

**GROUP HEALTH COOPERATIVE
CENTER FOR HEALTH STUDIES**

PRIVACY AND DATA USE AGREEMENT FOR RESEARCH

PROJECT INVESTIGATOR:

PROJECT TITLE:

HUMAN SUBJECTS REVIEW COMMITTEE REFERENCE NUMBER:

BACKGROUND:

Group Health Cooperative may use or disclose a Limited Data Set for research purposes without written authorization by the subjects whose data is used or disclosed only if the data recipient signs a contractual agreement (a "Data Use Agreement"). A Limited Data Set is defined under HIPAA as information that **does not include** the following direct identifiers of the individual or of the individual's relatives, employers, or household members:

Names
Postal address information, other than town or city, state, and zip code
Telephone numbers
FAX numbers
Electronic mail addresses
Social security numbers
Medical record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs)
Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice prints, and
Full face photographic images and any comparable images

This Data Use Agreement describes the data that will be released to the recipient and the conditions under which recipient may use this data.

AGREEMENT:

This Data Use Agreement ("Agreement") is made and entered into as of this _____ day of _____, 20__ by and between Group Health Cooperative, a Washington nonprofit corporation ("Covered Entity"), and _____ ("Data Recipient").

Recitals

WHEREAS, Covered Entity and Data Recipient are committed to compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and regulations promulgated thereunder; and

WHEREAS, the purpose of this Agreement is to satisfy the obligations of Covered Entity under HIPAA and to ensure the integrity and confidentiality of certain information disclosed or made available by Covered Entity to Data Recipient.

NOW, THEREFORE, in consideration of Covered Entity's authorization of Data Recipient to obtain, use and/or disclose this Limited Data Set, and Data Recipient's agreement to protect and administer such Limited Data Set as provided herein, the parties agree as follows:

1. Definitions.

1.1 Required By Law. "Required By Law" shall mean a mandate contained in state or federal law that compels an entity to make a use or disclosure of the information contained in the Limited Data Set and that is enforceable in a court of law and that otherwise complies with the term "required by law" contained in 45 CFR § 164.501.

1.2 Security. "Security" shall mean the administrative, technical and physical safeguards implemented by Data Recipient to ensure the integrity and confidentiality of the information subject to this Agreement, including but not limited to safeguards intended to prevent unauthorized access to or interception of such information.

2. **Scope and Purpose.**

2.1 This Agreement sets forth the terms and conditions pursuant to which Covered Entity will disclose the Limited Data Set to the Data Recipient.

2.2 The Limited Data Set disclosed by Covered Entity to Data Recipient is described below:

(Brief description of data to be released): _____

Date(s) or approximate date(s) of data release: _____

2.3 Except as otherwise specified herein, Data Recipient may make all uses and disclosures of the Limited Data Set necessary to conduct the research project named above and described below, and for no other purpose:

_____ (include a brief description of the research) ("Research Project").

2.4 Only the project investigator or designated individual(s) or classes of individuals listed below are permitted to use or receive the Limited Data Set. These individuals are responsible for using this information subject to the terms and conditions of this Agreement:

3. Obligations and Activities of Data Recipient.

3.1 Data Recipient agrees to not use or disclose the Limited Data Set for any other purpose other than as permitted by this Agreement or as otherwise Required by Law.

3.2 Data Recipient agrees to use appropriate Security to prevent the use or disclosure of the Limited Data Set other than as provided for by this Agreement.

3.3 Data Recipient agrees to report to Covered Entity any use or disclosure of the Limited Data Set not permitted by this Agreement of which it becomes aware.

3.4 Data Recipient agrees to ensure that any agents, including subcontractors, to whom it provides the Limited Data Set agree to the same restrictions and conditions that apply through this Agreement to Data Recipient with respect to such information.

3.5 Data Recipient agrees that it will not identify the information contained in the Limited Data Set or contact the individuals whose information is included in this Limited Data Set.

3.6 Prior to any publication or formal presentation, Data Recipient will offer the Center for Health Studies Director the opportunity to review and comment on any articles or papers that specifically identify or address Group Health Cooperative data. Any such publications or papers will carry a footnote acknowledging Group Health Cooperative participation and will acknowledge that findings and conclusions do not necessarily represent views of Group Health Cooperative.

3.7 Data Recipient shall conform with any changes in, or restrictions to, the use or disclosure of information contained in the Limited Data Set provided by Covered Entity pursuant to Section 4 of this Agreement.

4. Obligations of Covered Entity.

4.1 Revocation of Authorization. Covered Entity shall provide Data Recipient with any material changes in, or revocation of, permission by an individual to use or disclose information contained in the Limited Data Set, if Covered Entity reasonably believes that such changes affect Data Recipient's permitted or required uses and disclosures such information under this Agreement.

4.2 Restriction of Use or Disclosure. Covered Entity shall notify Data Recipient of any restriction to the use or disclosure of information contained in the Limited Data Set that Covered Entity has agreed to if Covered Entity reasonably believes that such restriction affects Data Recipient's permitted or required uses and disclosures.

5. Indemnification.

Data Recipient shall indemnify, defend and hold harmless Covered Entity and its employees, directors, officers, subcontractors, agents or other members of its workforce against all actual damages and any civil or criminal penalties (including reasonable attorneys fees incurred by Covered Entity in responding to any claim, investigation, compliance review or other administrative proceeding, and at trial, on appeal and any petition for review or certiorari, and any bankruptcy proceeding) incurred or suffered by Covered Entity, and all liability of Covered Entity to third parties arising from or in connection with any breach of this Agreement by Data Recipient or its employees, directors, officers or other members of its workforce as well as its subcontractors, agents or other persons to which Data Recipient has disclosed information contained in the Limited Data Set. Data Recipient's obligation to indemnify shall survive the termination of this Agreement.

6. Ownership of Information.

Unless explicitly stated otherwise in the Agreement, ownership in and all rights to all information contained in the Limited Data Set received by Data Recipient from Covered Entity shall not transfer to Data Recipient, and shall remain with Covered Entity. Except as expressly authorized in the Agreement, Data Recipient shall not create any derivative works using such information. The creation of any such derivative work or works shall be considered "work for hire" by the Data Recipient for the benefit and ownership of the Covered Entity. To the extent Data Recipient obtains any ownership or other rights in this information, Data Recipient irrevocably assigns such rights to Covered Entity.

7. Term and Termination.

7.1 Term. The Term of this Agreement shall begin on the date first set forth above, and shall terminate when all of the information contained in the Limited Data Set provided by Covered Entity to Data Recipient, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy such information, protections are extended to such information, in accordance with the termination provisions in this Section 7.

7.2 Termination for Cause. Upon Covered Entity's actual knowledge of a material breach of this Amendment by Data Recipient, Covered Entity may take action to cure such breach. If said breach is not cured, Covered Entity may terminate this Agreement. Covered Entity may also elect to immediately terminate this Agreement if Data Recipient has breached a material term of this Agreement. If neither termination nor cure are feasible, Covered Entity shall report the violation to the Secretary of the Department of Health and Human Services.

7.3 Effect of Termination.

(a) Except as provided in paragraph (b) of this section, upon termination of the Agreement for any reason, Data Recipient shall return or destroy all information contained in the Limited Data Set received from Covered Entity. This provision shall apply to such information that is in the possession of subcontractors or agents of Data Recipient and Data Recipient shall retain no copies of such information.

(b) In the event that Data Recipient determines that returning or destroying the information contained in the Limited Data Set is infeasible, Data Recipient shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the parties that return or destruction of such information is infeasible, Data Recipient shall extend the protections of this Agreement to such information and limit further uses and disclosures of such information to those purposes that make the return or destruction infeasible, for so long as Data Recipient maintains such information.

8. Miscellaneous.

8.1 Amendment. Except as otherwise provided herein, this Agreement may only be amended on written agreement of the parties.

8.2 Survival. The respective rights and obligations of Data Recipient under Section 5 and Section 7.3 of this Agreement shall survive the termination of this Agreement.

8.3 Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with HIPAA. If the terms of this Agreement conflict with HIPAA, the terms of the HIPAA shall control. In the event of a conflict between this Agreement, and any other agreement between the parties, the terms of this Agreement shall control.

8.4 No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the parties and the respective successors or assigns of the parties, any rights, remedies, obligations, or liabilities whatsoever.

8.5 Severability. If any provision of this Agreement is held unenforceable or inoperative by any court of competent jurisdiction, either in whole or in part, the remaining provisions shall be given full force and effect to the extent not inconsistent with the original terms of this Agreement.

8.6 Modification. All modifications to this Agreement must be in writing and signed by Data Recipient and the Covered Entity.

8.7 Governing Law/Venue. This Agreement shall be governed by and construed in accordance with the laws of the United States and the State of Washington. Any legal action or proceeding relating to this Agreement shall be instituted in state or federal court located in King County, Washington.

8.8 Conformity. If state or federal laws or regulations change and affect any provision of this Agreement, this Agreement will be deemed amended to conform with those changes the date the law or regulation becomes effective.

8.9 Changes in Law. If at any time during the term of this Agreement, any applicable state or federal law or regulation is amended, revised, or interpreted in such a manner as to require modification of the terms and conditions of this Agreement, Covered Entity may amend this Agreement as reasonably necessary to comply with applicable law or regulation upon sixty (60) days written notice to Data Recipient. Data Recipient will be deemed to have accepted such amendment if it does not object in writing thirty (30) days before the effective date of the amendment.

IN WITNESS WHEREOF, the parties have executed this Agreement on the date first written above.

GROUP HEALTH COOPERATIVE:

[INSERT NAME of Recipient Organization/Sponsor]:

The undersigned individual represents and warrants that he/she has authority to execute this Agreement on behalf of the Data Recipient.

By: _____
(signature of Institutional Official)

By: _____
(signature)

(print name)

(print name)

Title: _____

Title: _____

By: _____
(signature of Investigator/Individual)

By: _____
(signature of Investigator/Individual)

(print name)

(print name)

Title: _____

Title: _____