

THE INSTITUTE FOR SYSTEMS MEDICINE DATA SHARING AGREEMENT

AGREEMENT made this ___ day of _____ 20___, between the Institute for Systems Medicine (hereafter referred to as ISM), and _____ (hereafter referred to as Investigator).

Background

1. The Clinical Data Repository (CDR) is a covered component pursuant to the Health Insurance Portability and Accountability Act (HIPAA) and, therefore, must comply with federal and state laws and regulations pertaining to the confidentiality, use or disclosure of certain health care related information.
2. The Clinical Data Repository (CDR) is not a covered entity for purposes of HIPAA and must only comply with state laws pertaining to the confidentiality, use and disclosure of certain health care related information. However, the CDR has obtained a HIPAA waiver.
3. This agreement by which the ISM and Investigator will share data, also provides the terms under which parties shall maintain the confidentiality of the data to be shared.

Terms and Conditions

1. **Confidentiality of Information.** Investigator agrees to abide by the confidentiality and security provisions of HIPAA and Washington State Statute RCW 19.255.010. Investigator further agrees that access to information from the CDR will be restricted to Investigator authorized individuals directly involved in [Name of Study].
2. **Data Security.** Investigator agrees to store the ISM provided CDR information in a locked filing cabinet, in a restricted area, accessible only to individuals authorized pursuant to this agreement for purposes of data matching, the data exchange process or coordination of behavioral health services related to this agreement. If the data is stored in electronic format, individuals authorized pursuant to this agreement should only access it, through the use of a password protect data security system.
3. **Appropriate Use of the SCCDR.** Investigator has read the ISM Policy, CDR 1.1, “Appropriate/Inappropriate Use of the Clinical Data Repository” and agrees to and understands the terms in the document. Investigator has also read and understands The National Committee on Vital and Health Statistics (NCVHS), primer on data stewardship.
4. **Notification of Security Breaches.** The Washington State Database Security Breach Notification Law (RCW 19.255.010, RCW 42.56.590) delineates notification requirements in the event of a breach in the security of personal information. Investigator agrees that in the event of any breach or compromise of the security, confidentiality or integrity of computerized data obtained from ISM, or is reasonably believed to have been, acquired and/or accessed by an unauthorized person, Investigator shall notify ISM of the breach of the security system containing such data

within 24 hours, comply with all notification actions, and/or assist ISM with all notification actions required by the law.

5. **Prohibition on Mobile Devices and Removable Media.** Investigator shall have a written policy prohibiting the transfer or storage of unencrypted data on employee mobile devices or removable storage media for any reason. This policy shall be made available to each employee individually and shall be strictly enforced.
6. **Data Destruction.** Investigator agrees that when the intended use of the data has been completed, it shall dispose of the information through the use of any or a combination of the following destruction methods: (a) remove (e.g., scrub) from the hard drive or any other storage media all electronic files that contain ISM provided CDR information or (b) purge, shred, or burn any hard copy of the ISM provided CDR information such that the resulting residue prevents any recovery of the data file content.
7. **Use of Information.** ISM and Investigator both agree that the information received through this agreement shall not be used to the detriment of the individual nor for any purpose other than those stated in this agreement.
8. **Redisclosure of Data.** ISM and Investigator agree not to redisclose the information received by either party to a third party not covered by the agreement unless written permission by either party is received and redisclosure is not prohibited under applicable law.
9. **Term.** This agreement is effective on the last date signed by a party and shall remain in effect for a period of three years unless terminated under paragraphs 11 or 12.
10. **Indemnification.** Investigator shall defend, indemnify, release, and hold ISM harmless from and against all Claims, Losses, and Expenses when arising out of or incidental to this Agreement regardless of the negligence or fault of ISM or any other entity or person.
11. **Amendments and Alterations to this Agreement.** ISM and Investigator may amend this Agreement by mutual consent, in writing, at any time.
12. **Termination.** This agreement may be terminated by either party upon 30 days written notice to the other party.
13. **Notice.** Notice shall become effective on the date of receipt by a party.

Investigator**Date**

ISM Representative**Title****Date**

STATE OF WASHINGTON

COUNTY OF _____

On this day personally appeared before me _____,
to me known to be the individual(s) described in and who executed the within and foregoing
instrument, and acknowledged that he/she/they signed the same as his/her/their free and
voluntary act and deed, for the uses and purposes therein mentioned.

Given under my hand and seal of office this _____ day of _____, 20_____.

Notary Public residing at _____

Printed Name: _____

My Commission Expires:
