DELETE INSTRUCTIONS & FAQs PRIOR TO EACH USE

INSTRUCTIONS: DUA TEMPLATE

General Instructions
- Always **use track changes** when making edits to the document, so sites can quickly see how the pre-negotiated template was altered.

Page 1
- Covered entity: Enter the name of the organization disclosing the data
- Recipient: Enter the name of the organization to receive the data
- Project Title: Enter the study title.
- Disclosing Party IRB ID #: Enter the Internal IRB number utilized by the disclosing Party's IRB
- Date of IRB Protocol Approval, Disclosing Party: Enter the date of the IRB approval that authorized data to be shared. In the event that an IRB modification results in any alteration to the PHI to be disclosed from the IRB approval noted above, the parties agree that any such data disclosure is also bound by the terms of this DUA and a modification or addendum to this DUA is not necessary.

Page 3
- Optional paragraph 6.D.: Enter the date the Contract or Agreement was executed between the Parties. Delete if not applicable.
- Enter the names of the Parties.
- Covered entity: Enter the name of the organization disclosing the data
- Recipient: Enter the name of the organization to receive the data

Exhibit A
- Enter the names of the Parties and the date.
- For the site disclosing the data, enter name of the PI, project title, and their IRB reference number.
- Section 1. Enter a brief description of the study.
- Section 2. Enter a brief description of the limited data set to be shared. A listing of the classes of data elements being transmitted (pursuant to IRB approval) can be listed here.
- Section 3. List responsible individuals subject to terms and conditions at the Recipient site.
- Section 4: Check the box if no discloses are permitted, otherwise specific permitted disclosures.

This Data Use Agreement for a Limited Data Set ("Agreement") is effective on the date of the last signature below by and between   ("**Covered Entity**") with its principal place of business at   and   ("**Recipient**") with its principal place of business at   , hereinafter referred to individually as "**Party**" and collectively "the **Parties**".

Covered Entity is providing Recipient with a Limited Data Set of Protected Health Information ("**PHI**") as defined in 45 Code of Federal Regulations (CFR) §164 issued under the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended ("**HIPAA**"). To ensure that all PHI provided is handled in full compliance with the requirements of HIPAA and to protect the interests of both Parties, the Parties hereby agree as follows:

1. DEFINITIONS
Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in HIPAA.

A. "**Limited Data Set**", as defined in the Privacy Rule at 45 CFR Section 164.514(e), is PHI that can include specific identifiers and must exclude others considered to be PHI. A Limited Data Set may include: (a) dates (e.g., admission, discharge, and service dates, dates of birth and death); and (b) five-digit zip codes, state and city but not any other postal address information. A limited data set must exclude the following direct identifiers of an individual and his or her relatives, employer(s), and household members: name; postal address information (except town or city, state, and zip code which are permitted); telephone numbers; fax numbers; electronic mail addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; license plate numbers and other vehicle identifiers and serial numbers; device identifiers and serial numbers; URLs; Internet Protocol (IP) address numbers; biometric identifiers including finger and voice prints; and full-face photographic and any comparable images. In the event of any conflict between this description and the definition in the Standards for Privacy of Individually Identifiable Health Information (45 CFR, Parts 160 and 164, Subparts A and E) ("**the Privacy Rule**"), the Privacy Rule definition will govern.

B. "**Security Rule**" means the Standards for Security for the Protection of Electronic Protected Health Information, codified at 45 CFR parts 160 and 164, Subpart C, as amended.

C. The following terms shall also have the meanings given to them in the Privacy Rule: "**Covered Entity**", "**Individual**", "**Protected Health Information**", and "**Required by Law**".

2. USE OR DISCLOSURE
Recipient shall use or disclose PHI only for the purposes of the following research project and as limited by Section 3 of this Agreement, except as required by law:

Project Title:	
Disclosing Party IRB ID #:	
Date of IRB Protocol Approval, Disclosing Party[1]	

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[1] *In the event that an IRB modification results in any alteration to the PHI to be disclosed from the IRB approval noted above, the parties agree that any such data disclosure is also bound by the terms of this DUA and a modification or addendum to this DUA is not necessary.*

3. RESTRICTIONS ON USE

A. Recipient shall not use or further disclose PHI other than as permitted by this Agreement or as otherwise required by law.

B. Recipient shall use appropriate safeguards to prevent any use or disclosure of PHI other than as specified in this agreement. To the extent that Recipient receives, creates, maintains or transmits Electronic PHI, Recipient shall use appropriate administrative, physical and technical safeguards that comply with the Security Rule and that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic PHI.

C. Recipient shall not attempt to identify or contact the individuals to whom the PHI pertains. If it is determined that Recipient has sufficient information to identify individuals to whom PHI pertains, Recipient will immediately contact the Covered Entity and cease further sharing/dissemination of PHI until both Parties agree to continue operating pursuant to the terms of this Agreement.

D. Recipient shall ensure that any agent or subcontractor to whom it provides PHI, as permitted by Exhibit A, agrees in writing to the same terms set forth herein regarding the use and disclosure and security of PHI. Recipient shall terminate its agreement with any agent or subcontractor to whom it provides PHI if such agent of subcontractor fails to abide by any material term of such agreement requiring immediate return or documented destruction of PHI as directed by Covered Entity.

E. Recipient shall comply with applicable state and local security and privacy laws to the extent that they are more protective of the individual's privacy than the Privacy Rule and Security Rule.

4. REPORTING

Recipient shall report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement of which it becomes aware, or any Security Incident of which it becomes aware. Such reporting shall take place within 3 days of Recipient's becoming aware of the unauthorized use or disclosure.

5. TERMINATION

A. This Agreement shall be effective on the Effective Date set forth above and shall continue as long as Recipient retains the data, unless otherwise terminated by law.

B. Recipient may terminate this Agreement by returning or destroying the PHI as directed by Covered Entity and providing written verification of this action to Covered Entity.

C. If Covered Entity becomes aware of a pattern of activity or practice on the part of Recipient that constitutes a material breach of this Agreement, Covered Entity shall have the right to summarily terminate this Agreement and require return or documented destruction of PHI as directed by Covered Entity.

D. This Agreement is valid only if the data set of PHI being provided meets the definition of a "**Limited Data Set**" as specified in HIPAA. Both Parties believe that the PHI does meet this definition. If, subsequent to implementation of this Agreement, either Party becomes aware that the PHI data set exceeds the definition of a Limited Data Set, this Agreement shall be terminated, and Recipient shall follow Covered Entity's directions with respect to the return or destruction of the PHI. In this event, the Parties shall make reasonable efforts to devise alternative means of providing the PHI to recipient in compliance with HIPAA.

6. MISCELLANEOUS

A. Recipient shall mitigate, to the extent feasible and allowed by law, any harmful effect that is known or becomes known to Recipient that arises from a use or disclosure of the Limited Data Set by Recipient or its agents or subcontractors in violation of this Agreement, the Privacy Rule, or the Security Rule and implementing regulations during the term of this agreement and after termination.

B. When Covered Entity reasonably concludes that an amendment to the Agreement is necessary to comply with applicable law, Covered Entity shall notify Recipient in writing of the proposed modification(s) ("**Legally-Required Modifications**"). Covered Entity shall request Recipients written approval in the form of an amendment to this Agreement at the time of notification. Recipient shall have thirty (30) days to sign the amendment and return it to Covered Entity. Recipient's rejection of a Legally Required Modification is grounds for termination of the Agreement by Covered Entity on thirty (30) days written notice.

C. Use or disclosure of PHI is subject to protection under State and Federal law, including HIPAA, including the Security Rule, and implementing regulations as amended by the "**Final Omnibus Rule**," (78 Fed.Reg 5565, Jan 25, 2013) issued pursuant to HIPAA and the "**HITECH Act**," P.L. 111-5, Sections 13001 et seq ("**HIPAA Regulations**"), and the terms of any data transfer, data sharing, data use, materials transfer, or other similar agreement executed by the Parties with respect to this Study. Each Party shall comply with such law and implementing regulations during the term of this Agreement and after termination.

D. This Agreement shall supplement Subaward Agreement dated   by and between   and   and terms and conditions included therein shall apply hereto. Where there is a conflict the terms and conditions of this Agreement shall apply. Any ambiguity in this Agreement relating to the use and disclosure of the Limited Data Set by Recipient shall be resolved in favor of a meaning that further protects the privacy and security of the information.

In Witness Whereof, the authorized organizational signatories hereto have executed this Agreement on the month, day and year specified below:

COVERED ENTITY	RECIPIENT
By:	By:
Printed Name:	Printed Name:
Title:	Title:
Date:	Date:

BY AND BETWEEN
AND

DATED

Covered Entity Project Investigator:

Covered Entity Project Title:

Covered Entity Human Subjects Review Committee Reference Number:

1. SUMMARY DESCRIPTION OF THE STUDY

[Brief description of study]

2. DESCRIPTION OF THE LIMITED DATA SET

[Specific description of data]

3. PERMITTED USES

Except as otherwise specified herein, Recipient may only make such uses of the Limited Data Set as are necessary to conduct the research project named above and described below, and for no other purpose.

Only the project investigator, the specific entities, or designated individual(s) or classes of individuals listed below are permitted to use or receive the Limited Data Set. These individuals are responsible for using this information subject to the terms and conditions of this Agreement:

4. PERMITTED DISCLOSURES

Indicate ☐ None, or identify any permitted disclosures by Recipient: