INDIANA UNIVERSITY

HIPAA-P06
Use and Disclosure of De-Identified Data and Limited Data Sets

FULL POLICY CONTENTS

	Effective: July 1, 2014 **Last Updated:** January 13, 2016 **Responsible University Office:** *HIPAA Privacy and Security Compliance Office* **Responsible University Administrator** *Vice President for Clinical Affairs* **Policy Contact:** *University HIPAA Privacy Officer*

Scope

This policy applies to all personnel, regardless of affiliation, who have access to Protected Health Information ("PHI") under the auspices of Indiana University, designated for purposes of complying with the final provisions of the security and privacy rules regulated by the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. Please refer to the HIPAA Affected Areas document for a full list of units impacted within Indiana University.

This policy addresses the uses and disclosures of PHI, including determination of required authorization and verification, for research, health plans, health services, business associates and affiliates.

Policy Statement

Indiana University respects the privacy of all members of the IU community, and strives to implement measures to protect privacy consistent with the university mission and environment, applicable legal requirements and professional standards, generally accepted privacy norms, and available resources.

While HIPAA imposes many restrictions on the use and disclosure of protected health information, HIPAA does not regulate the use or disclosure of de-identified information and imposes lesser restrictions on the use and disclosure of Limited Data Sets. It is therefore the policy of Indiana University to use and/or disclose de-identified information or Limited Data Sets where appropriate, in accordance with the policy set forth below. De-identified information and/or limited data sets may still be subject to other confidentiality requirements (e.g., because the information is proprietary) and should be marked confidential when appropriate.

Reason for Policy

This policy has two purposes, which are as follows:

1. To specify the requirements for de-identifying Protected Health Information (PHI) in accordance with the HIPAA regulations so that the information will no longer be considered PHI and no longer subject to HIPAA.
2. To specify the requirements for removing certain identifying information from PHI in order to create a Limited Data Set that may be disclosed for research, public health, or health care operations purposes once the recipient of the PHI enters into a Data Use Agreement. Data in the form of a Limited Data Set is still considered PHI and protected under HIPAA.

Definitions

See HIPAA Glossary for a complete list of terms.

Policy

I. DE-IDENTIFIED INFORMATION POLICY:

Health Information is not subject to the HIPAA Privacy Rule if it is de-Identified in accordance with the HIPAA Privacy Rule. No authorization from an Individual is required to use or disclose Health Information that is de-Identified. Health Information is considered de-Identified if: (a) it does not identify an Individual; and (b) there is no reasonable basis to believe it can be used to identify an Individual.

The Department of Health and Human Services published a guidance document in January, 2013, *Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. A link to the guidance document is provided under RELATED INFORMATION.*

A. Methods for De-Identification

A covered entity covered entity may determine that health information is not individually identifiable health information only if one of two methods is used to de-Identify Health Information; expert determination or the Safe Harbor of removing identifiers.

1. *Method 1 – Expert Determination:* A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable.

a. Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
b. Documents the methods and results of the analysis that justify such determination.

2. *Method 2 – Removing Identifiers*: Removal of all of the following identifiers as they pertain to the Individual or to his/her relatives, employers or household members (collectively referred to below as "Individuals"):

a. Names.
b. All geographic subdivisions smaller than a State, including:
   (1) Street address of P.O. Box Number
   (2) City
   (3) County
   (4) Precinct
   (5) Town
   (6) Zip codes and their equivalent geocodes, except for the initial three digits of a zip code if, according to current publicly-available date from the Bureau of the Census:
      i. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
      ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people are changed to 000
c. All elements of dates (except year) for dates related to an individual including: dates of birth and death, and admission and discharge dates and all ages over 89, in which case the Individuals' ages must be categorized as 90 or older.
d. Telephone numbers
e. Fax numbers
f. E-mail addresses
g. Social Security numbers
h. Medical record numbers
i. Health plan beneficiary numbers
j. Account numbers
k. Certificate/license numbers
l. Vehicle identifiers and serial numbers, including license plate number
m. Device identifiers and serial numbers
n. Web Universal Resource Locators (URLs)
o. Internet Protocol (IP) address numbers
p. Biometric identifiers (including finger and voice prints).
q. Full-face photographic images.
r. Any other unique identifying number, characteristic or code

Exception: Any code used by the Indiana University to re-identify the information; provided, however, that any such code must not be related in any way to the identifiers that must be removed in order for the information to be de-identified and only the Indiana University can have access to the code and/or use the code for re-identification.

AND

After removing the identifiers, no one has actual knowledge that the remaining information could be used alone, or in combination with other information available to the recipient, to identify an Individual.

B. Elements that do not need to be removed

The following data elements do not need to be removed from health information in order for the data to be considered de-identified:

1. Age (except over 89, as specified above)
2. Gender
3. Race
4. Ethnicity
5. Marital status
6. State of residence
7. Parts of Zip Code numbers in certain circumstances (as explained above)

II. LIMITED DATA SET POLICY

A covered entity can use and disclose information in the form of a limited data set without the individual's authorization for purposes of research, public health or healthcare operations if the data are released in conjunction with a Data Use Agreement.

A. Limited Data Set:

A limited set is information from which "facial" identifiers have been removed. Specifically, as it relates to the individual or his or her relative, employers or household members, all of the following identifiers must be removed in order for health information to be a "limited data set":

1. Names.
2. Street addresses or RR numbers (other than town, city, state and zip code)
3. Telephone numbers
4. Fax numbers
5. E-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 number
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).
16. Full-face photographic images.

B. Health information that may remain in the information disclosed includes:

1. Dates such as date of birth, date of death, admission, discharge, service;

2. City, state, five digit zip code;
3. Ages in years, months or days or hours; and
4. Unique identifying numbers, characteristics or codes provided the unique identifiers cannot reasonable be used to identify an individual

C. **Data Use Agreement**:

The Data Use Agreement must contain the following elements:

1. A description of the permitted uses and disclosures of the Limited Data Set, which must be limited to and consistent with public health, research or health care operations purposes;
2. A description of those persons who are permitted to use or receive the Limited Data Set;
3. A statement requiring that the Limited Data Set recipient will:
   a. Not use or further disclose the information other than as permitted in the Data Use Agreement or as required by law;
   b. Use appropriate safeguards to prevent the use or disclosure of the information other than as permitted in the Data Use Agreement;
   c. Report to the Indiana University any use or disclosure of the information that is not permitted by the Data Use Agreement of which it becomes aware;
   d. Ensure that any of its agents or subcontractors to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply to the Limited Data Set recipient; and
   e. Not identify the information or contact the Individuals who are the subject of the information.

III. AUTHORIZED INDIVIDUAL TO DE-IDENTIFY DATA OR CREATE LIMITED DATA SETS

Only Indiana University Workforce and third-party Business Associates with whom Indiana University has contracted may de-identify health information or use the Health Information to create Limited Data Sets. If a third-party Business Associate is used for this purpose, then there must be a Business Associate Agreement in place with such third-party.

IV. NON-COMPLIANT LIMITED DATA SET RECIPIENTS

If at any time Indiana University becomes aware that a recipient of a Limited Data Set has violated his/her/its Data Use Agreement, then Indiana University must:

A. Take reasonable steps to end the breach of the agreement or cause the breach to be cured; or

B. If the breach cannot be ended or cured, then stop disclosing the Limited Data Set or other PHI to the recipient and report the problem to the Secretary of Health and Human Services.

Forms

Appendix 1 – De-Identification Checklist: A De-identification Checklist is attached to this policy. This document can be used to ensure all 18 elements defined by the HIPAA Privacy Rule are removed from the health information.

Appendix 2 – Limited Data Set Checklist: A Limited Data Set Checklist is attached to this policy. This document can be used to ensure all facial identifiers are removed from health information prior to being shared pursuant to a Data Use Agreement.

Appendix 3 – Sample Data Use Agreement: HIPAA requires the covered entity and the data recipient of a Limited Data Set enter into a Data Use Agreement (DUA). This is a sample DUA used by Indiana University when IU is the covered entity as of 08/01/2016.

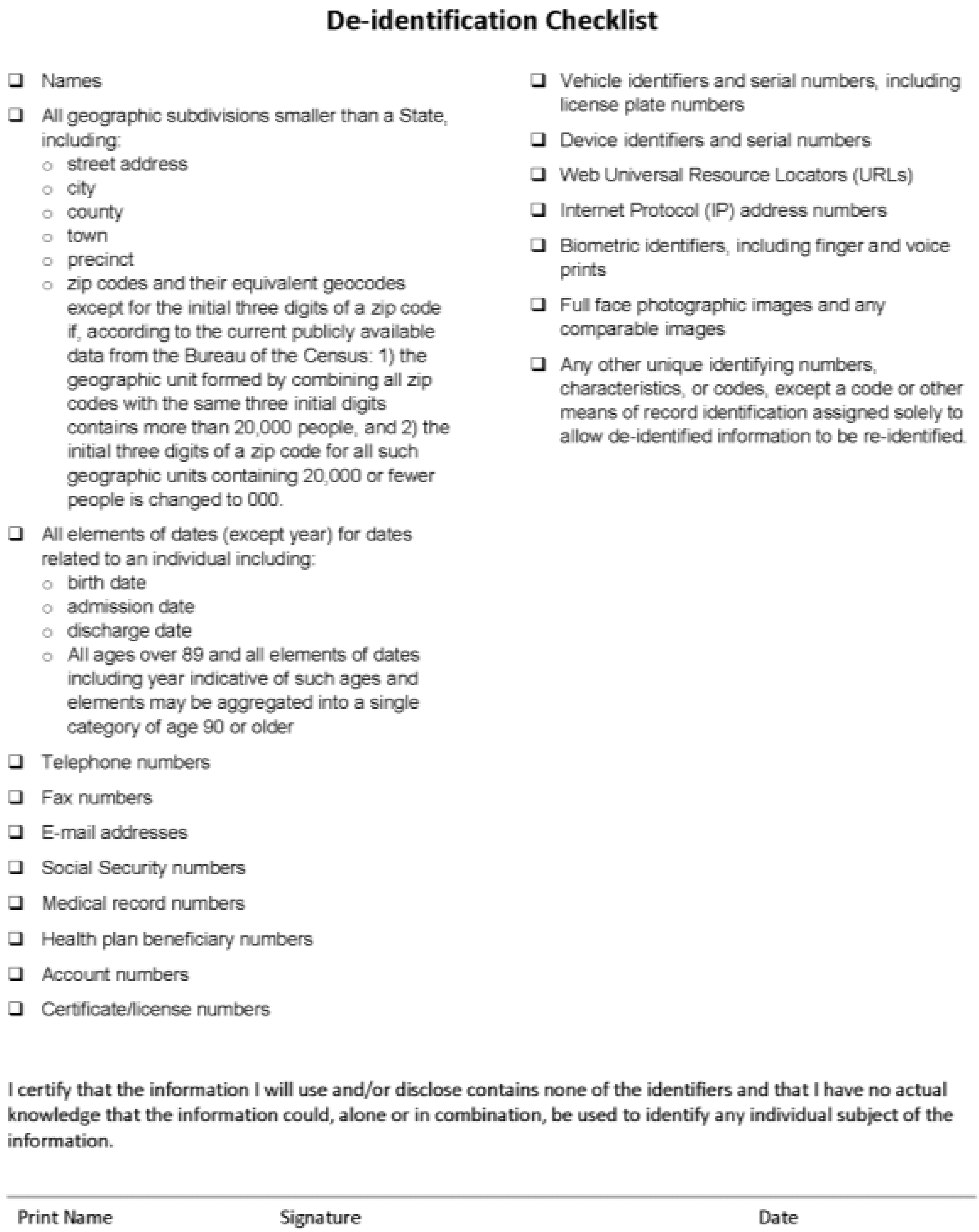
Related Information

HIPAA-A02	General Administrative
HIPAA-G01	HIPAA Sanctions Guidance
HIPAA-G04	Limited Data Set and Data Use Agreement Guidance
HIPAA-P01	Uses & Disclosures of Protected Health Information Policy
HIPAA-P02	Minimum Necessary Policy
HIPAA-P03	HIPAA Authorizations
	HHS De-identification Guidance:
	http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html

History

10/29/2013	Draft submitted to HIPAA Privacy and Security Compliance Council
07/01/2014	Final
01/13/2016	Updated Definitions Section
08/01/2016	Updated DUA Template – Appendix 3

Appendix 1: De-Identification Checklist



De-identification Checklist

□ Names

□ All geographic subdivisions smaller than a State, including:
- street address
- city
- county
- town
- precinct
- zip codes and their equivalent geocodes except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: 1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and 2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

□ All elements of dates (except year) for dates related to an individual including:
- birth date
- admission date
- discharge date
- All ages over 89 and all elements of dates including year indicative of such ages and elements may be aggregated into a single category of age 90 or older

□ Telephone numbers

□ Fax numbers

□ E-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

□ Web Universal Resource Locators (URLs)

□ Internet Protocol (IP) address numbers

□ Biometric identifiers, including finger and voice prints

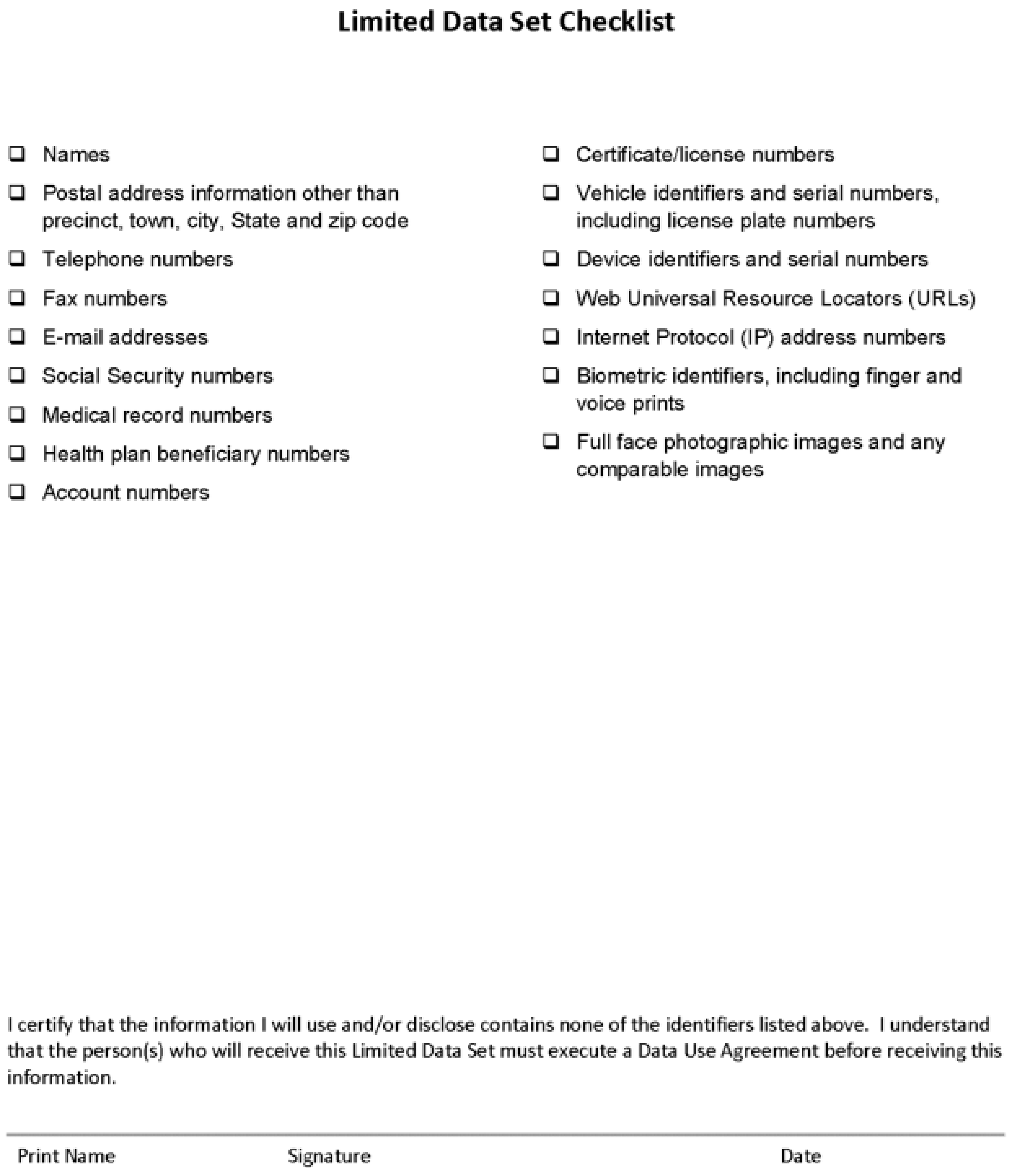
□ Full face photographic images and any comparable images

□ Any other unique identifying numbers, characteristics, or codes, except a code or other means of record identification assigned solely to allow de-identified information to be re-identified.

I certify that the information I will use and/or disclose contains none of the identifiers and that I have no actual knowledge that the information could, alone or in combination, be used to identify any individual subject of the information.

Print Name Signature Date

Appendix 2: Limited Data Set Checklist



Limited Data Set Checklist

- □ Names
- □ Postal address information other than precinct, town, city, State and zip code
- □ Telephone numbers
- □ Fax numbers
- □ E-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
- □ Web Universal Resource Locators (URLs)
- □ Internet Protocol (IP) address numbers
- □ Biometric identifiers, including finger and voice prints
- □ Full face photographic images and any comparable images

I certify that the information I will use and/or disclose contains none of the identifiers listed above. I understand that the person(s) who will receive this Limited Data Set must execute a Data Use Agreement before receiving this information.

____

Print Name Signature Date

Appendix 3: Sample Data Use Agreement

INDIANA UNIVERSITY
DATA USE AGREEMENT

This Terms of Access Agreement ("Agreement") is by and between The Trustees of Indiana University on behalf of [School/Department/Unit & PI] (Covered Entity) with its principal place of business in [City/State] and [Organization & PI] ("Data Recipient") with its principal place of business in [City/State]. This Agreement is effective as of the date of the last signature below ("Effective Date").

WITNESSETH:

WHEREAS, Covered Entity may disclose or make available to Data Recipient, and Data Recipient may Use, Disclose, receive, transmit, maintain or create from, certain information in conjunction with research described herein; and

WHEREAS, certain information the Covered Entity may Disclose or make available to the Data Recipient may be subject to the protections of the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder; and

WHEREAS, Covered Entity and Data Recipient are committed to compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and regulation promulgated thereunder; and

WHEREAS, the purpose of the Agreement is to satisfy the obligation of Covered Entity under HIPAA and to ensure the integrity and confidentiality of certain information Disclosed or made available to Data Recipient and certain information that Data Recipient Uses, Discloses, receives, transmits, maintains or creates, from Covered Entity.

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

Section I: Definitions

1.1 ***Disclosure*** shall be defined as the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information. "Disclose" shall have the corresponding meaning.

1.2 ***HIPAA*** shall be defined as the Health Insurance Portability & Accountability Act of 1996, Public Law 104-191.

1.3 ***Individua***l shall have the same meaning as the term "individual" 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.

1.4 ***Limited Data Set*** shall be defined for the purposes of this Agreement as: (insert a meaningful description of the data set):

[Describe the data elements in the Limited Data Set (e.g. Dates of service, Dates of birth, City, County, etc.)]____

____

1.5 ***Minimum Necessary Information*** shall be defined as the least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request. Unless an exception applies, this standard applies to a Covered Entity when using or disclosing PHI or when requesting PHI from another covered Entity. A Covered Entity that is using or disclosing PHI for research without authorization must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. A Covered Entity may rely, if reasonable under the circumstances, on documentation of IRB or Privacy Board approval or other appropriate representations and documentation under section 164.512(i) as establishing that the request for PHI for the research meets the minimum necessary requirements.

1.6 ***Protected Health Information (PHI)*** shall be defined as individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.

1.7 ***Required by Law*** shall have the same meaning as the term "required by law" in 45 CFR Sect. 164.501 of the Privacy Rule.

1.8 ***Research*** shall be defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research.

Other capitalized terms shall have the same meaning ascribed to them in the context in which they first appear. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR Parts 160-164. Any reference to a regulation or section in the Code of Federal Regulation ("CFR") shall include any corresponding regulations issued regardless of the date of issue.

Section II: Use

2.1 Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.

2.2 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.

2.3 Except as otherwise specified in this Agreement, Data Recipient may make Uses and Disclosures of the Limited Data Set for the specified research purposes described in the research application. The title of the research project and corresponding Institutional Review Board Protocol Number (research project) has been provided below:

[Title & IRB Protocol # or Study #]____

____

Section III: Access

3.1 In addition to the Data Recipient listed above, the individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set for purposes of the Research Project, include:

[e.g. members of the research team or specific names of the individual(s)]__________________

____

3.2 Covered Entity and Data Recipient agree that data will only be disclosed in the manner(s) listed below (please list all possible secure methods for sharing data such as Secure website, Secure transmission, encrypted thumb drive, Fax, U.S. Mail, etc.):

[List secure method(s) to be used to share data]____________________________________

____

Section IV: Assurances

4.1 Covered Entity represents, warrants and covenants that its transfer of Data to Data Recipient is compliant with all applicable rules, regulations and policies of any and all applicable Institutional Review Boards, the Health Insurance Portability and Accountability Act of 1996, as amended from time to time (“HIPAA”), as applicable patient informed consent documents, as well as all applicable federal, state and local laws, statutes, ordinances, rules and regulations regarding patient privacy and/or the transfer of the Data.

4.2 Data Recipient agrees to report to the Covered Entity any Use or Disclosure of the Limited Data Set not provided for by this Agreement, of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor, within ten (10) days of its discovery. Notification shall be to the other party’s address listed below or to another address as the other party may designate in writing by first class mail, email or hand delivery.

Indiana University

Principal Investigator

Indiana University School
Department/Division
Attn: ________________________________
Address: ______________________________
City, State Zip: _________________________
Phone: ________________________________
Email: ________________________________

Data Recipient Organization

Data Recipient

Name
____
Attn: __________________________
Address: ________________________
City, State Zip: ___________________
Phone: _________________________
Email: __________________________

Copy to:

Indiana University
University HIPAA Privacy Officer
980 Indiana Avenue, LV4441
Indianapolis, Indiana 46202
lpfeffer@iu.edu

4.3 Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.

4.4 Data Recipient agrees not to identify the information contained in the Limited Data Set or contact the individual.

4.5 Data Recipient agrees to mitigate any harmful effect that is known to the Data Recipient of a use or disclosure of PHI by the Data Recipient in violation of the requirements of this Agreement.

4.6 Data Recipient will defend, indemnify and hold harmless the Trustees of Indiana University (“Institution”), its affiliated hospitals and institutes, and their trustees, officers, employees, agents, and third parties acting on its/their behalf or with its/their authorization (hereafter collectively referred to as “Indemnitees”) from any and all suits, actions, claims, demands, judgments, costs or liabilities, including attorneys’ fees and court costs at the trial and appellate levels, for any loss, damage, injury, or loss of life caused by the actions of Data Recipient or its officers, employees, agents, or of third parties acting on behalf of or under authorization from Data Recipient, or Data Recipient’s use of the data, results, or materials, including any products or tangible items developed or made therefrom, received from the Principal Investigator or Covered Entity, provided that (i) Covered Entity promptly notifies Data Recipient in writing after Institution receives notice of any claim, (ii) Data Recipient is given the opportunity, at its option, to participate and associate with Covered Entity in the control, defense and trial of any claim and related settlement negotiations.

Section V: General Terms

5.1 In the event of an inconsistency between the provisions of this Agreement and the mandatory terms of HIPAA (as may be expressly amended from time to time by the HHS or as a result of final interpretations by HHS, an applicable court, or another applicable regulatory agency with authority over the Parties), HIPAA shall prevail.

5.2 The Covered Entity agrees to notify the Data Recipient of any change in policy, procedure, or protocol related to this Agreement within ten (10) days of the change in policy, procedure, or protocol.

5.3 Data Recipient agrees that no failure or delay by either party in exercising its rights under this Agreement shall operate as a waiver of such rights and no waiver of any breach shall constitute a waiver of any prior, concurrent, or subsequent breach.

5.4 Data Recipient shall have reasonable opportunity to correct any breach of any terms of this agreement.

5.5 Data Recipient agrees that this Agreement shall be construed in accordance with the laws of Indiana.

Section VI: Publication

6.1 In any publication about the Study, the covered entity will be acknowledged for its participation. Other than acknowledgement, Covered Entity will not be specifically mentioned in the publication without the written permission of an authorized representative of Covered Entity.

6.2 The Data Recipient is free to publish, present or use any results arising out of the performance of this Agreement for its own publication, presentation, instructional or non-commercial research objectives provided that the publication, presentation or use does not disclose any identifiable information furnished by Covered Entity.

6.3 Covered Entity agrees that de-identified and/or aggregated Data may be used by Data Recipient in publications regarding the study.

Section VII: Termination

7.1 Data Recipient agrees that the terms of this Agreement shall survive the termination of Data Recipient’s relationship with Indiana University.

7.2 Covered Entity may terminate this Agreement upon violation of any of the terms in this Agreement.

7.3 This Agreement shall terminate [Termination date or event]________

7.4 Upon termination of this agreement, all of the Limited Data Set provided by Covered Entity to Data Recipient shall be destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy the Limited Data Set, protections are extended to such information, in accordance with the termination provisions in this Section.

7.5 Upon mutual agreement of the Parties that return or destruction is infeasible, Data Recipient shall extend the protections of this Data Use Agreement and limit further uses of and disclosures of the Limited Data Set to those purposes that make the return or destruction infeasible, for so long as Data Recipient maintains any portion of the Limited Data Set.

[Signatures on Next Page]

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above.

Authorized Representative of

Indiana University

x ______________________________

Name: Leslie J. Pfeffer, BS, CHP

Title: University HIPAA Privacy Officer

Date: ______________________________

Read and Acknowledged

Principal Investigator

x ______________________________

Name: ______________________________

Title: ______________________________

____

Date: ______________________________

Authorized Representative of

[Recipient Institution]

x ______________________________

Name: ______________________________

Title: ______________________________

Date: ______________________________

Read and Acknowledged

Data Recipient Investigator

X ______________________________

Name: ______________________________

Title: ______________________________

Date: ______________________________