

Knowledge Network Data Use Agreement

This Data Use Agreement (hereinafter the "Agreement"), effective as of _____, 2010, is made by and among _____ (herein referred to as "Covered Entity") and Centerstone Research Institute (hereinafter known as "Recipient"). Covered Entity and Recipient shall collectively be known herein as the "Parties".

WHEREAS, a Data Use Agreement is an assurance between a covered entity and other parties using a Limited Data Set that the data will only be used for specific uses and disclosure;

WHEREAS, a Limited Data Set is Protected Health Information¹ that has all direct identifiers removed. However, the minimum necessary² standard applies. A Limited Data Set **EXCLUDES** the following direct identifiers of the individual or of relatives, employers or household members of the individual:

- Names
- Postal Address (other than town or city, State and zip code)
- Telephone Numbers/Fax Numbers
- E-mail Addresses/Web Universal Resource Locators (URLs)/Internet Protocol (IP) Address Numbers
- Social Security Numbers, Medical Record Numbers, Health Plan Beneficiary Numbers, Account Numbers, Certificate/License Numbers, Vehicle Identifiers/Serial Numbers including license plate numbers
- Device Identifiers and Serial Numbers
- Biometric Identifiers (e.g. finger or voice prints)
- Full face photographic images and any comparable images;

WHEREAS, the following identifiers can be **INCLUDED** in the Limited Data Set. Check below all that apply:

- Dates (of treatment, birth dates)
 - Geographic information (not street address)
 - Other unique identifying numbers, characteristics or codes that are not expressly excluded (list below):
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WHEREAS, both Parties maintain certain information that each wishes to use and /or disclose for research, public health, or health care operations such as quality assurance or benchmarking purposes permitted under 42 C.F.R. 164.514(e);

¹*Protected Health Information is defined as individually identifiable health information transmitted or maintained in any form (electronic means, paper, or oral communication) that relates to the past, present, or future health or conditions of an individual.*

²*Minimum Necessary is defined as only the minimum information needed for the immediate use of disclosure should be made available by the health care provider or other covered entity.*

NOW, THEREFORE, the Parties, in consideration of the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. Covered Entity shall provide the Recipient with access to certain data (the “Limited Data Set” and “LDS”) in accordance with the terms and conditions of this Agreement. Under no circumstances shall either party be required under this Agreement to provide the other party with any information that does not qualify as part of a “Limited Data Set” under 42 C.F.R. 164.514(e) and 45 C.F.R. 164.514.
2. The Parties, and any Authorized Party on the Parties’ behalf, may use the Limited Data Set only for the following purposes:
 - a. To create a registry to be used for quality assurance, bench marking and research with appropriate permission and in accordance with the requirements of the “Common Rule” 45 CFR 46 and the Privacy regulations 45 CFR 160 and 164.
 - b. *Any use of the data beyond the Parties named herein this Agreement must agree to and sign an equivalent data use agreement (at minimum) specifying restrictions around the Limited Data Set and its usage as per 42 C.F.R and 45 C.F.R. Access may be terminated at any time by Covered Entity if unauthorized use occurs by parties not named herein.*
3. The Parties agree as follows:
 - a. Not to use or further disclose the Limited Data Set or any information contained therein other than as permitted by this Agreement or required by applicable law.
 - b. To use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement.
 - c. To report to the other Party any use or disclosure of the Limited Data Set or any part of it not provided for by this Agreement of which either Party becomes aware.
 - d. To ensure any agents, including subcontractors, to whom a Party provides the Limited Data Set or any part of it to agree to the same restrictions and conditions that apply to the Parties under this Agreement.
 - e. Not to use the information contained in the Limited Data Set to identify the individuals whose information is contained in the Limited Data Set, nor to contact them under any circumstances.
4. In the event any Party becomes aware of any use of the Limited Data Set or any part of it that is not authorized under this Agreement or required by applicable law, they may (i) terminate this Agreement upon notice; (ii) disqualify (in whole or in part) the Party at fault and/or any authorized parties from receiving protected health information in the future; and/ or (iii) report the inappropriate use or disclosure to the Secretary of the Department of Health and Human Affairs. Further sanctions may apply under 42 C.F.R. parts 160 and 164.

5. Term and Termination.

- a. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Recipient regains the LDS, unless sooner terminated as set forth in this Agreement.
 - b. Recipient may terminate this Agreement at any time by notifying the Covered Entity and returning or destroying the LDS.
 - c. Covered Entity may terminate this Agreement at any time by providing thirty (30) days prior written notice to Recipient.
 - d. Covered Entity shall provide written notice to Recipient within ten (10) days of any determination that Recipient has breached a material term of this Agreement. Covered Entity shall afford Recipient an opportunity to cure said material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for immediate termination of this Agreement b Covered Entity.
 - e. Sections 2, 3, and 5.e of this Agreement shall survive any termination of this Agreement under subsections 5.c or 5.d.
6. The Parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both Parties' obligations under this Agreement. Provided, however, that if the Parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either party may terminate this Agreement as provided in section 5.
7. Nothing in this Agreement shall confer upon any person other than the Parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
8. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instruments.

WHEREFORE, the Parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.

COVERED ENTITY:

By: _____
Name: _____
Title: _____
Date: _____

RECIPIENT:

By: _____
Name: _____
Title: _____
Date: _____