

[GPM Note: This Template Data Use Agreement is to be used when a covered entity seeks to disclose a limited set of PHI to another entity for research, public health, and/or health care operations purposes. The PHI being disclosed must qualify as a “Limited Data Set” under HIPAA (see 45 C.F.R. § 164.514(e)(2)) and exclude direct identifiers of the individual or of relatives, employers, or household members of the individual. If the covered entity also seeks to disclose PHI that *includes* direct identifiers to a party to create the limited data set, a business associate agreement with that party is also required. Applicable provisions from the Template Business Associate Agreement can be combined with this Data Use Agreement to create one document. Note that this Template Data Use Agreement does not include business associate agreement provisions].

DATA USE AGREEMENT

This Data Use Agreement (the “Agreement”) is entered into and made effective the ____ day of _____ (the “Effective Date”), by and between _____ (“Covered Entity”); and _____ (“Data Recipient”) (each a “Party” and collectively the “Parties”).

WHEREAS, In conjunction with _____ **[GPM Note: Further describe the purpose(s) for which the limited data set will be disclosed. Permitted purposes include research, public health, or health care operations.]** (the “Purpose”), Covered Entity may from time to time disclose to Data Recipient, and Data Recipient may use, disclose, receive, transmit, or maintain, PHI in the form of a Limited Data Set (“Limited Data Set Information”) **[GPM Note: Limited Data Set Information, although devoid of direct identifiers, is still considered PHI and arguably would still qualify as “Health Records” under the Minnesota Health Records Act (the “MHRA”). Consequently, disclosure of Limited Data Set Information must comply with the MHRA.];**

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

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

ARTICLE 1 **DEFINITIONS**

Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning ascribed to them in the HIPAA Regulations. Limited Data Set Information will have the meaning ascribed to “Limited Data Sets” in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to Limited Data Set Information transmitted from or on behalf of

Covered Entity to Data Recipient or an agent or subcontractor of Data Recipient, or created by Data Recipient or its agent or subcontractor on behalf of Covered Entity. Unless otherwise specified, the use of the term PHI will be interpreted to include Limited Data Set Information.

ARTICLE 2

EFFECT AND INTERPRETATION

The provisions of this Agreement shall apply with respect to the Use or Disclosure of any Limited Data Set Information by the Parties in conjunction with the Purpose. This Agreement sets forth the terms and conditions pursuant to which Covered Entity will Disclose the Limited Data Set Information to Recipient. Covered Entity will limit the PHI it Discloses or makes available to Data Recipient to Limited Data Set Information. In the event of any conflict or inconsistency between this Agreement and any other agreement(s) between the Parties pertaining to the Purpose or the Limited Data Set Information, the terms of this Agreement will govern. The provisions of this Agreement are intended in their totality to implement 45 C.F.R. 164.514(e) as it concerns Data Use Agreements.

ARTICLE 3

GENERAL OBLIGATIONS OF DATA RECIPIENT

Section 3.1 Use and Disclosure of Limited Data Set Information. Data Recipient agrees to not Use or further Disclose Limited Data Set Information other than as permitted by Article 4 of this Agreement, or as otherwise Required By Law.

Section 3.2 Safeguards. Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by Article 4 of this Agreement. Without limiting the generality of the foregoing, Data Recipient further agrees to:

- a. Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic Limited Data Set Information it creates, receives, maintains, or transmits on behalf of Covered Entity;
- b. Ensure that any agent, including any subcontractor, to whom it provides such Limited Data Set Information agrees to implement reasonable and appropriate safeguards to protect such information;
- c. Report promptly (and in no case later than five (5) business days) to the Covered Entity any Security Incident or Breach of Unsecured PHI of which Data Recipient becomes aware.

Section 3.3 Reports of Impermissible Use or Disclosure of Limited Data Set Information. Data Recipient will report promptly (and in no case later than five (5) business days) to Covered Entity any Use or Disclosure of the Limited Data Set Information not permitted by Article 4 of this Agreement of which Data Recipient becomes aware.

Section 3.4 Identification and Contact of Individuals. Data Recipient will not attempt to identify the Individuals to whom the Limited Data Set Information pertains, or attempt to contact such Individuals, except with the prior written consent of Covered Entity.

Section 3.5 Agents. Data Recipient agrees to require that any agent to whom it, directly or indirectly, provides Limited Data Set Information will agree in writing to comply with the same restrictions and conditions that apply through this Article 3 to Data Recipient.

ARTICLE 4
PERMITTED USES AND DISCLOSURES BY DATA RECIPIENT

[GPM Note: HIPAA permits covered entities to use and disclose a Limited Data Set for the purposes of research, public health, and health care operations. However, due to the requirements under the MHRA related to obtaining consent for disclosures of health records to an external researcher solely for purposes of medical or scientific research, some covered entities may not want research to be an intended purpose of the activities that would otherwise be permitted under the Data Use Agreement. Two options are outlined below. Option 1 permits Data Recipient to use and disclose Limited Data Set Information for public health, health care operations, and research purposes. Option 2 permits Data Recipient to use and disclose Limited Data Set Information for public health and health care operations purposes only.]

[Option 1—Use and Disclosure for research, public health, and health care operations permitted. Delete if Option 2 is selected.]

Data Recipient may, consistent with this Agreement, Use or Disclose Limited Data Set Information to a third party for purposes of Public Health, Health Care Operations or Research in accordance with the provisions of the HIPAA Regulations concerning Limited Data Sets, provided that such Use or Disclosure is (i) limited to the minimum information necessary to accomplish the Purpose; and (ii) would not violate the HIPAA Regulations if done by Covered Entity. Covered Entity represents and warrants that it has obtained consent to disclose Limited Data Set Information for the purpose of external Research or has otherwise determined that the Disclosure is permitted in accordance with Minnesota law.

[Option 2—Use and Disclosure permitted for public health and health care operations only. Delete if Option 1 is selected.]

Data Recipient may, consistent with this Agreement, Use or Disclose Limited Data Set Information to a third party for purposes of Public Health or Health Care Operations in accordance with the provisions of the HIPAA Regulations concerning Limited Data Sets, provided that such Use or Disclosure is (i) limited to the minimum information necessary to accomplish the Purpose; and (ii) would not violate the HIPAA Regulations if done by Covered Entity. Data Recipient acknowledges that while HIPAA generally would permit Use and Disclosure of Limited Data Set Information of Covered Entity for Research purposes, such Use and Disclosure is not an intended purpose under this Agreement. Accordingly, Data Recipient agrees that it will not Use or Disclose Limited Data Set Information of Covered Entity for Research purposes of Data Recipient itself or of any third party.

ARTICLE 5
TERM AND TERMINATION

Section 5.1 Term. This Agreement will commence as of the Effective Date and will remain in effect as long as Data Recipient retains the information described herein, unless this

Agreement is terminated sooner in accordance with Sections 5.2 or 5.3 of this Article.

Section 5.2 Termination for Material Breach. Any Party may terminate this Agreement based upon a material breach of this Agreement by the other Party, provided that the non-breaching Party gives the breaching Party ten (10) days written notice and the opportunity to cure such breach, and the breach is not cured during the notice period. In the event such material breach is not cured, the non-breaching Party may terminate this Agreement immediately upon the expiration of the notice period. In the event it is not possible to cure such material breach, the non-breaching Party may terminate this Agreement immediately and without any notice. **[GPM Note: Timing for termination and notification in this and other paragraphs in this document is just a suggestion and may vary based on the parties' needs and standard business practices].**

Section 5.3 Termination Permitted Due to Change in Law. Any Party may terminate this Agreement as permitted in accordance with Section 7.2 of this Agreement upon a change in an applicable law that causes performance in compliance with this Agreement to violate the law.

Section 5.4 Effect of Termination. The Parties acknowledge and agree that the provision of Limited Data Set Information to Data Recipient is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the Parties agree that Covered Entity will refrain from submitting Limited Data Set Information to Data Recipient, and Data Recipient will refrain from accepting Limited Data Set Information from Covered Entity. In the event the Parties engage in negotiations undertaken in accordance with Section 7.2 of this Agreement, the Parties will suspend during such period of negotiation any Use or Disclosure of Limited Data Set Information that the Party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations. Upon termination of this Agreement, Data Recipient agrees to promptly return or destroy, except to the extent infeasible, all Limited Data Set Information, including any Limited Data Set Information which Data Recipient has Disclosed to its subcontractors or agents. In the event that return or destruction of some or all of the Limited Data Set Information is infeasible, Data Recipient will continue to extend the protections of this Agreement to such Limited Data Set Information that is not returned or destroyed. The obligations of this Section 5.4 will survive any expiration or termination of this Agreement.

ARTICLE 6 **INDEMNIFICATION**

[GPM Note: Indemnification is not required by HIPAA or state privacy laws. However, given increased scrutiny and heightened penalties for HIPAA violations, Covered Entities may want to consider its inclusion. The provision below is an example of a one-way indemnification commitment running from Data Recipient to Covered Entity. Another alternative would be to use a mutual indemnification provision. Whether the Data Recipient can exclude this provision from the Data Use Agreement, and whether the Covered Entity will be successful in obtaining a one sided provision, likely will be a consequence of the negotiating leverage of the parties.]

Data Recipient will indemnify and hold harmless Covered Entity from and against any claim, cause of action, liability, direct losses, damages, costs and expenses (including without limitation reasonable attorney's fees) suffered by Covered Entity arising out of or in connection with any unauthorized Use or Disclosure of Limited Data Set Information or any other breach of this Agreement by Data Recipient or any of its subcontractors or agents. The Parties' obligations under this Article 6 regarding indemnification will survive any expiration or termination of this Agreement.

ARTICLE 7 **MISCELLANEOUS**

Section 7.1 Regulatory References. A reference in this Agreement to a section in the HIPAA Regulations means the section as in effect or as amended from time to time and for which compliance is required.

Section 7.2 Amendment. This Agreement may not be amended except by the mutual written agreement of the Parties. Notwithstanding the foregoing, the Parties agree to work together in good faith to take such action as is necessary to make technical amendments to this Agreement from time to time if necessary for Covered Entity and/or Data Recipient to comply with the requirements of HIPAA, the HIPAA Regulations, or any applicable provisions of any other federal or state law, as such laws or regulations may be amended from time to time. However, should any state or federal law or regulation now existing or enacted after the Effective Date of this Agreement, including without limitation HIPAA or the HIPAA Regulations, be amended or interpreted by judicial decision or a regulatory body in such a manner that a Party reasonably determines renders any provision of this Agreement in violation of such law or regulation or adversely affects the Parties' abilities to perform their obligations under this Agreement, the Parties agree to negotiate in good faith to amend this Agreement so as to comply with such law or regulation and to preserve the viability of this Agreement. If, after negotiating in good faith, the Parties are unable to reach agreement as to any necessary amendments, either Party may terminate this Agreement without penalty.

Section 7.3 Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Covered Entity and Data Recipient to comply with the HIPAA Regulations.

Section 7.4 Third Party Beneficiaries. There are no intended third party beneficiaries to this Agreement. Without limiting the generality of the foregoing, the Parties agree that Individuals whose Limited Data Set Information is Used or Disclosed to Data Recipient or its agents or subcontractors under this Agreement are not third-party beneficiaries of this Agreement.

Section 7.5 Waiver. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving Party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

Section 7.6 Correspondence. Any notice required or permitted under this Agreement will be given in writing and delivered personally or sent by certified mail, return receipt requested, or by reputable overnight delivery service, such as Federal Express, to the following addresses:

Covered Entity

Data Recipient

Section 7.7 Independent Contractors. The Parties are independent contractors and nothing in this Agreement shall be deemed to make them partners or joint venturers or make Data Recipient an agent of Covered Entity.

Section 7.8 Assignment. No Party may assign its respective rights or obligations under this Agreement without the prior written consent of the other Party.

Section 7.10 Governing Law. To the extent that federal law does not govern this Agreement, this Agreement shall be governed in accordance with the laws of the State of Minnesota, excluding its conflict of law provisions.

IN WITNESS WHEREOF, the Parties have executed this Agreement to be effective as of the Effective Date.

Covered Entity:

Data Recipient:

By: _____

By: _____

Title: _____

Title: _____