**DELETE INSTRUCTIONS PRIOR TO USE**

INSTRUCTIONS: HCSRN V1 RECIPROCAL DUA TEMPLATE

**Pre-negotiated Templates**

HCSRN sites have pre-negotiated templates to fast track study start up. All sites have had the opportujity to input into their development. The sites listed below agree to use THIS template as a starting place for negating reciprocal data use agreements. Only project specific modifications are needed.

**HCSRN SITES ACCEPTING THIS RECIPROCAL DUA TEMPLATE**

* Essentia Institute of Rural Health
* Geisinger Clinic
* Group Health Cooperative
* Harvard Pilgrim Health Care, Inc.
* HealthPartners Institute for Education and Research
* Henry Ford Health System
* Kaiser Foundation Research Institute (for all regions)
* Marshfield Clinic Research Foundation
* Palo Alto Medical Foundation Research Institute
* Scott and White Memorial Hospital

**When to Use the HCSRN Reciprocal Data Use Agreement Template**

This Reciprocal DUA template may be used with any contractual or subaward agreement in place.

*This differs from the HCSRN standard (unidirectional) DUA template – which may only be used in conjunction with the HCSRN subaward template.*

**General Instructions**

* Always **use track changes** when making edits to the document, so sites can quickly see how the pre-negotiated template was altered.

**Page 1**

Insert study name in document heading and section A.

Insert sponsor name and awardee name in section A.

**Signature Pages**

* Complete as outlined. Add or delete sections, as needed.

**Appendix A**

* Enter a brief description of the limited data set to be shared. List the type of data elements to be transmitted; avoid listing specific variables.

**Appendix B**

* Insert the study name as listed on page 1 and the number of participating sites (as noted by the signatory pages)
* List permitted disclosures.
* List permitted uses.



RECIPROCAL DATA USE AGREEMENT

FOR RESEARCH IN

[Insert Study Name Per Subaward Agreement]

This Reciprocal Data Use Agreement for Research (“Agreement”) is entered into by each of the research organizations listed in the signatory pages (the “Study Site(s)” or a “Party”) for the purposes described below. This Agreement will be effective as of the last date it is executed by a Party hereto (the “Effective Date”).

1. Each Party is participating in a research project known as the “[Insert Study Name Per Subaward Agreement]” (“the Study”), awarded by [Insert Sponsor Name] (“Sponsor”) to [Insert Awardee's Name].
2. The Parties desire to set forth the terms and conditions for the Uses and Disclosures of the Study Data Set(s) described in Appendix A (Elements of Data Set(s)), by each of the Study Sites (each a “Disclosing Party”) to other Study Sites (each a “Data Recipient”) for purposes of conducting the Study, as described in Appendix B (Permitted Disclosures and Uses).

NOW, THEREFORE, in consideration of the mutual promises and considerations set forth below, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. The recitals set forth above are hereby incorporated into and shall be deemed a part of this Agreement. Any capitalized terms used but not defined herein shall have the meanings set forth in 45. C.F.R. Parts 160 – 164 issued under the Health Insurance and Portability and Accountability Act of 1996, P.L. 104-191 (“HIPAA”), as amended.
2. As specified in this Agreement, each Data Recipient may make only the Uses and Disclosures of the Study Data Set(s) (collectively, the “Data”) as are minimally necessary to conduct the Study.
3. All Uses and Disclosures of Data permitted by this Agreement shall be conducted by each Party in compliance with applicable laws and regulations, protocols, authorization and consent forms, if any, IRB approvals and HIPAA regulations.
4. With respect to the Data, each Party shall comply with the HIPAA Standards for Security for the Protection of Electronic Protected Health Information (“PHI”), codified at 45 CFR parts 160 and 164, Subpart C, effective April 20, 2005, as may be amended thereafter, and the Health Information Technology for Economic and Clinical Health (HITECH) Act, effective February 17, 2009, and all regulations promulgated thereunder, as they may be amended.
5. Except as Required by Law, no Party shall Use or further Disclose PHI or any part of the Data other than as expressly permitted by this Agreement as further described in Appendix B and in accordance with the then-current approved protocol(s) as approved by the IRB(s) of record.
6. The workforce members, or classes of workforce members, at each Study Site who are permitted to Use and Disclose the Data in accordance with this Agreement for purposes of the Study, are: the investigators and co-investigators identified on the signature pages of this Agreement or their respective IRB-approved successors, and the staff assigned to work on the Study at each Study Site.
7. Each Data Recipient must:
	1. Not Use or Disclose the Data or share any secondary information derived from the Data for any purpose other than the Study or as Required by Law.
	2. Use appropriate safeguards as Required by Law to prevent any Use or Disclosure of the Data other than as provided for by this Agreement. Upon request by any Party, the Data Recipient shall describe the safeguards being used to prevent unauthorized Use or Disclosure of the Disclosed Data.
	3. To the extent that a Data Recipient receives, creates, maintains or transmits Electronic PHI for the Study, use appropriate administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic PHI, in accordance with the then-current approved protocol(s) as approved by the IRB(s) of record.
	4. Report to their Institutional Privacy Officer or other designated individual and to the IRB(s) of record, within one (1) business day of receiving knowledge of any Security Incident or unauthorized Use or Disclosure of the Data not provided for by this Agreement. Data Recipient shall also report within one (1) business day of receiving knowledge of such Security Incident or unauthorized Use or Disclosure, to the Investigator and Authorized Official of the Party that initially provided the information (“Source Party”). Furthermore, within five (5) business days of such discovery Data Recipient shall provide a written report to its Institutional Privacy Officer, the IRB(s) of record, and the Source Party that initially provided the Data, setting forth the facts and a proposed corrective action plan to mitigate the Security Incident or unauthorized Use or Disclosure.

At the expense of the Data Recipient, the Disclosing Party shall have the right to cure any data breach in a Security Incident, and shall give the Data Recipient notice of its election to cure any such data breach. Data Recipient shall cooperate fully in the efforts by the Disclosing Party to cure the data breach. The Data Recipient shall pay the Disclosing Party within thirty (30) days of request therefore, for any costs reasonably incurred by Disclosing Party in curing any such data breach. All requests for payment for such services shall be paid within thirty (30) days.

* 1. Ensure that any person, including any subcontractor, consultant or other agent to whom Data Recipient provides the Data in accordance with this Agreement and any subaward or subcontract agreement entered into by such Party with respect to the Study, agrees to the same restrictions and conditions that apply to Data Recipient under this Agreement. Before providing the Data to any such person who is not a Workforce member, Data Recipient shall notify the Disclosing Party and confirm that the person has made that agreement in writing.
	2. Not use the information in the Data to identify, attempt to identify, or contact any individuals, except if and as expressly permitted in an IRB-approved protocol for the Study.
	3. Data Recipient agrees to establish and implement procedures for mitigating any deleterious effect from the Use or Disclosure of PHI in violation of this Agreement.
	4. If Required by Law, the Disclosing Party shall report the violation to the Secretary of the Department of Health and Human Services and any other government agency with jurisdiction of the matter in accordance with the Disclosing Party’s institutional procedures.

Term and Termination

a. The provisions of this Agreement shall be effective as of the Effective Date and shall terminate with respect to a Data Recipient when all of the Data and any other Protected Health Information provided by any Disclosing Party (as defined below) to that Data Recipient are destroyed or returned to the Disclosing Party, or, if it is infeasible to return or destroy the Data, protections are extended to the Data in accordance with the termination provisions in this Agreement.

b. Upon any Disclosing Party’s knowledge of a breach of this Agreement by any Data Recipient, the Disclosing Party shall take any or all of the following actions, as necessary:

Provide the Data Recipient with written notice of the breach of the Agreement and an opportunity to cure the breach within ten (10) working days of receipt of such notice (or other such time period as the Parties may mutually agree). If the Data Recipient fails to cure the breach within the notice period, this Agreement may be terminated with respect to that Data Recipient; or

* + - * 1. Immediately terminate this Agreement (without opportunity to cure) with respect to the Data Recipient if the Disclosing Party determines, in its sole discretion, that the Data Recipient has breached a material term of this Agreement.
1. A Party may terminate the application of this Agreement solely with respect to such Party by giving thirty (30) days prior written notice to all other Parties.
2. Effect of Termination

a. Except as provided in paragraph (b) of this section, upon termination of the Agreement as to any Party for any reason (the “Terminated Party”), the Terminated Party shall return or destroy all information contained in the Data received from any Party under this Agreement, as directed in writing from the Disclosing Party. If the Terminated Party destroys the Data, the Terminated Party shall certify in writing to the other Parties that the Data in that Party’s possession has been destroyed. The Terminated Party shall retain no copies of such information.

b. In the event a Terminated Party determines that returning or destroying the information contained in the Data is infeasible, the Terminated Party shall provide to other Parties a written explanation of the conditions that make return or destruction infeasible. Upon a written mutual agreement of the Parties that return or destruction of such information is infeasible, the Terminated Party shall extend the protections of this Agreement to such information as mutually agreed by the Parties and limit further uses and disclosures of such information to those purposes that make the return or destruction infeasible, for so long as Terminated Party maintains such information.

c. The termination of this Agreement as to one Party shall not terminate or affect the status of or the enforceability of this Agreement as to all other Parties.

1. Ownership of Data. All Data initially Disclosed by a Disclosing Party shall remain exclusively owned by the Disclosing Party. If any Party withdraws from participation in the Study, such Party may request that the other Parties to this Agreement return or destroy the Data that was initially provided by the withdrawing Party in accordance with the termination provisions of this Agreement. All other Parties shall comply with such request to the extent that such request is reasonable and feasible.
2. No Party shall use the names, logos, symbols or trademarks of another Party or the other Party’s affiliates or related entities, without the express written permission of the other Party, except that Parties may identify each other in annual reports and like documents that generally describe or refer to the Study.
3. This Agreement in no way limits any obligations of any Data Recipient or its workforce members under any law or policy that is otherwise applicable to the Data Recipient, such as an obligation to comply with their institution’s policies and procedures.
4. If any provision of this Agreement is found to be invalid, illegal or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall continue in full force and effect, unless the absence of such invalidated provision materially and adversely affects the substantive rights of the Parties hereto. Each Party hereby waives any right to assert that any provision of law renders any provision of this Agreement invalid, illegal or unenforceable in any respect. The Parties shall negotiate in good faith to substitute a valid, legal, and enforceable provision that reflects the intent of such invalid, illegal or unenforceable provision and implements the purpose of such provision.
5. Indemnification
	1. Hold Harmless. Except as between those entities which are members of the Kaiser Permanente Medical Care Program and except to the extent allowed by law, each Party shall defend, indemnify, and hold any other Party, its officers, employees, and agents harmless from and against any and all liability, damage, loss or expense (including reasonable attorneys' fees), incurred in connection with any claims, suits, actions, demands or judgments arising from any cause of action or theory of liability for injury or damages arising out of or relating to the performance or breach of this Agreement but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the acts or omissions of the indemnifying Party, its officers, employees, or agents.
	2. Notice. The indemnified Party shall give the indemnifying Party prompt notice in writing of any claim, action, or suit for which the indemnified Party seeks indemnification, and to cooperate fully with the indemnifying Party in the investigation and defense thereof. Upon written acknowledgement of its assumption of full responsibility for the results of the action or claim, the indemnifying Party will have the right to assume and control the defense and settlement of such action or claim, in such case the indemnified Party may employ its own counsel if it wishes to do so, at its own expense. Regardless, the indemnifying Party shall not settle or compromise any claim or suit without prior written consent of the indemnified Party. The Parties’ obligations under this section shall survive termination of this Agreement until all claims involving any of the indemnified matters are fully and finally resolved or barred by applicable statutes of limitation.
6. Any ambiguity in this Agreement or any conflict between the terms of this Agreement and any other agreement between any Parties to this Agreement relating to the Use and Disclosure of the Data by any Party shall be resolved in favor of a meaning that further protects the privacy and security of the information.
7. Any failure by a Party to enforce the strict performance of any provision of this Agreement shall not be deemed a waiver of its right to enforce such provision or any other provision of this Agreement.
8. All notices related to this Agreement shall be provided in writing to the investigator and authorized official designated below for each Party at the address specified in signatory pages.
9. Each Party represents and warrants that the authorized official executing this Agreement on its behalf is fully authorized to bind the Party represented.
10. This Agreement may be executed in any number of counterparts, including by facsimile and electronic transmission, which together shall constitute one and the same Agreement.

**[The remainder of this page is intentionally left blank.]**

**SIGNATORY PAGES**

The Investigators identified below are not Parties to this Agreement. Their signatures indicate their acknowledgement they have read and understand the obligations applicable to each investigator and institution under this Agreement.

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| **Organizational Name:**  |
| Site InvestigatorName:Address:Phone: Email: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| Site Authorized OfficialName:Address:Phone: Email: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| **Organizational Name:**  |
| Site InvestigatorName:Address:Phone: Email: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| Site Authorized OfficialName:Address:Phone: Email: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
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| Site Authorized OfficialName:Address:Phone: Email: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
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| **Organizational Name:**  |
| Site InvestigatorName:Address:Phone: Email: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| Site Authorized OfficialName:Address:Phone: Email: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
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*Add additional rows, as needed*

**APPENDIX A**

| **Elements of Data Set(s)** |
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|  |

**APPENDIX B**

**Permitted Uses and Disclosures**

The study titled “[Insert Study Name]”, has [Insert #] participating sites as noted on the signatory pages.

Note: In addition to direct use (e.g., analysis) of the data for the study, be sure to include any Uses or Disclosures to a data coordinating center or to a site for quality assurance purposes.

**Permitted Disclosures:**

**Permitted Uses:**