

Palliative Care Quality Collaborative

STANDARD FORM BUSINESS

ASSOCIATE AGREEMENT AND

data use agreement

This BUSINESS ASSOCIATE AGREEMENT AND Data Use Agreement (“Agreement”) is entered into and made effective on \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Effective Date”), by and between the Palliative Care Quality Collaborative, NFP, an Illinois not-for-profit corporation, with its principal place of business at 8735 W Higgins Rd, Ste #300, Chicago, IL, 60631 (“PCQC”) and \_\_\_\_\_\_\_\_\_\_\_\_\_ (“Participant”). PCQC and Participant are each a Party to this Agreement and are referred to collectively as the “Parties.”

WHEREAS, PCQC and Participant are Parties to that certain Participation Agreement, dated as of \_\_\_\_\_\_\_\_\_\_\_, (“Participation Agreement”) setting forth the terms of Participant’s participation in the PCQC Registry (“Registry”);

WHEREAS, the Participation Agreement permits and provides for the Participant, acting as a Covered Entity, to submit data to the Registry, and for PCQC, acting as a Business Associate, to conduct data analyses that relate to the Participant’s Health Care Operations, including but not limited to Data Aggregation, quality assessment and improvement, and peer review functions;

WHEREAS, the Participation Agreement may from time to time require the Registry’s receipt, Use, and/or Disclosure of Protected Health Information (“PHI”) from Participant;

WHEREAS, the Participation Agreement may from time to time require the Disclosure of PHI in the form of a Limited Data Set (“Limited Data Set Information”) for PCQC to provide services to Participant related to its Health Care Operations and for Research purposes; and

WHEREAS, the Parties desire to allocate responsibility for the Use and Disclosure of PHI, including 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”), 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”), and the regulations promulgated thereunder codified at 45 CFR Parts 160 and 164, (commonly known as the Privacy and Security Rules) (collectively referred to herein as the “HIPAA Regulations”);

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

**SECTION 1**

DEFINITIONS

Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning ascribed to them in the HIPAA Regulationsor the Participation Agreement, as the case may be. Except as otherwise specified herein, the term “Agreement” refers to this Business Associate Agreement and Data Use Agreement and not the Participation Agreement. PHI will have the meaning ascribed to it in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Participant to PCQC or a Subcontractor of PCQC, or created by PCQC or its Subcontractor on behalf of Participant. PHI will include PHI in an electronic form (“Electronic PHI”) unless specifically stated otherwise. 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 Participant to PCQC or a Subcontractor of PCQC, or created by PCQC or its Subcontractor on behalf of Participant. “Subcontractor” shall have the meaning ascribed to it by the HIPAA Regulations, and shall include any agent or other person who acts on behalf of an entity, provided that PCQC is not acting as an agent of Participant in its role as an independent contractor herein. Unless otherwise specified, the use of the term PHI will be interpreted to include Limited Data Set Information.

**SECTION 2**

EFFECT AND INTERPRETATION

 The provisions of this Agreement shall apply with respect to the Use or Disclosure of any PHI by the Parties under the Participation Agreement. In the event of any conflict or inconsistency between the Participation Agreement and this Agreement concerning the Use or Disclosure of PHI, the terms of this Agreement will prevail unless the Parties mutually agree that the applicable terms of the Participation Agreement would be more protective of PHI. The provisions of this Agreement are intended in their totality to implement the HIPAA Regulations as they concern Business Associate Contracts and 45 CFR 164.514(e) as it concerns Data Use Agreements. The provisions of the Participation Agreement will remain in full force and effect and are amended by this Agreement only to the extent necessary to effectuate the provisions set forth herein.

**SECTION 3**

GENERAL OBLIGATIONS OF PCQC

 Section 3.1. Business Associate Obligations.

 The obligations set out in this Subsection 3.1 apply with respect to PCQC’s Use or Disclosure of PHI, other than Limited Data Set Information.

1. PCQC agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law and agrees to maintain the security and privacy of all PHI in a manner consistent with all applicable laws; provided that Participant will inform PCQC of any specific state laws that it believes are applicable to PHI submitted by Participant and would require PCQC to take compliance steps beyond those required under the HIPAA Regulations.
2. PCQC agrees to use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI, to prevent Use or Disclosure of PHI other than as provided for by this Agreement. Without limiting the generality of the foregoing, PCQC further agrees to:
	1. implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.308; 164.310; 164.312;
	2. ensure that any Subcontractor, to whom it provides such PHI agrees to implement reasonable and appropriate safeguards to protect the PHI and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI; and
	3. report promptly, but in no case later than five (5) business days after discovery (as defined by 45 CFR 164.410(a)), to the Participant any Security Incident or Breach of Unsecured PHI that is known to or reasonably should be known to PCQC and shall mitigate, to the extent practicable, any harmful effects of said Security Incident or Breach of Unsecured PHI; provided however, that the Parties acknowledge and agree that this Subsection 3.1(b)(iii) constitutes notice by PCQC to Participant of the ongoing existence and occurrence or attempts of Unsuccessful Security Incidents for which no additional notice to Participant shall be required. “Unsuccessful Security Incidents” means, without limitation, pings and other broadcast attacks on firewall, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, Use or Disclosure of PHI.
3. PCQC agrees to report promptly, but in no case later than five (5) business days after discovery (as defined by 45 CFR 164.410(a)), to Participant any Use or Disclosure of PHI which is not authorized by this Agreement of which PCQC becomes aware.
4. PCQC agrees to ensure that any Subcontractor that creates, receives, maintains, or transmits PHI, on behalf of PCQC, will agree in writing to comply with the same restrictions and conditions with respect to such information that apply through this Agreement to PCQC. For the purposes of this Agreement, all PHI provided at PCQC’s direction to a Subcontractor of PCQC will be deemed to have been provided to PCQC.
5. If PHI provided to PCQC, or to which PCQC otherwise has access, constitutes a Designated Record Set, PCQC agrees to provide Participant with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Participant’s request, to provide an Individual with access to his or her PHI in order to meet the requirements under 45 CFR 164.524 concerning access of Individuals to PHI. In the event an Individual contacts PCQC or its Subcontractor directly about gaining access to his or her PHI, PCQC will not provide such access but rather will forward such request to Participant within three (3) business days of such contact, unless otherwise required by law.
6. If PHI provide to PCQC, or to which PCQC otherwise has access, constitutes a Designated Record Set, PCQC agrees to make timely amendment(s) to such PHI as Participant may direct or agree to pursuant to 45 CFR 164.526. In the event an Individual contacts PCQC or its Subcontractor directly about making amendments to his or her PHI, PCQC will not make such amendments, but rather will promptly forward such request to Participant, unless otherwise required by law.
7. PCQC agrees to make internal practices, books, and records relating to the Use and Disclosure of PHI available to the Secretary of the United States Department of Health and Human Services, during regular business hours, for purposes of the Secretary’s determining compliance with the HIPAA Regulations.
8. PCQC agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. In addition, PCQC agrees to provide promptly to Participant or an Individual, upon Participant’s reasonable request, information collected in accordance with this Subsection 3.1(h) in order to permit Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. Notwithstanding the foregoing, this Subsection 3.1(h) will not apply with respect to Disclosures made to carry out Participant’s Health Care Operations or the Disclosure of Limited Data Set Information, in accordance with the exceptions to 45 CFR 164.528 as set forth in the HIPAA Regulations, provided that this exception shall not apply to Disclosures of PHI through an electronic health record.
9. PCQC shall mitigate, to the extent practicable, any adverse effect from any improper Use and/or Disclosure of PHI by PCQC that are known to PCQC.

Section 3.2. Limited Data Set Recipient Obligations.

 The obligations set out in this Subsection 3.2 apply only with respect to PCQC’s Use or Disclosure of Limited Data Set Information.

1. PCQC agrees to not Use or further Disclose Limited Data Set Information other than as permitted by this Agreement, or as otherwise Required By Law.
2. PCQC agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by this Agreement. Without limiting the generality of the foregoing, PCQC further agrees to:
	1. implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic Limited Data Set Information that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.308; 164.310; 164.312;
	2. ensure that any Subcontractor to whom it provides such Limited Data Set Information agrees to implement reasonable and appropriate safeguards to protect such information and that are substantially similar to the terms of this Agreement;
	3. report promptly, but in no case later than five (5) business days after discovery (as defined by 45 CFR 164.410(a)), to the Participant any Security Incident or Breach of Unsecured PHI of which PCQC becomes aware; provided that the Parties acknowledge and agree that this Subsection 3.1(b)(iii) constitutes notice by PCQC to Participant of the ongoing existence and occurrence or attempts of Unsuccessful Security Incidents for which no additional notice to Participant shall be required. “Unsuccessful Security Incidents” means, without limitation, pings and other broadcast attacks on firewall, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, Use or Disclosure of PHI.
3. PCQC will report promptly, but in no cases later than five (5) business days after discovery (as defined by 45 CFR 164.410(a)), to Participant any Use or Disclosure of the Limited Data Set Information not permitted by this Agreement of which PCQC becomes aware.
4. PCQC will not attempt to identify the Individuals to whom the Limited Data Set Information pertains, or attempt to contact such Individuals, provided that this restriction will not be interpreted to prevent PCQC from conducting such activities under the Business Associate provisions of this Agreement. Under no circumstances will PCQC attempt to contact Individuals except with Participant’s prior written consent.
5. PCQC agrees to require that any Subcontractor 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 Section 3.2 to PCQC.
6. PCQC agrees to enter into a written agreement with each third party to which it Discloses Limited Data Set Information that includes the terms and provisions required by the HIPAA Regulations for such Disclosures.

**SECTION 4**

PERMITTED USES AND DISCLOSURES BY PCQC

1. General Business Associate Use and Disclosure Provisions.

Except as otherwise limited in this Agreement, PCQC may Use or Disclose PHI on behalf of, or in order to provide services to, Participant to the extent such Use or Disclosure is reasonably necessary to facilitate Participant’s participation in the Registry, consistent with the Participation Agreement, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant. In providing these services, PCQC will be acting as an independent contractor and not as an employee or agent of Participant. PCQC shall have no authority, express or implied, to commit or obligate Participant in any manner whatsoever.

1. Specific Business Associate Use and Disclosure Provisions.
	1. Except as otherwise limited in this Agreement or the Participation Agreement, PCQC may Use PHI for the proper management and administration of PCQC or to carry out the legal responsibilities of PCQC.
	2. Except as otherwise limited in this Agreement or the Participation Agreement, PCQC may Disclose PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or PCQC otherwise obtains reasonable assurances from the person to whom it Discloses the PHI that such person will a) protect the Confidentiality of the PHI; b) Use or further Disclose the PHI only as Required By Law or for the purpose for which it was Disclosed to the person; and c) promptly notify PCQC of any instances of which the person is aware that the Confidentiality of the PHI has been Breached.
	3. Except as otherwise limited in this Agreement or the Participation Agreement, PCQC may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).
	4. PCQC may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR 164.514(b), including without limitation any documentation requirements. PCQC may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this Agreement; provided that such Use or Disclosure is consistent with the Participation Agreement and applicable law.
	5. PCQC may partially de-identify any PHI to create a Limited Data Set, provided such de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2).
2. Minimum Necessary Requirement. The Parties agree that the permissible Uses and Disclosures of PHI set forth in the Participation Agreement and this Agreement are consistent with Participant’s minimum necessary policies and procedures.
3. Uses and Disclosures of Limited Data Sets. Notwithstanding Subsection 4(b) above, PCQC may, consistent with this Agreement, Use or Disclose PHI that consists solely of Limited Data Set Information to a third party for Research, 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 facilitate Participant’s participation in the Registry or for PCQC’s Research purposes; (ii) is consistent with the Participation Agreement; and (iii) would not violate the HIPAA Regulations if done by Participant. The term Health Care Operations as used here includes Data Aggregation.

**SECTION 5**

GENERAL OBLIGATIONS OF PARTICIPANT

1. Participant’s Notice of Privacy Practices, Permissions, and Restrictions.
	1. Participant acknowledges and agrees that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and any other applicable provisions of the HIPAA Regulations. Participant will provide PCQC with a copy of its Notice of Privacy Practices upon request.
	2. Participant will provide PCQC with any changes in, or revocation of, the permission by an Individual to Use or Disclose PHI, if such changes affect PCQC’s permitted or required Uses and Disclosures.
	3. Participant will ensure on a continuing basis that all Disclosures of PHI made to PCQC are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual’s PHI to PCQC impermissible. Participant will notify PCQC of any specific or general restrictions on the Use or Disclosure of PHI submitted to PCQC that Participant has agreed to in accordance with 45 CFR 164.522, if such restrictions affect PCQC’s permitted or required Uses or Disclosures.
2. Permissible Requests by Participant. Participant will not ask PCQC to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by Participant, provided that Participant may, as otherwise permitted under this Agreement, request that PCQC Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of PCQC, as provided for in 45 CFR 164.504(e)(4).

**SECTION 6**

TERM AND TERMINATION

1. Term. This Agreement will commence as of the Effective Date and will remain in effect for a period that is coterminous with the Participation Agreement, unless (i) this Agreement is terminated sooner in accordance with either Subsection (b) or (c) of this Section 6; or (ii) the Participation Agreement is amended by written agreement of the Parties in a manner that the Parties mutually agree renders the provisions of this Agreement unnecessary.
2. Termination for Material Breach. Either 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 thirty (30) 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.
3. Termination Permitted Due to Change in Law. Either Party may terminate this Agreement as permitted in accordance with Subsection 8(b) of this Agreement upon a change in an applicable law that causes performance in compliance with this Agreement to violate the law. Except as otherwise specified herein, this Agreement shall terminate immediately upon the termination of the Participation Agreement.
4. Effect of Termination.
	1. Except as provided in paragraph (ii) of this Subsection 6(d), upon termination of this Agreement for any reason, PCQC will return or destroy all PHI received from Participant, or created or received by PCQC on behalf of Participant. PCQC will retain no copies of PHI, except as provided in paragraph (ii) of this Subsection 6(d).
	2. In the event that PCQC reasonably determines that returning or destroying the PHI is infeasible due to inclusion of such PHI in a Database or for other reason, PCQC will not return or destroy the PHI, may retain copies of the PHI to the extent it has been entered into the Registry and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, PCQC will extend the protections of this Agreement to such PHI and limit any further Use or Disclosure of such PHI to those purposes that make the return or destruction infeasible, for so long as PCQC maintains such PHI.
	3. The Parties acknowledge and agree that the provision of any PHI to PCQC in accordance with the Participation Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the Parties agree that Participant will refrain from submitting PHI to PCQC, and PCQC will refrain from accepting PHI from Participant. In the event of a termination under either Subsection (b) or (c) of this Section 6, either Party may also elect to terminate the Participation Agreement. In the event the Parties engage in negotiations undertaken in accordance with Subsection 8(b) of this Agreement, the Parties will suspend during such period of negotiation any provision of the Participation Agreement requiring or obligating either Party to Use or Disclose PHI in a manner that either Party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations.
	4. The obligations of this Subsection 6(d) will survive any expiration or termination of this Agreement.

**SECTION 7**

INDEMNIFICATION; BREACH NOTIFICATION

1. Indemnification. PCQC agrees to indemnify and hold harmless Participant from direct losses and damages relating to third-party claims suffered by Participant as a result of PCQC’s breach of its obligations under this Agreement. Participant agrees to indemnify and hold harmless PCQC from direct losses and damages relating to third-party claims suffered by PCQC as a result of Participant’s breach of its obligations under this Agreement. Under no circumstances, however, will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement. The Parties’ obligations under this Section 7(a) regarding indemnification will survive any expiration or termination of this Agreement.

[IF PARTICIPANT IS A GOVERNMENT INSTITUTION THAT IS NOT ABLE TO PROVIDE INDEMNIFICATION, THE FOLLOWING ALTERNATIVE PROVISION MAY BE SUBSTITUTED FOR THE ABOVE SECTION 7(a):

1. Responsibilities of the Parties. Each Party to this Agreement agrees that it will be responsible for its own acts and omissions and the results thereof; and, shall not be responsible for the acts and omissions of the other Party and the results thereof. Each Party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees under this Agreement. Under no circumstances will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.]
2. Breach Notification. Participant and PCQC agree that if either fails to adhere to any of the provisions set forth in this Agreement or the Participation Agreement and, as a result, PHI or other confidential information is unlawfully accessed, used, or disclosed, the Party or Parties responsible for the Breach agree to pay all (or their proportionate share of) costs associated with any notification to affected individuals that is required by law, and the Party or Parties responsible will also pay any and all (or their proportionate share of) fines and/or administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting. Unless otherwise agreed upon by the Parties, if PCQC notifies Participant of a Breach of Unsecured PHI, Participant shall be responsible for providing notification to comply with Breach Notification requirements set forth in the HIPAA regulations. Such notification shall not identify PCQC unless agreed upon by PCQC in writing.

**SECTION 8**

MISCELLANEOUS

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.
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 Participant and/or PCQC 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 either 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.
3. Assignment. Neither this Agreement nor either Parties’ rights and obligations in this Agreement may be assigned to a third party without the prior written consent of the non-assigning Party.
4. Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participant and PCQC to comply with the HIPAA Regulations or applicable state patient privacy laws or regulations. Where provisions of this Agreement are different from those mandated in the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this Agreement will control.
5. No Third Party Beneficiaries. PCQC and Participant agree that Individuals whose PHI is Used or Disclosed to PCQC or its Subcontractors under this Agreement are not third-party beneficiaries of this Agreement or the Participation Agreement.
6. 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.
7. Correspondence. The Parties will send any reports or notices required under this Agreement to the addresses set forth in the notice provision of the Participation Agreement.

[ Signature Page to Follow ]

 IN WITNESS THEREOF, the Parties hereto have entered into this Agreement on the dates set forth below, so that it may take effect as of the Effective Date.

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| --- | --- |
| PCQC | PARTICIPANT |
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| By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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