



Data Use Agreement

This Data Use Agreem ent ("Ag reement") is made and entered into as of this day of ______, 20__ (the "Effective Date") by and between University of Maryland, Baltimore ("UMB") and ______ ("Data Recipi ent") for purposes of compliance with the Hea Ith In surance Portability and Accounta bility Act of 1996 ("HIPAA"), as it may be amended from time to time.

WITNESSETH:

WHEREAS, UMB may Disclose or make available certain information to Data Recipient, and Data Recipient may use, disclose, receive, transmit, maintain or create from, that information in conjunction with research; and

WHEREAS, UMB and Data Recipient are committed to compli ance with HI PAA and regulations promulgated thereunder; and

WHEREAS, t he purpose of this Agreement is to satis fy the obligations of the parties under HIPAA and to en sure the inte grity and confid entiality of certain information disclosed or make available to Data Recipient by UMB.

NOW, T HEREFORE, in consideration of the fore going recital s a nd othe r goo d and valuable consideration, the receipt and sufficiency of which is he reby acknowledged, the parties agree as follows:

1. DEFINITIONS

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule.

- A. <u>Individual</u> shall have the same meaning as the term "in dividual" in 45 CFR Sect. 164.501 of the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.
- B. Limited Data Set shall have the same meaning as the term "limited data set" in 45 CFR 164.514(e) of the Privacy Rule. A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: names, postal address information (other than town or city, state, and zip code), telephone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (including license plate numbers), device identifiers and serial numbers, biometric identifiers (including finger and voice prints), full face photographic images, and any comparable images.



University of Maryland, Baltimore · Institutional Review Board · FWA #00007145

Data Use Agreement

- C. <u>Privacy Rule</u> shall mean the Standa rds for P rivacy of Indivi dually Identif iable Information at 45 CFR Pa rt 160 and Pa rt 164, Subp arts A and E, as ame nded from time to time.
- D. <u>Protected He alth Informati on or PHI</u> shall have the same me aning as the term "protected he alth information" in 4 5 CF R Sect. 16 4.501 of the Privacy Rule, t o the extent such information is created or received by Data Re cipient from the University of Maryland, Baltimore.
- E. <u>Required by Law</u> shall have the same meaning as the term "required by law" in 45 CFR Sect. 164.501 of the Privacy Rule.

2. SCOPE AND PURPOSE

- A. This Agreem ent sets fort h the term s and conditions pursuant to which UM B will disclose the Limited Data Set to the Data Recipient.
- B. Data Recipient will only use or disclose the Limited Data Set for the limited purposes necessary to conduct the research described herein: <u>(include a brief d escription of t he resea rch an d/or UMB IRB proto col number)</u>-("Research Proje ct"). Data Re cipient represents that Data Recipient's request that Covered Entity disclose certain PHI to Data Recipient is limite d in scope to the min imum info rmation ne cessary to accomplish Data Recipient's purpose in connection with the Research Project.
- C. In addition to the Data Re cipient, the in dividuals, or classes of individuals, who are permitted to use or receive the Limited Data Set for purposes of the Research Project, include:

3. OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT

- A. Data Recipient agrees to not use or di sclose the Limited Data Set for any purpose other than as described in this Agreement or as required by law.
- B. Data Recipient agrees to use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided for by this Agreement.
- C. Data Recipient agrees to report in writing to the UMB Privacy Official any use or disclosure of any portion of the Limited Data Set not provided for by this Agreement of which it becomes aware, including without limitation, any disclosure to an unauthorized subcontractor or any other individual or entity not named in Section B.3 above, within ten (10) days of its discovery.
- D. Data Reci pient agree s th at it shall obtain and m aintain, for the term of this Agreement, a written a greement with each contractor or with any agent, in cluding a subcontractor, to whom it provides any portion of the Limited Data Set holding them to the same restrictions and conditions that apply through this Agreement to the Data



University of Maryland, Baltimore • Institutional Review Board • FWA #00007145

Data Use Agreement

Recipient with respect to such information. Further, upon request, Data Recipient will provide copies of such agreements to UMB.

- E. Data Recipient agrees not to identify the information contained in the Limited Data Set or contact any individual whose PHI is contained in the Limited Data Set.
- F. Data Recipient will ind emnify, defend and h old h armless UMB and it s re gents, agents, officers, servants, and employ ees, and their respective su ccessors, heirs, subcontractors and ass igns ("Indemnitees") from and against any claim, cau se of action, liability, damage, cost or exp ense (including, without limitation, rea sonable attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Di sclosure of the Limit ed Data Set or any other brea ch of this Agreement b y Data Re cipient or any sub contractor, agent or person und er Data Recipient's control or failure to perform the obligations hereunder by Data Recipient, its employees, officers, volunteers, assigns or contractors.
- G. Data Recipient agrees to notify UMB in writing within five (5) business days of Data Recipient's receipt of any request or subpoena for any portion of the Limited Data Set or any information related to this Agreement. To the extent that UMB assumes responsibility for challenging the validity of such request, Data Recipient will cooperate fully with UMB in any such challenge.

4. TERM AND TERMINATION

- A. The provisions of this Agreement shall be effective as of the Effective Date and shall terminate when all of the Limited Data Set provide d by UMB to Data Reci pient is destroyed or returned to UMB, or, if it is in feasible to return or destroy the Limited Data Set, protection s are extended to such information, in accorda nce with the termination provisions in this Section.
- B. Upon UMB's knowledge of a material breach by Data Recipient, UMB shall:
 - i. Provide Data Recipient with written notice of the breach and an opportunity to cure the breach within ten (10) days of receipt of such notice. If Data Recipient fails to cure the breach within the notice period, UMB may immediately terminate this Agreement; or
 - ii. Immediately terminate this Agreement (without opportunity to cure) if UMB determines, in its sole discretion, that Data Recipient has breached a material term of this Agreement; or
 - iii. UMB shall report the violation to the Secretary of the Department of Health and Human Services.

5. MISCELLANEOUS

- A. A reference in this Agreement to a section in the Privacy Rule means the section as amended or as renumbered.
- B. The parties agree to take such action as is necessary to amend this Agreement from



University of Maryland, Baltimore • Institutional Review Board • FWA #00007145

Data Use Agreement

time to time as is necessary for UMB to comply with the requirements of the Privacy Rule and HIPAA.

- C. The respective rights an d obligation s of Data Re cipient under Section C of this Agreement shall survive termination of this Agreement.
- D. Any ambiguity in this Agreement shall be resolved to permit UMB to comply with the Privacy Rule.
- E. There are no intended third party beneficiaries to this Agreement. Without in any way limiting the foreg oing, it is the p arties' specific intent that nothin g contained in this Agreement gives rise to any right or cause of a ction, contractual or othe rwise, in or on beh alf of the individu als who se P HI is u sed or di sclosed pursua nt to this Agreement.
- F. No provision of this Agree ment may be waived exce pt by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.
- G. The persons signing below have the right and authority to exe cute this Agre ement and no further approvals are necessary to create a binding agreement.
- H. In the event of any conf lict betwe en the terms a nd con ditions stated within n this Agreement a nd tho se contained within any other agreement or un derstanding between the parties, written, oral or implied, the terms of this Agreement shall govern. Without limiting the fore going, no provision of a ny other agreement or understanding between the parties limiting the liability of Data Recipient to UMB shall apply to the breach of any covenant in this Agreement by Data Recipient.
- I. This Agreement shall be construed in accordance with and governed by the laws of the State of Maryland.

IN WITNESS WHEREOF, the parties execute this Agreement.

UNIVERSITY OF MARYLAND, BALTIMORE

DATA RECIPIENT

Print Name:	Print Name:	
Title:	Title:	
Date:	Date:	



University of Maryland, Baltimore · Institutional Review Board · FWA #00007145

Data Use Agreement

RECOMMENDED BY:

Principal Investigator:

Principal Investigator:

Print Name:	Print
Title:	
Date:	Date:

Name: ____ Title: ____