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## **BEHAVORAL HEALTH AND RECOVERY DIVISION**

## **RESEARCH AND EVALUATION DATA SHARING AGREEMENT**

1. **SUBJECT**

The following Data Sharing Agreement (Agreement) is entered into between the King County Behavioral Health and Recovery Division (BHRD) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Data Recipient) on \_\_\_\_\_\_\_\_\_\_\_\_, and shall expire on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, or if no date is inserted, shall expire one year after the signature date.

1. **DEFINITIONS**

Confidential information means information that is exempt from disclosure to the public or other unauthorized persons under 45 Code of Federal Regulations (CFR), or other Federal or State laws. Confidential information includes, but is not limited to, personal information and/or individually identifiable health information.

Data means the information, whether initially provided by the Data Recipient and that is disclosed or exchanged by Data Provider as described by this Agreement. The information initially provided by the Data Recipient shall be considered to be owned by the Data Provider for as long as it is combined with information that originated with the Data Provider.

Data Provider means the entity that is disclosing their Data for use by the Data Recipient for completion of this Agreement. For this agreement the Data Provider is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Data Recipient means the entity that is receiving the Data from the Data Provider for purposes of completion of this Agreement. For this agreement the Data Recipient is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Individually Identifiable Health Information means health information, including demographic information, collected from an individual, that is created or received by a covered entity; and relates to the past, present or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual; and identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Designated Staff means the Data Recipient’s employee(s) whom the Data Recipient has authorized to access Data. Each Designated Staff shall complete and submit the Oath of Confidentiality (Appendix 21C) to: BHRD Privacy Officer, 401 Fifth Avenue, Suite 400, Seattle, WA 98104

## Encrypt means to encipher or encode electronic data using software that generates a minimum key length of 128 bits.

Protected Health Information (PHI) means any individually identifiable health information that is transmitted by electronic media; maintained in electronic media; or transmitted or maintained in other form or medium.

1. **PURPOSE**

The purpose of this Data Sharing Agreement (Agreement) is for BHRD to provide Data that is individually identifiable health information to the Data Recipient as described in the attached application entitled “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.”

A copy of the BHRD Research and Evaluation Proposal Application, and if requested by the Data Provider, a copy of the research application to the Institutional Review Board (IRB), are attached to, and made part of, this Agreement.

If the application requires IRB approval, a copy of the IRB determination is also attached to, and made part of, this Agreement. The IRB has determined that disclosure of individually identifiable health information shall be accomplished by:

IRB Waiver of Informed Consent Participant’s Informed Consent / Authorization

Limited Data Set

1. **STATEMENT OF WORK**

The Data Recipient shall provide the services and staff, and otherwise do all things necessary for or incidental to the performance of work, as set forth below:

* 1. Purpose

Activity for which the Data is needed: *(Insert summary of proposal from R&E Proposal application)*

How Data Recipient will use the Data: *(Insert summary of proposal from R&E Proposal application)*

* 1. Description of Data

BHRD shall develop and provide the Data Recipient an electronic Data file with the following:

* Inclusion criteria (filter variables)
* File format
* Data Elements *(provide detailed listing)*

The Data Recipient will notify the BHRD Contact if other identifiable data not specified in this Agreement are needed for the study. In the event that additional data are needed for the study, a revision to this Agreement may be required.

* 1. Source of Data

King County IT on behalf of BHRD will provide Data from the King County Behavioral Health and Recovery Services databases.

Time frame (s) for Data disclosure or exchange: *To be determined by each agreement*

* 1. Data Retention

Data Identifiers will be destroyed on \_\_/\_\_/\_\_, or at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining identifiers. In studies where participant authorization is obtained, use and retention of the Data must be consistent with the authorization form that the participant signed.

The Data Recipient will maintain, document and retain records of informed consent from each participant or the participant’s legally authorized representative required by law and stipulated by the IRB unless the IRB determines that waiver of some or all of the elements of informed consent has been approved for this research.

* 1. Management of Data Identifiers

The Data Recipient will create a master identifier file which links names and direct identifiers with arbitrary study codes, protect this master file via a secure method, (i.e., password or permission-limited folder) known only to the Data Recipient’s Designated Staff, and maintain all copies of the master file in a secure, locked location at all times when not in use.

The Data Recipient will remove names, and other data elements which could identify individuals, from records in the study data base, identify records in the database only with arbitrary study codes, and ensure that, without access to the master identifier file or BHRD information, all database records are unidentifiable.

Conditions under which, if any, that Data disclosed or exchanged can be linked to other data:

BHRD information or Data shall not be linked with information or data from sources other than those identified in the BHRD Research and Evaluation Proposal application without the express written permission of the BHRD Contact.

* 1. Data Access Transfer Method

All data transfers will occur via an encrypted disc, or via the KCIT/ BHRD secure server file transfer protocol (FTP).

* 1. Requirements for Access

Access to Data shall be limited to Data Recipient’s Designated Staff whose duties specifically require access to such Data in the performance of their assigned duties. Prior to making Data available to its Designated Staff, Data Recipient will notify all such persons of the BHRD Oath of Confidentiality, a sample of which is attached to this Agreement, as Appendix 21C. Each such notified person shall then sign a copy of this Oath in which they agree to adhere to the Oath of Confidentiality requirements. The Data Recipient will send the signed Oaths to:

King County BHRD Privacy Officer

401 Fifth Avenue, Suite 400

Seattle, WA 98104

* 1. Frequency of Exchange

The frequency for which data is to be disclosed to the Data Recipient is \_\_\_\_\_\_\_\_\_\_\_\_\_.

* 1. Security of Data

The Data Recipient shall exercise due care to protect Data from unauthorized physical and electronic access. Due care includes establishing and maintaining security policies, standards, and procedures which comply with the Data Security Requirements (Appendix 21A), Protection of Data.

The Data Recipient shall comply with Appendix 21A, Data Security Requirements with regard to Data Segregation and Data Disposition.

When the research has been completed or when no longer needed, whichever is earlier, the Data shall be returned to BHRD, or destroyed using one or more of the methods of destruction described in Appendix 21A, Data Security Requirements, 3) Data Disposition. Upon destruction or return of the data, the Data Recipient must complete Appendix 21B, Data Disposition Certification and return to the BHRD Privacy Officer.

* 1. Confidentiality and Nondisclosure

The Data Recipient may use BHRD information or Data gained by reason of the Agreement only for the purposes of this Agreement.

The Data Recipient shall not disclose, publish, provide access to, or otherwise make known any individually identifiable information in BHRD Data or de-identified limited data set provided under this Agreement, except as provided by law.

The Data Recipient shall maintain the confidentiality of all individually identifiable information and Data gained by reason of this Agreement.

The Data Recipient shall not link the Data with individually identifiable information or Data from any other source nor re-disclose or duplicate the Data unless specifically authorized to do so in this Agreement or by the prior written consent of BHRD.

The Data Recipient shall not contact or attempt to contact any person identified in the information provided by BHRD without the express written permission of the BHRD Contact.

* 1. Data Security Compromise

The Data Recipient shall report to the BHRD Privacy Officer any security or confidentiality compromise or potential security or confidentiality compromise of shared Data within one business day of discovery.

1. **NOTICES**

Whenever one party is required to give notice to the other party under this Agreement, it shall be deemed given if mailed by the United States Postal Service, registered or certified mail, return receipt requested, postage prepaid and addressed as follows:

In the case of notice to the Data Recipient, notice shall be sent to the point of contact submitted to BHRD on the Research and Evaluation Proposal Application;

In the case of notice to BHRD, notice shall be sent to:

King County BHRD Privacy Officer

401 Fifth Avenue, Suite 400

Seattle, WA 98104

Said notice shall become effective on the date delivered as evidenced by the return receipt or the data returned to sender for non-delivery other than for insufficient postage. Either party may at any time change its address for notification purposes by mailing a notice in accordance with this Section, stating the change and setting forth the new address, which shall be effective on the 10th day following the effective date of such notice unless a later day is specified in the notice.

1. MISCELLANEOUS

BHRD assumes no responsibility for the accuracy or integrity of data derived or created from the Data provided under this Agreement, or for the accuracy or integrity of the Data once the Data Recipient has altered or modified the Data, or linked the Data with other data files.

BHRD assumes no responsibility for the accuracy or validity of published or unpublished conclusions based in whole or in part on analyses of Data provided to the Data Recipient.

The Data Recipient will hold BHRD harmless from any damage or other liability which might be assessed against BHRD as a result of any information or Data received pursuant to this Agreement.

The Data Recipient agrees that BHRD shall have the right, at any time, to monitor, audit and review activities and methods in implementing this Agreement in order to assure compliance.

1. SANCTIONS

Unauthorized disclosure or use of any Data provided under this Agreement may result in State and/or Federal civil and/or criminal penalties (RCW 42.48.050; CFR Part 45, Subpart D, 160.404, 408, and 418; CFR Part 2.32).

1. AMENDMENTS

Either party to this agreement may request changes to this Agreement, including amendments. Proposed changes that are mutually agreed upon will be incorporated by written amendment to this agreement.

The Data Recipient will seek an amendment when there is a substantial change in study design and methods, changes that may affect approved study purposes, and/or use of this information of thesis, dissertation, or other educational purposes that are not described in the Data Recipient’s original proposal.

1. TERMINATION

In the event the Data Recipient fails to comply with any terms of this Agreement, BHRD shall have the right take such action, as it deems appropriate, including termination of this Agreement. If the Agreement is terminated, the Data Recipient will return all information and Data provided by BHRD, including all materials derived from this information, or make such alternative disposition of provided and derived information as directed by BHRD. The exercise of remedies pursuant to this section shall be in additional to all sanctions provided by law, and to legal remedies available to parties injured by unauthorized disclosure.

Signed:

King County: Data Recipient:

Authorized Signature Authorized Signature

Print Name Print Name

Print Title Print Title

Date Date

Mailing Address Mailing Address

City, State, Zip + 4 City, State, Zip + 4