

# The Clinical Data Warehouse

## Data Use Agreement

I am a faculty member, medical staff member, employee, or sponsored end-user that is engaged in healthcare-related research activities that are benefitted from the use of the Clinical Data Warehouse (referred to herein as “*I*” or “*me*”) of a participating institution, organization, entity, or person (each a “*Participant*,” and collectively the “*Participants*”) that has each entered in a Data Collaboration Agreement (“*DCA*”) with Health Sciences Health Improvement, LLC (“*HSHI*”), a South Carolina limited liability company. The purpose of the DCA is to establish an agreement to collaborate, use, and manage an electronic data warehouse (“*Clinical Data Warehouse*” or “*CDW*”) by and among the Participants and HSSC.

This Data Use Agreement is designed to permit authorized researchers that are sponsored by a Participant to access the i2b2 tools, a research tool of the CDW designed for the purpose of requesting aggregate clinical data from one or more Participants that (i) are considered a Covered Entity under the Health Insurance Portability and Accountability Act of 1996, as amended from time to time, and accompanying regulations and (ii) have agreed to transmit data to the CDW. Your acceptance of this agreement certifies that you understand and agree to all applicable terms contained herein.

I assert that I am a researcher authorized by a Participant to gain access to the i2b2 tools.

I understand and agree that access to the i2b2 tools is currently limited to authorized researchers sponsored by a Participant.

I understand and agree that my authorization to use the i2b2 tools is restricted to research purposes and that I may not use the i2b2 tools under this Data Use Agreement for patient care. My use of the i2b2 tools as authorized under this Data Use Agreement for any patient care purposes is expressly prohibited.

I understand and agree that the results returned by the i2b2 tools may not be distributed outside of the Participant who has sponsored me or with any other person that is not listed as an additional principal investigator on an IRB-approved research study.

I understand that only aggregate numbers of patients satisfying any given data query will be provided by the i2b2 tools.

I understand that all searches executed by the i2b2 tools and within the CDW are recorded and will be examined as part of routine compliance audits. My identity for any such request is recorded along with information related to each search executed.

I will not share my login information with any other person for purposes of accessing the CDW, the i2b2 tools, or any element, service, function, capability, or component thereof.

I understand that the data retrieved using the i2b2 tools or the CDW may not be used to identify or contact any individual or to attempt to learn the identity of any household, family, person, establishment, or sampling unit included in these data, unless otherwise approved by the appropriate Institutional Review Board.

I understand that any violation of this agreement may result in a disciplinary action by my sponsoring Participant, result in suspension or termination of my rights to access the CDW, the i2b2 tools, or any element, service, function, capability, or component thereof.

I agree to restrict individual queries to legitimate research topics.

I agree that any queries of the CDW or the i2b2 tools will specifically be targeted toward the minimum necessary data to accomplish the goals of my research.

I acknowledge the additional level of ethical sensitivity inherent in accessing data from electronic medical records and agree to exercise exemplary ethical conduct when so doing.

I understand and agree that any effort to determine the identity of any patient, or to use any data obtained from the CDW for any purpose other than indicated above, is prohibited.

I have completed the appropriate “Code of Conduct / HIPAA / Information Security” training in CATTS or other system as required by my sponsoring Participant.

I shall not store sensitive data on end-user computing, storage, and communication devices, including, but not limited to, desktop computers, laptops, tablets, PDAs, thumb drives, memory cards, or communication devices such as cell phones or smart phones. Notwithstanding the foregoing, if there is an unavoidable business need to store sensitive data on an end-user device, then I shall comply with all applicable data protection policies and standards, including the use of encryption technologies, approved by the Participants pursuant to the DCA.

I understand and agree that I am required to report any security incident or breaches that affect any data from the CDW to the appropriate compliance officer of my sponsoring Participant and to HSSC. In the event that I discover an information security breach, a significant vulnerability that could lead to a breach, or a compromise of the CDW that may result in the disclosure of data, I acknowledge and agree that I am required to follow the procedures in the applicable incident response policy of my sponsoring Participant. I have reviewed the incident response policy, have had an opportunity to ask questions of the appropriate representatives of my sponsoring Participant, and represent that I understand its terms.

[I ACCEPT]

[CANCEL AND EXIT]