**Collaborative Research Attestation and Data Use Agreement**

1. Proposal Number:

2. Project Title:

3. Project Leader:

4. ACT Investigator:

5. Other Collaborators:

6. ACT Data Request and Manuscript Proposal Approval Date:

7. Purpose of Data request (check all that apply):

Data to support a new manuscript

Data to support a new scholarly work (e.g., conference workshop, lecture, etc.)

Data to assess feasibility of, or prepare for a study

Other, please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Data Use Limitations**

This Attestation sets forth the terms and conditions pursuant to which the Project Leader may request ACT Data. Requests made without acknowledgement and acceptance of these terms will not be approved. If your request is approved by ACT, your institution shall enter into a Data Use Agreement (“DUA”) included here with ACT prior to the transfer of ACT Data. Project Leader should provide the DUA template to their institutional official(s) for review to ensure that they can comply with the terms below as they are non-negotiable for the use of ACT data.

**Project Leader Obligations**

**1.** Only the Project Leader, co-investigators, or designated individual(s) are permitted to use or receive the Data for approved purposes. These individuals are responsible for using this information subject to the terms and conditions of this document, the Data Use Agreement below and in accordance with the ACT Study [Proposals & Publications Policy](https://actagingresearch.org/download_file/6fd2dc9e-d337-4301-9d72-86d1b1fc6eb0/9).

**2.** Project Leader agrees to obtain IRB approval at their institution for any requests of individual-level Data (i.e., not aggregate data). ACT will not release individual-level Data until proof of IRB approval or exemption is obtained.

**3.** If Project Leader moves to another institution, s/he needs to destroy the Data and notify ACT in writing within 30 days that this has been done. If Project Leader takes these Data to the new institution, then s/he must provide ACT with updated contact information and a copy of the new IRB approval for the new institution. If the Data remain at the initial organization, then the Project Leader must designate who is responsible for the files and ensure that s/he signs a copy of this document and provides written acknowledgement of reading and understanding the fully executed Data Use Agreement.

**4.** No findings or information derived from ACT Data may be released if they contain any combination of Data elements that might allow the deduction of a patient’s identity. In tables, cell sizes less than 5 must be suppressed unless prior approval facilitated by the ACT Proposals & Publications Committee has been obtained. The ACT Proposals & Publications Committee will be the sole judge as to whether any finding derived from the ACT Data would, with reasonable effort, permit one to identify an individual, or to deduce the identity of an individual or provider to a reasonable degree of certainty.

**5.** Any publications and/or abstracts arising from the Data must be reviewed and approved by ACT following the [Proposals & Publications Policy](https://actagingresearch.org/download_file/6fd2dc9e-d337-4301-9d72-86d1b1fc6eb0/9) before submitting any manuscripts to journals or abstracts to conferences. This does not apply to previously published ACT Data. ACT agrees to review the manuscript(s) and make a determination about approval and notify the Project Leader within two (2) weeks after the review [one (1) week for abstracts]. Project Leader also agrees not to submit such findings to any third party until receiving ACT approval to do so.

A purpose of ACT’s review is to ensure that data confidentiality is maintained and that individual patients cannot be identified. Thus, ACT may withhold approval of a manuscript or abstract if it determines that the format in which data are presented may result in identification of individual patients.

**6.** Project Leader agrees that if ACT determines (or has reasonable belief) that s/he has violated any terms of this agreement, ACT may request that s/he destroy all local copies of the Data and all derivative files and provide a written statement certifying that no Data has been retained. Additionally, as a result of the determination or reasonable belief that a violation of this agreement has taken place, ACT may refuse to release further ACT Data.

**7.** Significant changes to approved Proposals require review and approval by ACT before any analyses may be conducted or research findings may be disseminated. If the Project Leader is unsure whether there is a significant change, please request ACT review.

**8.** Project Leader agrees to complete a brief progress report biannually and return it to ACT within two (2) weeks.

**9.** Any publications and/or abstracts arising from the Data must properly acknowledge the contributions of ACT, as described in more detail in the[ACT Manuscript Acknowledgement Guide](https://actagingresearch.org/download_file/e59f1d9f-50d1-45ad-b824-c29c2ca75c5d/9).

**10.** As of April 7, 2008, NIH requires that any publications, which arose from an NIH award, be submitted to PubMed Central (<http://publicaccess.nih.gov/>).

**11.** **A copy of the final analytic datasets along with the documented program(s) will be provided to ACT to be stored indefinitely. They will become part of the ACT Repository according to ACT’s approved procedures. Project Leader’s institution may not retain an archival copy of the final analytic datasets. However, a copy may be requested after destruction.**

**12.** The Project Leader will destroy **all** ACT datasets two (2) years after publication of their results and/or completion of grant funding period.

IN WITNESS WHEREOF, the parties have executed this Agreement on the last date signed below.

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| **Signature from ACT leadership:** |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ACT Principal Investigator

Linda K. McEvoy, PhD

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| **Signature of Project Leader:** |

Signatory acknowledges that s/he has read and understands the above stated provisions.

(Signature) (Title)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Print name) (Date)

Institution/Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Street Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City/State/ZIP code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
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| **Required for Students and Fellows: Signature of Department Chair or Advisor:** |

Signatory acknowledges that s/he has read and understands the above stated provisions.

(Signature) (Title)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Print name) (Date)

Institution/Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Street Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City/State/ZIP code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DATA USE AGREEMENT**

This Data Use Agreement (“Agreement”) with respect to a Limited Data Set is entered into as of the date of last signature below (“Execution Date”) by and between **Kaiser Foundation Health Plan of Washington**, a Washington nonprofit public benefit corporation, through the Kaiser Permanente Washington Health Research Institute, and on behalf of the Washington Permanente Medical Group, P.C. (hereafter referred to as “**Data Provider**”) and  (hereinafter referred to as “**Data** **Recipient**”). Provider and Recipient may each be referred to as a “**Party**” or collectively as the “**Parties**”.

**RECITALS**

Whereas, the Adult Changes in Thought (“ACT”) Study Data Repository, created under the ACT Consortium, prospectively collects and provides data related to Alzheimer's Disease (“AD”) and dementia;

Whereas, the ACT Consortium supports a broad program of AD and dementia research within complementary areas of medicine;

Whereas, the ACT Study and Consortium are funded and supported under NIH Grant number 5U19AG066567-02 provided by the National Institute on Aging (NIA) and operating under a Data and Management Sharing Plan approved by NIA;

Whereas, Data Recipient Project Leader has reviewed ACT Data Sharing Policies and Procedures, data use terms herein and submitted a data request and study proposal;

Therefore, Data Provider and Data Recipient desire to set forth the terms and conditions under which Data Provider will disclose to Data Recipient certain Protected Health Information (“PHI”) in the form of a limited data set described in this Agreement (“the Limited Data Set”) solely for the purpose of the Data Recipient’s use on the research study entitled **“ ”** (“**the Study**”), on the terms and conditions stated herein, as more specifically described in Exhibit A.

In consideration of the mutual promises below, the Parties agree as follows:

**ARTICLE I**

**DEFINITIONS**

1.1 **Limited Data Set,** as defined in the Privacy Rule at 45 CFR Section 164.514(e), is PHI that can include specific identifiers and must exclude others considered to be PHI. A limited data set may **include**: 1) dates (e.g., admission, discharge, and service dates, dates of birth and death); and 2) five-digit zip codes and state, county, city, and precinct, but not any other postal address information. A limited data set must **exclude** the following direct identifiers of an individual and his or her relatives, employer(s), and household members: name; postal address information (except town or city, state and zip code which are permitted); telephone numbers; fax numbers; electronic mail addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; license plate numbers and other vehicle identifiers and serial numbers; device identifiers and serial numbers; URLs; Internet Protocol (IP) address numbers; biometric identifiers including finger and voice prints; and full-face photographic and any comparable images. In the event of any conflict between this description and the definition in the Standards for Privacy of Individually Identifiable Health Information (45 CFR, Parts 160 and 164, Subparts A and E) (“the Privacy Rule**”**), the Privacy Rule definition will govern.

1.2 Security Rulemeans the Standards for Security for the Protection of Electronic Protected Health Information, codified at 45 CFR parts 160 and 164, Subpart C, effective April 20, 2005.

1.3 The following terms shall also have the meanings givento them in the Privacy Rule: Covered Entity, Individual, Protected Health Information, and Required by Law.

**ARTICLE II**

**DATA PROVIDER’S OBLIGATIONS**

2.1. Data Provider will disclose to Data Recipient the Limited Data Set for the purposes of the research study entitled “” which study is more specifically described in Exhibit A (“the Study”). Exhibit A, which also describes the Limited Data Set, is attached to, and by this reference incorporated in, this Agreement.

2.2. Data Provider shall not request Data Recipient to use or disclose the Limited Data Set in any manner that would violate the Privacy Rule if done by a Covered Entity.

# **ARTICLE III RECIPIENT’S OBLIGATIONS UTILIZING ACT DATA**

3.1. Unless specifically stated otherwise in this Agreement, Data Recipient’s obligations with respect to the Limited Data Set apply to the whole and to any part of the Limited Data Set.

3.2. Data Recipient shall not use or disclose the Limited Data Set for any purpose other than the Study or as Required by Law. In addition, Data Recipient shall not use or disclose the Limited Data Set in any manner that would violate the Privacy Rule if done by a Covered Entity.

3.3. Exhibit A specifies who is permitted to use or receive the Limited Data Set for the purposes of the Study.

3.4. Data Recipient may not subcontract its performance obligations, or assign its rights, under this Agreement without the express written consent of Data Provider. Data Recipient shall ensure that any subcontractor agrees in writing to the same terms and conditions regarding a Limited Data Set that apply to Data Recipient under this Agreement.

3.5. Data Recipient must have appropriate safeguards to prevent the use or disclosure of the Limited Data Set in any manner not permitted by this Agreement.

3.6. Data Recipient must not identify or contact (or attempt to do so) either directly or through another person, any Individual in the Limited Data Set.

3.7 A copy of the final analytic datasets along with the documented program(s) will be provided to ACT to be stored indefinitely. It will become part of the ACT Repository according to ACT’s approved procedures. Project Leader’s institution may not retain an archival copy of the final analytic datasets. However, a copy may be requested after destruction.

**ARTICLE IV**

**HIPAA REQUIREMENTS**

4.1. Data Recipient must notify Data Provider within twenty-four (24) hours by phone, and in writing within five (5) business days, after Data Recipient becomes aware of any use or disclosure not authorized by the Agreement and any actual or suspected breach of Data Recipient’s security.

4.2. Data Recipient agrees to mitigate, to the extent feasible and allowed by law, any harmful effect that is known or becomes known to Data Recipient that arises from a use or disclosure of the Limited Data Set by Data Recipient or its agents in violation of this Agreement or the Privacy Rule.

4.3. Data Recipient acknowledges that Data Recipient has no ownership rights in the Limited Data Set.

4.4. Within ten (10) business days of a written request by Data Provider, Data Recipient shall allow Data Provider to conduct a reasonable inspection of Data Recipient’s facilities, systems, books, records, agreements, and policies and procedures relating to the use or disclosure of the Limited Data Set for the purpose of determining Data Recipient’s compliance with this Agreement. Any failure of Data Provider to inspect or to detect or notify Data Recipient of an unsatisfactory practice does not constitute acceptance of the practice by Data Provider or a waiver of any remedy or right Data Provider has under the Agreement or applicable law.

4.5. Standards for Electronic PHI. To the extent that Data Recipient creates, receives, maintains, or transmits electronic PHI, Data Recipient shall also have administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any electronic Protected Information that may be transmitted in conformity with the requirements of the Security Rule.

4.6. Reporting of Security Incidents. If the Data Recipient creates, receives, maintains, or transmits electronic PHI, Data Recipient shall appropriately report any incident, as defined by the Security Rule.

4.7. Mitigation of Security Incidents. Data Recipient shall mitigate promptly, to the extent practicable, any harmful effect that is known to Data Recipient caused by a security incident regarding electronic Protected Information by Data Recipient in violation of this Agreement, the Security Rule, or other applicable federal or state law.

4.8. Data Recipient shall comply with state security and privacy laws to the extent that they are more protective of the Individual’s privacy than the HIPAA Privacy Rule.

4.9. Data Recipient shall indemnify, hold harmless and defend Data Provider from and against any and all claims, losses, liabilities, costs and other expenses (including attorneys fees) that result from or arise directly or indirectly out of or in connection with any negligent act or omission or willful misconduct of Data Recipient, its officers, employees, agents or subcontractors relative to the Limited Data Set, including without limitation, any violation of Data Recipient’s responsibilities under this Agreement with respect to the Limited Data Set.

## **ARTICLE V**

**AMENDMENT AND TERMINATION**

5.1 When Data Provider reasonably concludes that an amendment to the Agreement is necessary to comply with applicable law, Data Provider shall notify Data Recipient in writing of the proposed modification(s) (“Legally-Required Modifications”). Data Provider shall request Data Recipients written approval in the form of an amendment to this agreement at the time of notification. Data Recipient shall have thirty (30) days to sign the amendment and return it to Data Provider. Data Recipient’s rejection of a Legally Required Modification is grounds for termination of the Agreement by Data Provider on thirty (30) days written notice.

5.2. A breach by Data Recipient of any provision of the Agreement, as determined by Data Provider, shall constitute a material breach and grounds for immediate termination of the Agreement by Data Provider. At its sole discretion, Data Provider may give Data Recipient 30 days to cure the breach.

5.3. Data Recipient shall return or destroy the Limited Data Set under any of the following conditions: 1) upon termination of this Agreement for any reason; 2) upon completion of the grant funding period; or 3) two (2) years after Recipient publishes Study Results. If return or destruction is not feasible, Data Recipient shall explain to Data Provider why, in writing, to the address given in this Agreement.

5.3.1. If Required by Law, Data Recipient may retain documentation for the time specified as necessary to comply with the law.

5.3.2. Data Recipient’s obligations under this Agreement shall continue until Data Recipient destroys the Limited Data Set or returns the information to Data Provider; provided however, that on termination of the Agreement, Data Recipient shall not further use or disclose the Limited Data Set except as Required by Law.

5.4 If Data Recipient elects to destroy the Limited Data Set, Data Recipient shall certify in writing to Data Provider that the Limited Data Set has been destroyed.

**ARTICLE VI**

**MISCELLANEOUS**

6.1. Exhibit A may be modified by the parties at any time pursuant to a writing executed by both parties. No use or disclosure different from that permitted by the currently in force Exhibit A may be made until the new Exhibit A has been signed by both parties.

6.2. Any ambiguity in this Agreement relating to the use and disclosure of the Limited Data Set by Data Recipient shall be resolved in favor of a meaning that further protects the privacy and security of the information.

6.3 All notices required or permitted under the Agreement to be in writing may be delivered personally, by electronic facsimile (with a confirmation by registered or certified mail placed in the mail no later than the following day), or by registered or certified mail, postage prepaid, addressed to a party as indicated below:

|  |  |
| --- | --- |
| **If to Data Provider:**  Director, Grants Administration  Kaiser Permanente Washington Health Research Institute  1730 Minor Avenue, Suite 1600  Seattle, WA 98101-1466  Phone: 206-287-2826  Facsimile No: 206-287-2871  Email: kpwhrigrants@kp.org | **If to Data Recipient:**  <Name>, <Title>  <Institution>  <Address>  <City>, <State> <Zip>  Phone: <Phone>  Email: <Email> |

Notice shall be deemed to have been given on receipt of communications personally delivered or transmitted by electronic facsimile (delivery confirmed) and, for communications made by United States mail, on the third (3rd) day after mailing. The above addresses may be changed by giving written notice as described in this section.

6.4. Data Recipient’s obligations under Article IV of this Agreement shall survive the termination of the Agreement.

6.5 If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions shall continue in full force and effect.

6.6 Attachments; Order of Precedence. Any conflict between or among the documents comprising this Agreement shall be resolved using the following order of precedence:

1. The terms and conditions stated in the body of this Agreement before the signatures affixed hereto;

2. Exhibit A.

6.7. This Agreement shall be governed by the laws of Washington, without regard to its choice of law rules.

6.8. The Agreement is entered into as of ***the last date signed below*** (“Effective Date”).

IN WITNESS WHEREOF, the parties agree as follows:

|  |  |
| --- | --- |
| **Kaiser Foundation Health Plan of Washington** | **Data Recipient** |
| By: | By: |
| Name: Will L. Smith | Name: |
| Title: Director, Research Administration  Kaiser Permanente Washington Health Research Institute | Title: |
| Date: | Date: |

**EXHIBIT A**

**To the Data Use Agreement**

**By and Between Kaiser Foundation Health Plan of Washington**

**And Institution’s legal name**

**Study Title:**

1. **Description of the Study** (in one paragraph)**:**

1. **Limited Data Set 1**:

**Date(s) or approximate dates(s) of actual data release:**

**Date range when data was created/collected:**

3. **Permitted Uses:** Data Recipient may only use Protected Health Information solely for the purposes under the Study as described in the Study Protocol.

4. **Permitted Disclosures.** Data Recipient may only disclose the Limited Data Set for the Study as described in the Study Protocol. No secondary disclosures are permitted.

5. **Limited Data Set 2**:

**Date(s) or approximate dates(s) of actual data release:**

**Date range when data was created/collected:**

6. **Permitted Uses:** Data Recipient may only use Protected Health Information solely for the purposes under the Study as described in the Study Protocol.

7. **Permitted Disclosures.** Data Recipient may only disclose the Limited Data Set for the Study as described in the Study Protocol. No secondary disclosures are permitted.

IN WITNESS WHEREOF, the parties agree as follows:

|  |  |
| --- | --- |
| **Kaiser Foundation Health Plan of Washington** | **Data Recipient** |
| By: | By: |
| Name: Will L. Smith | Name: |
| Title: Director, Research Administration  Kaiser Permanente Washington Health Research Institute | Title: |
| Date: | Date: |
|  |  |
|  | ***Read and acknowledged:*** |
|  | By: |
|  | Name: |
|  | Title: |
|  | Date: |