University of Connecticut/UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components Research Related Data Use Agreement (DUA)	
Relates to Policy: UConn Health 2003-30	
SOP#: 312 - 17	Version 1.0
Prepared by: J. Kulko Rubow	Original date: June 28, 2017
Approved by:	Date approved: July 1, 2017

Purpose and Applicability:
A Research Related Data Use Agreement (DUA) is an agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected[1]. The purpose of this document is to establish a uniform process for the preparation, review, negotiation and approval of Research Related DUA's at UConn and UConn Health.

Background and Significance:
UConn/UConn Health may **use or disclose** Protected Health Information (PHI) as a limited data-set for purposes of public health, research, and health care operations only if UConn/UConn Health enters into a DUA with the recipient/covered entity. A limited data set is PHI that may be used without obtaining either an individual's Authorization, a waiver or an alteration of Authorization for its use and disclosure with a data use agreement. A data use agreement excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

1. Names;
2. Postal address information, other than town or city, State, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images

A limited data set may include the following (potentiality identifying) information:

[1] Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule https://privacyruleandresearch.nih.gov/pdf/hipaa_privacy_rule_booklet.pdf

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1. Admission, discharge and service dates
2. Birth or death dates
3. Age (including 90 and over) expressed in years, months, days or hours
4. Five digit Zip Code or any other geographic subdivision, such as state, county, city precinct, and their equivalent geocodes (except street address)
5. Gender
6. Race
7. Treatment information

Implementation Specifications: Research Related Data Use Agreement:

A. *Agreement required.*

a. UConn/UConn Health may use or disclose a limited data set only if UConn/UConn Health obtains satisfactory assurance, in the form of a DUA that the limited data set recipient will only use or disclose the protected health information (PHI) for limited purposes.

b. *When **UConn Health** is the Covered Entity - Data Recipient* will indemnify, defend and hold harmless Covered Entity and any of Covered Entity's affiliates, and their respective trustees, officers, directors, employees and agents ("Indemnitees") from and against any claim, cause of action, liability, damage, cost or expense (including, without limitations, reasonably attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of Limited Data Set or any other breach of this Agreement by Data Recipient or any subcontractor, agent or person under Data Recipient's control.

B. *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

a. Establish the permitted uses and disclosures of such information by the limited data set recipient. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the agreement if done by the covered entity

b. Establish who is permitted to use or receive the limited data set and provide that the limited data set recipient will:

i. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law

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ii. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement
iii. Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware
iv. Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information
v. Not identify the information or contact the individuals

C. *Compliance.*
a. A covered entity is not in compliance if the covered entity knows of a pattern of activity or practice of the limited data set recipient that constitutes a material breach or violation of the data use agreement, unless the covered entity takes reasonable steps to cure the breach or end the violation, as applicable, and, if such steps are unsuccessful:
i. Discontinues disclosure of protected health information to the recipient; and
ii. Reports the problem to the Secretary
b. A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the HIPAA Privacy Rule requirements

Scope:
Applies to all UConn/UConn Health work-force including:
Employees; including faculty and staff
Volunteers
Students and residents
Temporary staff
Agency and contracted staff
Credentialed staff
Members of the Board of Directors

Responsibilities:
The investigator is responsible for sending research DUA to the SPS/OCTR Contracts Specialist for review and negotiation. SPS/OCTR Contracts Specialist has the delegated

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authority to negotiate DUA's on behalf of the institution. This applies to DUA's whether they are standalone documents, or a component of other research related agreements. SPS/OCTR will seek opinion, input, clarification and review from other individuals and offices as they find necessary, but there is no expectation of mandatory review or sign-off by other individuals or offices of research related DUA.
SPS/OCTR Contracts Specialist has the delegated authority to execute these agreements, consistent with the institutional policy regarding signatory authority. It is agreed that because DUA's establish institutional obligations and bind the institution, individuals not delegated signature authority by institutional policy, such as investigators, are not authorized to execute research DUA's.

Procedural Steps:

A. <u>The Sponsored Program Services (SPS) or the Office of Clinical and Translational Research (OCTR) SPS/OCTR Contracts Specialist</u> is responsible for the following:

a. Review and negotiation, of all institutional Research Related DUA's
b. This includes:
    i. This includes instances where UConn/UConn Health is the covered entity and instances where UConn/UConn Health is the data recipient.

B. <u>The OCTR Fiscal Administrator/SPS</u> <u>administrator</u> is responsible for the following:

a. Obtaining the signature of the institutional official on the DUA
b. Recording completion dates in the database
c. Sending copy to Principal Investigator/research team

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Revision date:	Revised by:
Reason for revision:	
Date revised version sent to archives & current revision version # advanced:	