHL will use commercially reasonable efforts to provide Participant with advance notice of any suspension or interruption of SDHL and to restore availability. Participant is responsible for securing EHI through other means during any periods when SDHL is not available.
- (d) SDHL will establish and maintain administrative, technical, and physical safeguards against destruction, loss, or alteration of data and against unauthorized access to EHI. This includes the use of appropriate security controls in accordance with industry standards including the periodic assessment or risks, threats, and vulnerabilities to ensure the confidentiality, integrity, and security of EHI in compliance with the HIPAA Security Rule (45 CFR Part 160 and Subparts A and C of Part 164).

### 2. SDHL Access

- (a) SDHL will make SDHL data available only to Participants, Authorized Users and SDHL Vendor(s) for the purposes of Treatment, Payment and Operations and public health reporting as authorized or required by applicable law.
- (b) SDHL will provide instructions on how to access and use available services during the onboarding process after the Participation Agreement and BAA are fully executed.
- (c) Usernames and Passwords for each Authorized User will be issued by SDHL that permits such Authorized User to access the system and use the application. If an individual is removed as an Authorized User by reason of termination of employment or otherwise, the Participant shall disable the SDHL username and password of the individual within twenty-four hours.
- (d) SDHL partners with other State HIEs through the eHealth Exchange to promote the exchange of EHI in accordance with applicable laws and regulations including but not limited to the Trusted Exchange Framework and Common Agreement (TEFCA) and in compliance with information blocking rules.
- (e) Certain types of data may not be available in SDHL to comply with applicable laws related to informed consent and specially protected data.
- (f) All requests for secondary use of deidentified data will be submitted in writing to SDHL personnel and shall be considered a "use case" as defined in Exhibit A Definitions.

- (g) Where required, SDHL may grant access to the audit trail of queries for the Participating Organizations own patients.
- (h) SDHL will promptly notify the Participant should a response to a subpoena, court order or other legal process be required. If Participant is subpoenaed and ordered to use SDHL for the purpose of compiling health data not already available in Participants records, the Participant will immediately notify SDHL.
- (i) If, at any time a Participant's use of SDHL causes SDHL to act as a "Qualified Service Organization" (as defined in 42 C.F.R. Part 2), the Participant and SDHL shall enter into a separate Qualified Service Organization Agreement.
- (j) Patients have the right to opt-out of SDHL through the submission of an Opt-out form to SDHL. Data will not be available after the date the Opt-out form is submitted. SDHL will suppress data already in the system making it unavailable. Patients may change their Opt-out status at any time.

# 3. Participant Obligation

- (a) Participant is a "covered entity" as defined in the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR §160.103, and will abide by the rules and regulations set forth in 45 CFR Parts 160 and 164 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act §§ 13400-13424, 42 U.S.C. §§ 17921-17954 (2009). HIPAA exempts from the Business Associate Agreement requirement those disclosures between covered entities and health care providers concerning the treatment of an individual (45 CFR §164.502 (e)(1)(ii)).
- (b) Participant acknowledges that Participant is responsible for reviewing the Policies and Procedures on the SDHL website on a regular basis as described in Section 4.
- (c) Participant is responsible for having written policies and procedures for Participant Users that are authorized to access and use SDHL Services. This will include at a minimum information related to use and disclosure of EHI in compliance with HIPAA and other applicable laws and regulations.
- (d) Participant may transmit and/or use Data through SDHL only for permitted uses and disclosures based on HIPAA Privacy Rule minimum necessary standard and in accordance with the terms of this Agreement.
- (e) Participant shall be responsible for its own compliance, including Participant's Authorized User compliance, with all SDHL Policies, applicable laws, including information blocking, privacy, security, and confidentiality of EHI.
- (f) Participant shall identify its Authorized Users and the level of access to SDHL, and guard against unauthorized access to or use of EHI.
- (g) Participant shall restrict access to the system(s) and, if applicable, use of application(s) only to the Authorized Users the Participant has identified and to whom the Participant has issued a username and password in accordance with sections 5.a and 5.b.
- (h) Participant will be responsible for its Participant Users use of data, the accuracy of its information and integrity of any messages sent using SDHL services.

- (i) Participant shall be responsible for the costs of supplying equipment necessary for operation of its EHR system in conjunction with this Agreement. Participant further assumes responsibility for all costs charged by vendors, internet service or telecommunications providers necessary to connect Provider's computer network to SDHL.
- (j) Participant may not re-sell or supply XDR Direct Addresses provided by SDHL to any other nonaffiliated individual or organization.

# 4. SDHL Policies, Procedures and Flow Down Terms

- (a) SDHL has established policies and procedures available at <u>SD Health Link</u> that govern SDHL's and Participant's use of SDHL including to but not limited to Patient Consent and Data Use. Participant's use of SDHL constitutes acceptance of Policies and Procedures and failure to comply with such Policies and Procedures by either SDHL or Participant shall constitute a material failure to comply with the terms and conditions of this Agreement.
- (b) SDHL may change or amend Policies and Procedures at its discretion. SDHL shall provide Participant notice of such changes. Any changes will be effective 90 days following adoption by SDHL, unless SDHL determines that an earlier effective date is required to address a legal requirement, a concern relating to the privacy or security of Data, or an emergency situation. Participant will have no ownership or other property rights in Policies and Procedures, or other materials or services provided by SDHL.
- (c) When accessing the eHealth Exchange through SDHL the Participant shall comply with all eHealth Exchange policies found in Appendix C and at the following link <u>Policies - eHealth</u> <u>Exchange</u>.

## 5. Limited Warranties and Disclaimers

- (a) SDHL will use its best efforts to correctly transmit data between Participants on a timely basis. SDHL makes no representation nor will warranty that the data delivered to the Participant be correct or complete. SDHL makes no warranty or representation regarding the accuracy or reliability of any information technology system used for the transfer. SDHL disclaims all warranties regarding any product, services, or resources provided by it, or data transmitted, pursuant to this Agreement including, but not limited to, any warranty of merchantability or fitness for a particular purpose.
- (b) EACH PARTICIPANT EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES REGARDING THE PATIENT DATA OF THE PARTICIPANT THROUGH THE SYSTEM(S), INCLUDING, AND WITHOUT LIMITATION, ANY AND ALL WARRANTIES OF ACCURACY, COMPLETENESS, FITNESS FOR A PARTICULAR USE AND ANY OTHER EXPRESS OR IMPLIED WARRANTIES. EACH PARTICIPANT ACKNOWLEDGES AND AGREES THAT ANY DATA ACCESSED BY THE PARTICIPANT OR ITS AUTHORIZED USERS IS PROVIDED ON AN "AS-IS" AND "WHERE-IS" BASIS, AND SDHL AND EACH DATA PARTICIPANT SHALL TAKE ALL REASONABLE EFFORTS NECESSARY TO INFORM AUTHORIZED USERS OF THEIR RESPONSIBILITY TO REVIEW, UPDATE AND CONFIRM THE ACCURACY OF ANY INFORMATION ACCESSED THROUGH THE SYSTEM(S). USE OF THE SYSTEM(S) IS NOT A SUBSTITUTE FOR A HEALTH CARE PROVIDERS STANDARD PRACTICE OR PROFESSIONAL JUDGMENT. ANY DECISIONS

WITH RESPECT TO THE APPROPRIATENESS OF DIAGNOSES OR TREATMENTS OR THE VALIDITY OR RELIABILITY OF INFORMATION IS THE SOLE RESPONSIBILITY OF THE PATIENT'S HEALTH CARE PROVIDER. NOTHING IN THIS SECTION IS INTENDED TO LIMIT A PARTICIPANT'S OBLIGATIONS UNDER SECTION 5 OF THIS AGREEMENT.

## 6. Term and Termination

- (a) This Agreement commences on the Effective Date and replaces any prior Business Associate or Participation Agreement that predates the Effective Date of this document.
- (b) This Agreement may be terminated by either party upon sixty (60) days prior written notice.
- (c) The Agreement may be terminated by SDHL for cause if participant materially breaches this Agreement and fails to substantially remedy its obligations under this Agreement within (30) days of receipt of notice of such a material breach. Upon the effective termination date of the Agreement, SDHL will cease providing Participant and its Authorized Users access to SDHL, and Participant and its Authorized Users will stop using SDHL.
- (d) Participant's User Agreement shall commence on the Effective Date and remain in force until terminated by either party. Any terms of this Agreement which by intent or meaning have validity beyond the termination shall survive termination of this Agreement.
- (e) Immediately following termination or expiration of the Participation Agreement all EHI will be returned or destroyed to the extent that it cannot be recalled or reproduced in compliance with 45 CFR 164.310(d)(2).
- (f) If it is determined to not be feasible to return or destroy EHI, the Participant or their Business Associate will submit in writing to SDHL the reason and formal plan to limit further uses and disclosures of EHI to only those purposes which make the return or destruction not feasible.

## 7. Fees and Cost

- (a) Annual participation or membership fees will be discussed at the time the Participation
  Agreement is under review. SDHL will invoice participant annually. Payment is due within sixty
  (60) days of receipt of invoice.
- (b) Participants shall be responsible for their connectivity and infrastructure cost. SDHL is not responsible for any ongoing or reoccurring costs Participant may incur. SDHL shall not pay for any costs related to Participant's EHR maintenance, support, and upgrades.
- (c) One-Time fees will be the participant's responsibility. Participants are subject to late fees. Changes to fee schedule will be communicated to participants in advance of the next billing cycle.
- (d) Participant agrees that, once paid, all Membership Fees are nonrefundable for any reason, including termination of participation in South Dakota Health Link services by either party.

## 8. State of South Dakota Provisions

(a) CHOICE OF LAW AND FORUM: The terms and conditions of this agreement are subject to and will be construed under the laws of the State of South Dakota. The parties further agree that any

dispute arising from the terms and conditions of this agreement, which cannot be resolved by mutual agreement, will be tried in the Sixth Judicial Circuit Court, Hughes County, South Dakota.

- (b) INTEGRATION: This agreement is a complete version of the entire agreement between the parties with respect to the subject matter within this agreement and supersedes all prior or contemporaneous written or oral understandings, agreements, and communications between them with respect to such subject matter. This agreement may be modified or amended only by a writing signed by both parties.
- (c) NOTICE: Any notice or other communication required under this agreement shall be in writing and sent to the address set forth below. Notices shall be given by and to the SDHL Contact Person on behalf of SDHL, and by and to the Participant Contact Person on behalf of Participant, or such authorized designees as either party may from time to time designate in writing. Notices or communications to or between the parties shall be deemed to have been delivered when mailed by first class mail, provided that notice of default or termination shall be sent by registered or certified mail, or, if personally delivered, when received by such party.
- (d) ASSURANCES: The Participant agrees to abide by all applicable provisions of the following assurances: Lobbying Activity, Byrd Anti Lobbing Amendment (31 USC 1352), Drug-Free Workplace, Executive Order 11246 Equal Employment Opportunity, Title VI of the Civil Rights Act of 1964, Title VIII of the Civil Rights Act of 1968, Section 504 of the Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, Drug Abuse Office and Treatment Act of 1972, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970, Age Discrimination Act of 1975, Americans with Disabilities Act of 1990, Pro-Children Act of 1994, Hatch Act, Health Insurance Portability and Accountability Act (HIPAA) of 1996, Clean Air Act, Federal Water Pollution Control Act, Charitable Choice Provisions and Regulations, Equal Treatment for Faith-Based Religions at Title 28 Code of Federal Regulations Part 38, the Violence Against Women Reauthorization Act of 2013, American Recovery and Reinvestment Act of 2009, and Section 106 (g) of the Trafficking Victims Protection Act of 2002, as amended (22 U.S.C. 7104) as applicable.
- (e) CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION: Participant agrees that neither Participant, nor any of Participant's principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in transactions by any Federal department or agency. Participant will provide immediate written notice to the Department of Health, Division of Administration (600 East Capitol Avenue, Pierre, SD 57501 (605) 773-3361), if Participant, or any of Participant's principals, becomes debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in transactions involving Federal funding. Participant further agrees that if this agreement involves federal funds or federally mandated compliance, then Participant is in compliance with all applicable regulations pursuant to Executive Order 12549, including Debarment and Suspension and Participants' Responsibilities, 29 C.F.R. § 98.510 (1990).
- (f) NONASSIGNMENT/SUBCONTRACTING: Participant shall not assign this agreement, or any portion thereof, without the prior written consent of SDHL. Participant's assignment or attempted assignment of this agreement, or any portion thereof, without SDHL's prior written

consent constitutes a material breach of contract. The Participant may not use subcontractors to perform the services described herein without the express prior written consent of SDHL. Participant will include provisions in its subcontracts requiring its subcontractors to comply with the applicable provisions of this Agreement, to indemnify SDHL, and to provide insurance coverage in a manner consistent with this Agreement. Participant will cause its subcontractors, agents, and employees to comply with applicable federal, state and local laws, regulations, ordinances, guidelines, permits and requirements and will adopt such review and inspection procedures as are necessary to assure such compliance.

- (g) FEDERAL AND STATE LAWS: Participant agrees that it will comply with all federal and state laws, rules and regulations as they may apply to the provision of services pursuant to this agreement, including the Americans with Disabilities Act (ADA) of 1990, 42 U.S.C. §§ 12101-12213, and any amendment thereto, Section 306 of the Clean Air Act, and Section 508 of the Clean Water Act. Both parties further agree to provide services covered by this agreement without regard to race, color, national origin, sex, age or disability as prohibited by state or federal law.
- (h) REPORTING OF PERSONAL INJURIES AND/OR PROPERTY DAMAGE: Participant agrees to report promptly to SDHL any event encountered in the course of performance of this agreement which results in injury to the person or property of third parties, or which may otherwise subject Participant or SDHL to liability. Reporting to SDHL under this section does not satisfy Participant's obligation to report any event to law enforcement or other entities as required by law.
- (i) SEVERABILITY: In the event that any term or provision of this agreement shall violate any applicable law, such provision does not invalidate any other provision hereof.
- (j) FORCE MAJEURE: Neither Participant nor SDHL shall be liable to the other for any delay in, or failure of performance of, any covenant or promise contained in this agreement, nor shall any delay or failure constitute default or give rise to any liability for damages if, and only to the extent that, such delay or failure is caused by "force majeure". As used in this agreement, "force majeure" means acts of God, acts of the public enemy, acts of the State and any governmental entity in its sovereign capacity, fires, floods, epidemics, quarantine restrictions, strikes or other labor disputes, freight embargoes, or unusually severe weather.
- (k) RECORD RETENTION/EXAMINATION: Participant agrees to maintain all records that are pertinent to this agreement and retain them for a period of three years following final payment against the agreement. SDHL agrees to assume responsibility for these items after that time period. These records shall be subject at all reasonable times for inspection, review or audit by SDHL, other personnel duly authorized by SDHL, and federal officials so authorized by law.
- (I) LICENSING AND COMPLIANCE: The Participant agrees to comply in full with all licensing and other standards required by Federal, State, County, City or Tribal statute, regulation or ordinance in which the service and/or care is provided for the duration of this agreement. The Participant will maintain effective internal controls in managing the federal award. Liability resulting from noncompliance with licensing and other standards required by Federal, State, County, City or Tribal statute, regulation or ordinance or through the Participant's failure to ensure the safety of all individuals served is assumed entirely by the Participant.

- (m) CONFIDENTIALITY OF INFORMATION: For the purpose of the sub-paragraph, "State Proprietary Information" shall include all information disclosed to the Participant by SDHL. Participant acknowledges that it shall have a duty to not disclose any State Proprietary Information to any third person for any reason without the express written permission of a SDHL officer or employee with authority to authorize the disclosure. Participant shall not: (i) disclose any State Proprietary Information to any third person unless otherwise specifically allowed under this agreement; (ii) make any use of State Proprietary Information except to exercise rights and perform obligations under this agreement; (iii) make State Proprietary Information available to any of its employees, officers, agents or consultants except those who have agreed to obligations of confidentiality at least as strict as those set out in this agreement and who have a need to know such information. Participant is held to the same standard of care in guarding State Proprietary Information as it applies to its own confidential or proprietary information and materials of a similar nature, and no less than holding State Proprietary Information in the strictest confidence. Participant shall protect confidentiality of SDHL's information from the time of receipt to the time that such information is either returned to SDHL or destroyed to the extent that it cannot be recalled or reproduced. State Proprietary Information shall not include information that (i) was in the public domain at the time it was disclosed to Participant; (ii) was known to Participant without restriction at the time of disclosure from SDHL; (iii) that is disclosed with the prior written approval of SDHL's officers or employees having authority to disclose such information; (iv) was independently developed by Participant without the benefit or influence of SDHL's information; (v) becomes known to Participant without restriction from a source not connected to the State of South Dakota. State's Proprietary Information shall include names, social security numbers, employer numbers, addresses and all other data about applicants, employers or other clients to whom SDHL provides services of any kind. Participant understands that this information is confidential and protected under applicable State law at SDCL 1-27-1.5, modified by SDCL 1-27-1.6, SDCL 28-1-29, SDCL 28-1-32, and SDCL 28-1-68 as applicable federal regulation and agrees to immediately notify SDHL if the information is disclosure, either intentionally or inadvertently. The parties mutually agree that neither of them shall disclose the contents of the agreement except as required by applicable law or as necessary to carry out the terms of the agreement or to enforce that party's rights under this agreement. Participant acknowledges that the State and its agencies are public entities and thus are bound by South Dakota open meetings and open records laws. It is therefore not a breach of this agreement for SDHL to take any action that SDHL reasonably believes is necessary to comply with the South Dakota open records or open meetings laws. If work assignments performed in the course of this Agreement require additional security requirements or clearance, the Participant will be required to undergo investigation.
- (n) CONFLICT OF INTEREST: Participant agrees to establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal organizational conflict of interest, or personal gain. Any potential conflict of interest must be disclosed in writing.
- (o) RECYCLING: SDHL strongly encourages Participant to establish a recycling program to help preserve our natural resources and reduce the need for additional landfill space.

[END OF TERMS AND CONDITIONS] 

# **Exhibit C: Business Associate Agreement**

### **BUSINESS ASSOCIATE AGREEMENT**

This BUSINESS ASSOCIATE AGREEMENT ("BAA") is made and entered into by and between South Dakota Health Link, organized under the laws of the State of South Dakota ("Covered Entity") and the Participant ("Business Associate") in accordance with the meaning given to those terms at 45 CFR §164.501. In this BAA, Covered Entity and Business Associate are each a "Party" and, collectively, are the "Parties".

## BACKGROUND

South Dakota Health Link through its affiliation with the Department of Health is a "covered entity" as defined in the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR §160.103, and will abide by the rules and regulations set forth in 45 CFR Parts 160 and 164 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act §§ 13400-13424, 42 U.S.C. §§ 17921-17954 (2009).

Participant is a Business Associate of the Department of Health pursuant to requirements of the Health Insurance Portability and Accountability Act, 45 CFR Parts 160 and 164 (HIPAA) Subparts A and E (collectively, the "Privacy Rule"); and, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act §§ 13400-13424, 42 U.S.C. §§ 17921-17954 (2009). To comply with the State's Administrative Policies and Procedures Statement No. 24, as modified from time to time during the term of this agreement, is incorporated by reference and made a part of this agreement as if fully set forth herein.

- I. The Parties have entered into or will enter into one or more agreements under which Business Associate provides or will provide certain specified services to Covered Entity (collectively, the "Agreement");
- II. In providing services pursuant to the Agreement, Business Associate will have access to Protected Health Information.
- III. By providing the services pursuant to the Agreement, Business Associate will become a "business associate" of the Covered Entity as such term is defined under HIPAA.
- IV. Both Parties are committed to complying with all federal and state laws governing the confidentiality and privacy of health information, including, but not limited to, the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR Part 160 and Part 164, Subparts A and E (collectively, the "Privacy Rule"); and
- V. Both Parties intend to protect the privacy and provide for the security of Protected Health Information disclosed to Business Associate pursuant to the terms of this Agreement, HIPAA and other applicable laws.
- VI. To be subject to and follow all HIPAA provisions including any potential penalties and/or other consequences relating to a failure to comply with such requirements.

## AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein and the continued provision of EHI by Covered Entity to Business Associate under the Agreement in reliance on this BAA, the Parties agree as follows:

- 1. **Definitions**. For purposes of this BAA, the Parties give the following meaning to each of the terms in this Section 1 below. Any capitalized term used in this BAA, but not otherwise defined, has the meaning given to that term in the Privacy Rule or pertinent law.
  - A. "Affiliate" means a subsidiary or affiliate of Covered Entity that is, or has been, considered a covered entity, as defined by HIPAA.
  - B. "Agreement" means this document and any exhibits or appendices attached hereto and incorporated herein.
  - C. "Authorized User" means an individual authorized by Data Participant and SDHL to access Data for a Permitted Use.
  - D. "Breach" means the acquisition, access, use, or disclosure of EHI in a manner not permitted under the Privacy Rule which compromises the security or privacy of the EHI, as defined in 45 CFR §164.402.
  - E. "Breach Notification Rule" means the portion of HIPAA set forth in Subpart D of 45 CFR Part 164.
  - F. "Data" means patient record elements relevant to the scope of work of SDHL and includes all written or electronic patient information relating to patient's identity, medical history, diagnosis, treatment, tests or prognosis which is accessible to Participant through SDHL. Such information may also include, but not be limited to, any medical or laboratory services or prescription medications.
  - G. "Data Participant" means an organization that has entered into this Agreement whereby SDHL may provide access to SDHL data for "treatment," "payment," or "health care operations" purposes as those terms are defined in this Agreement.
  - H. "Designated Record Set" has the meaning given to such term under the Privacy Rule, including 45 CFR §164.501.B.
  - I. "De-Identify" means to alter the EHI such that the resulting information meets the requirements described in 45 CFR §§164.514(a) and (b).
  - J. "Electronic Health Record System" and the abbreviation "EHR" mean an electronic data system that stores current and historical information about patient diagnosis and treatment, including test results, provider notes, treatment notes, medication history, problem lists and other information related to care of the patient such as billing, scheduling, and registration data.
  - K. "Electronic EHI" means any EHI maintained in or transmitted by electronic media as defined in 45 CFR §160.103.
  - L. "Health Care Operations" shall have the definition assigned to it by the HIPAA Privacy and Security Regulations at 45 C.F.R. § 164.501.
  - M. "HIPAA Privacy and Security Regulations" means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR. Parts 160 and 164 and the Security Standards for the Protection of Electronic Protected Health Information at 45 C.F.R. Parts 160 and 164, as amended by the Health Information Technology for Economic and Clinical Health Act §§ 13400-13424, 42 U.S.C. §§ 17921-17954 (2009).

- N. "Individual" has the same meaning given to that term in 45 CFR §§164.501 and 160.130 and includes a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).
- O. "Permitted Use" means the use of any Data available for query on SDHL only as allowed by the state or federal law pursuant to the Policies and Procedures of SDHL.
- P. "Privacy Rule" means that portion of HIPAA set forth in 45 CFR Part 160 and Part 164, Subparts A and E.
- Q. "Protected Health Information" and the abbreviation "EHI" shall have the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the individually identifiable health information created or received by, from or on behalf of a Participant. Such term shall also include Electronic Protected Health Information.
- R. "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.
- S. "Security Rule" means the Security Standards for the Protection of Electronic Health Information provided in 45 CFR Part 160 & Part 164, Subparts A and C.
- T. "Treatment" shall have the definition assigned to it by the HIPAA Privacy and Security Regulations at 45 C.F.R. § 164.501, namely the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party, consultation between health care providers relating to a patient, or the referral of a patient for health care from one health care provider to another.
- U. "Unsecured Protected Health Information" or "Unsecured EHI" means any "protected health information" as defined in 45 CFR §§164.501 and 160.103 that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the HHS Secretary in the guidance issued pursuant to the HITECH Act and codified at 42 USC §17932(h).

## 2. Use and Disclosure.

- i. Except as otherwise provided in this BAA, Business Associate may use or disclose EHI as reasonably necessary to provide the services described in the Agreement to Covered Entity, and to undertake other activities of Business Associate permitted or required of Business Associate by this BAA or as required by law to meet its obligations in this and any other agreements with State.
- ii. Notwithstanding the prohibitions set forth in this agreement, Consultant may use and disclose EHI if necessary for its proper management and administration or to carry out its legal responsibilities, provided the following requirements are met:
  - a. the disclosure is required by applicable law, rule or regulation; or
  - b. reasonable assurances are obtained from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed. Such person shall notify SDHL of any instances of which it is aware in which the confidentiality of the information has been breached.
- iii. As permitted by HIPAA, and any amendments to HIPAA, and subject in particular to limits set forth in 45 CFR § 164.514 (e) (2) (limited data sets) and 45 CFR § 164.502(b) (minimum necessary disclosure requirements).

- iv. Upon request, Business Associate will make available to Covered Entity any of Covered Entity's EHI that Business Associate or any of its agents or subcontractors have in their possession.
- v. Business Associate may use EHI to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR §164.502(j)(1).
- **3. Safeguards Against Misuse of EHI.** Participant is solely responsible for all acts and omissions of the Participant and the Participant's Authorized Users (if the acts or omissions of those Authorized Users were due to negligent or intentional failure of the Participant to comply with its obligations under this article or the HIPAA Security Rule) with respect to the System, the Applications, any confidential, and other information accessed in connection with in SDHL. In addition, Participant is solely responsible for acts or omissions of any individual who accesses the System(s) or uses the Application(s) either through the Participant or by use of any passwords or log-on received or obtained from the Participant if the access or use was due to the negligent or intentional failure of the Participant to comply with its obligations under this section of the HIPAA Security Rule.
- **4. Reporting Disclosures of EHI and Security Incidents**. To notify State **in writing** of any discovery or a breach of unsecured EHI as defined in the HITECH Act or accompanying regulations pursuant to the terms of 45 CFR § 164.410 and cooperate in State's breach analysis procedures, if requested.
- 5. Reporting Breaches of Unsecured EHI. A breach shall be treated as discovered by business associate as of the first day on which such breach is known, or, by exercising reasonable diligence, would have been known, and requires written notification to State without unreasonable delay and in no event later than thirty (30) calendar days after discovery of the breach.
- 6. Mitigation of Disclosures of EHI. Business Associate will take reasonable measures to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of any use or disclosure of EHI by Business Associate or its agents or subcontractors in violation of the requirements of this BAA.
- 7. Agreements with Agents or Subcontractors. To ensure that its agents, including a subcontractor for which Consultant has received prior written consent from State pursuant to "Other Provisions" section G to whom it provides EHI received from or created by Business Associate on behalf of State, agrees to the same restrictions and conditions applicable to Business Associate, and agrees to implement reasonable and appropriate safeguards to protect all Electronic Protected Health Information (EEHI). Business Associate also agrees to create and enforce business associate agreements (BAAs) with any and all subcontractors and to monitor such subcontractors for compliance with HIPAA provisions and to take reasonable steps to ensure that its employees' actions or omissions do not cause a breach of the terms of this agreement.
- 8. Audit Report. Upon request, Business Associate will provide Covered Entity, or upstream Business Associate, with a copy of its most recent independent HIPAA compliance report (AT-C 315), HITRUST certification or other mutually agreed upon independent standards based third party audit report. Covered entity agrees not to re-disclose Business Associate's audit report. Participant may request SDHL to initiate an audit regarding another Participant's Authorized User for a good faith belief of improper use, access, or disclosure of information on the SDHL.

#### 9. Access to EHI by Individuals.

- i. Upon request, Business Associate agrees to furnish Covered Entity with copies of the EHI maintained by Business Associate in a Designated Record Set in the time and manner designated by Covered Entity to enable Covered Entity to respond to an Individual's request for access to EHI under 45 CFR §164.524.
- ii. In the event any Individual or personal representative requests access to the Individual's EHI directly from Business Associate, Business Associate within ten business days, will forward that request to Covered Entity. Any disclosure of, or decision not to disclose, the EHI requested by an Individual or a personal representative and compliance with the requirements applicable to an Individual's right to obtain access to EHI shall be the sole responsibility of Covered Entity.

### 10. Amendment of EHI.

- i. Upon request and instruction, the Business Associate "Participant" or "other Participant" will amend EHI or a record about an Individual in a Designated Record Set that is maintained by, or otherwise within the possession of, Business Associate as directed by Covered Entity in accordance with procedures established by 45 CFR §164.526. Any request by Covered Entity to amend such information will be completed by Business Associate within fifteen (15) business days of Covered Entity's request. The covered Entity is not responsible for the correction of the record. The Business Associate is considered to be the source of truth, therefore the correction in the record must be completed by the Business Associate.
- ii. In the event that any Individual requests that Business Associate amend such Individual's EHI or record in a Designated Record Set, Business Associate within ten (10) business days will forward this request to Covered Entity. Any amendment of, or decision not to amend, the EHI or record as requested by an Individual and compliance with the requirements applicable to an Individual's right to request an amendment of EHI will be the sole responsibility of Covered Entity.

### **11.** Accounting of Disclosures.

Notwithstanding the prohibitions set forth in this agreement, Business Associate may use and disclose EHI if necessary for its proper management and administration or to carry out its legal responsibilities, provided the following requirements are met:

- i. to make EHI available for purposes of accounting of disclosures, as required by 45 CFR § 164.528 and Section 13405(c)(3) of the HITECH Act; and
- ii. to cooperate in providing any accounting required on a timely basis.
- **12.** Availability of Books and Records. Business Associate will make available its internal practices, books, agreements, records, and policies and procedures relating to the use and disclosure of EHI, upon request, to the Secretary of HHS for purposes of determining Covered Entity's and Business Associate's compliance with HIPAA, and this BAA.
- **13. Responsibilities of Covered Entity.** With regard to the use and/or disclosure of Protected Health Information by Business Associate, Covered Entity agrees to:

- i. Notify Business Associate of any limitation(s) in its notice of privacy practices in accordance with 45 CFR §164.520, to the extent that such limitation may affect Business Associate's use or disclosure of EHI.
- ii. Notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of EHI.
- iii. Notify Business Associate of any restriction to the use or disclosure of EHI that Covered Entity has agreed to in accordance with 45 CFR §164.522, to the extent that such restriction may affect Business Associate's use or disclosure of EHI. Business Associate agrees to comply with any request for restrictions on certain disclosures of EHI pursuant to 45 CFR § 164.522, as agreed by State and with notice to Business Associate;
- iv. Except for data aggregation or management and administrative activities of Business Associate, Covered Entity shall not request Business Associate to use or disclose EHI in any manner that would not be permissible under HIPAA if done by Covered Entity.
- **14. Data Ownership**. Business Associate's data stewardship does not confer data ownership rights on Business Associate with respect to any data shared with it under the Agreement, including any and all forms thereof.

## **15.** Term and Termination.

- i. Termination and Participant's User Agreement. Participant's User Agreement shall commence on the Effective Date and remain in force until terminated by either party. Any terms of this Agreement which by intent or meaning have validity beyond the termination shall survive termination of this Agreement.
- ii. This Agreement may be terminated by either party upon sixty (60) days prior written notice and may be terminated by SDHL for cause if Data Participant materially breaches this Agreement and Data Participant fails to substantially remedy its obligations under this Agreement within thirty (30) days of receipt of notice of such a material breach. Upon the effective termination date of this Agreement, SDHL will cease providing Data Participant and its Authorized Users access to SDHL, and Data Participant and its Authorized Users will discontinue use of SDHL.
- iii. Upon termination of the Agreement Business Associate shall return or destroy all EHI received from, created, or received on behalf of State, at termination of this agreement, or upon request of the DOH, whichever occurs first, or, if such return or destruction is not feasible, to extend the protections of this agreement to the information and limit further uses and disclosures of such EHI.

## 16. Effect of BAA.

- i. This BAA is a part of and subject to the terms of the Agreement, except that to the extent any terms of this BAA conflict with any term of the Agreement, the terms of this BAA will govern.
- ii. Except as expressly stated in this BAA or as provided by law, this BAA will not create any rights in favor of any third party.
- **17. Regulatory References**. A reference in this BAA to a section in HIPAA means the section as in effect or as amended at the time.

- **18.** Notices. Any notice or other communication required under this agreement shall be in writing and sent to the address set forth below. Notices shall be given by and to the SDHL Contact Person on behalf of SDHL, and by and to the Data Participant Contact Person on behalf of Data Participant, or such authorized designees as either party may from time to time designate in writing. Notices or communications to or between the parties shall be deemed to have been delivered when mailed by first class mail, provided that notice of default or termination shall be sent by registered or certified mail, or, if personally delivered, when received by such party.
- **19. HITECH Act Compliance**. Parties shall comply with all requirements pursuant to the HITECH Act and its implementing regulations, and all additional applicable requirements of the Privacy Rule, including those contained in 45 CFR §§ 164.502(e) and 164.504(e)(1)(ii). Consultant will not directly or indirectly receive remuneration in exchange for any EHI, subject to the exceptions contained in the HITECH Act and without a valid authorization from the applicable individual. Consultant will not engage in any communication which might be deemed to be "marketing" under the HITECH Act and will comply with all applicable security requirements in 45 CFR §§ 164.308, 164.310, 164.312, and 164.316.

In light of the mutual agreement and understanding described above, the Parties execute this BAA as of the date first written above on the signature page in the Participation Agreement.