Center for Health Informatics Data Use Agreement

This rolls up to UC Enterprise policies.

Online Form Version 1.2

Updated September 28, 2020

This Data Use Agreement ("DUA") governs the disclosure and use of clinical research data from the institutional Honest Broker, the Center for Health Informatics (CHI). This includes fully-identified data or Limited Data Sets based on IRB approvals.

- 1. This agreement sets forth the terms and conditions pursuant to which CHI hereafter referred to as the Holder, will disclose certain protected health information, hereafter "PHI", in the form of a Data Set with PHI, hereafter "Data Set" to the Recipient.
- 2. Terms used, but not otherwise defined, in this Agreement shall have the meaning given the terms in the HIPAA Regulations at 45 CFR Part 160-164.
- 3. Permitted Uses and Disclosures
 - 1. Except as otherwise specified herein, Recipient may make all uses and disclosures of the Data Set necessary to conduct the research associated with this specific project.
 - 2. Only persons listed on the IRB-approved protocol are allowed to view the data.
- 4. Recipient Responsibilities
 - 1. Recipient will not use or disclose the Data Set for any purpose other than permitted by this Agreement or as permitted or required by law;
 - Recipient will use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Data Set other than as provided for by this Agreement as required by law storage of the data in the UC Secure Data Center is strongly encouraged;
 - 3. Recipient will report to the Holder any use or disclosure of the Data Set not provided for by this Agreement of which the Recipient becomes aware within five days of becoming aware of such use or disclosure:
 - 4. Recipient agrees to require that any co-investigators, collaborators or agents to whom Recipient, directly or indirectly, provides data from Data Set will agree to comply with the same restrictions and conditions that apply through this Agreement to Recipient;
 - Recipient will not identify the individuals from the information contained in the Data Set outside of the research protocol; and
 - 6. Recipient will not contact the individuals who are the subject of the PHI contained in the Data Set outside of the process as outlined by the research protocol.
 - 7. The Recipient verifies they are the PI (or Co-PI) on this research.
 - 8. Recipient acknowledges any PHI copied from the UC data center servers will be stored on an encrypted device.

5. Term and Termination

- The terms of this Agreement shall be effective as of the current date and shall remain in effect until all PHI in the Data Set provided to the Recipient is destroyed or returned to the Holder with the expiration date specified by the IRB protocol approval. If a subsequent dataset is supplied for any reason, the previous dataset will be destroyed.
- 2. If the Recipient leaves his/her current institution, the Recipient shall return the data to the Holder without retaining a copy. If the Recipient wishes to continue using the data at a new institution, the data will be transferred to the new institution by the Holder using secure and auditable processes after approval by the IRB and Director of Research per UC Policy 3361:10-43-18. Except as provided herein, the Recipient will neither transport nor destroy the data supplied under this agreement without the Holder's express written consent.
- 3. Upon the Holder's knowledge of a material breach of this Agreement by the Recipient, the Holder shall provide an opportunity for Recipient to cure the breach. If efforts to cure the breach are not successful within the reasonable time period specified by the Holder, the Holder shall discontinue disclosure of PHI to the Recipient and report the problem to UC Health as outlined in the Business Associate Agreement. The Holder shall immediately discontinue disclosure of the Data Set to the Recipient if the Holder determines cure of the breach is not possible.

6. General Provisions

- 1. Recipient and Holder understand and agree that individuals who are the subject of Protected Health Information are not intended to be third party beneficiaries of this Agreement.
- 2. This Agreement shall not be assigned by Recipient without the prior written consent of the Holder.
- 3. Each party agrees that it will be responsible for its own acts and the results thereof to the extent authorized by law and shall not be responsible for the acts of the other party or the results thereof.

activity to be published is subject to IRB approval.

4. The Holder may not use the data supplied under this Agreement in any publication unless the