

# INSTRUCTIONS FOR ACH DATA USE AGREEMENT FOR THE LIMITED DATA SET

The Data Use Agreement template is to be used for research that exchanges limited PHI with a non-ACH entity. A limited data set is defined in the HIPAA regulations and in outlined IRB HIPAA Research Policy 3.1.27 as:

## Limited Data Set

The limited data set option is less restrictive than complete de-identification but does not allow unfettered access to identifiable information but requires certain safeguards. A limited data set is one that has been stripped of the following elements:

1. Name
2. Street address (specifically, a postal address other than city, State and Zip code)
3. Telephone and fax numbers
4. E-mail address
5. Social security number
6. Certificate/license number
7. Vehicle identifiers and serial numbers
8. URLs and IP addresses
9. Full face photos and any other comparable images
10. Medical record numbers, health plan beneficiary numbers, and other account numbers
11. Device identifiers and serial numbers
12. Biometric identifiers, including finger and voice prints

The key differences between a de-identified data set and a limited data set would be the inclusion, in the latter, of dates and some geographic codes. The use of a limited data set requires a data use agreement. A copy of this agreement must be submitted to the IRB.

## If you think your research may require the use of a data use agreement:

Contact:

Andrea W. Dixon, JD, LL.M.  
Assistant General Counsel, *Research*  
13 Children's Way, Slot 842  
Little Rock, AR 72202  
[DixonAW@archildrens.org](mailto:DixonAW@archildrens.org)  
501-364-3571

**DATA USE AGREEMENT**

This **Data Use Agreement** (the "Agreement") is by and between Arkansas Children's Hospital ("ACH") with its principal place of business in Little Rock, Arkansas, and \_\_\_\_\_ ("User") and is effective as of \_\_\_\_\_ (the "Effective Date").

**WHEREAS**, Congress enacted the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which provides protection for confidential health information;

**WHEREAS**, the United States Department of Health and Human Services ("DHHS") promulgated, pursuant to HIPAA, a "Privacy Rule" governing confidential health information; "Privacy Rule" means the regulations promulgated by DHHS to implement the portions of HIPAA that concern the confidentiality of health information, as may be amended or otherwise changed from time to time. References to 45 CFR in this Agreement refer to sections within the Privacy Rule. At the date of this Agreement, these include 45 CFR §160 and §164, Subparts A and E;

**WHEREAS**, ACH maintains certain information that User wishes to use and /or disclose for research, public health, or health care operations purposes permitted under 45 C.F.R. §164.514(e) of the Privacy Rule; and

**WHEREAS**, prior to releasing any confidential health information to User, the Privacy Rule requires ACH to enter into an agreement under which User agrees to certain restrictions on the use and disclosure of the information.

NOW, THEREFORE, the parties, in consideration of the premises and the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. **Access to Data.** ACH shall provide User with access to certain data (the "Limited Data Set") in accordance with the terms and conditions of this Agreement. Under no circumstances shall ACH be required under this Agreement to provide the User with any information that does not qualify as part of a "limited data set" under 45 C.F.R. §164.514(e).
2. **Authorized Parties.** The below named individual Principal User, Principal Investigator or Primary Responsible Person, and persons under his/her direct supervision (collectively the "Authorized Parties"), are authorized to use the Limited Data Set or any part of it on behalf of User and agree to abide by the terms of this Agreement:

\_\_\_\_\_  
Name of Principal User, Principal Investigator or Primary Responsible Person      Signature: \_\_\_\_\_

*(If there is more than one Principal User, Principal Investigator or Primary Responsible Person, use an attachment to identify that person and obtain his/her signature. The attachment also must be signed by authorized representatives of User and ACH.)*

The Principal User, Principal Investigator or Primary Responsible Person is responsible for seeing that those persons under his/her supervision comply with the terms of this Agreement.

3. **Permitted Use.** User, and any Authorized Party on User's behalf, may use the Limited Data Set only for the following purposes (which shall be limited to research, public health activities, and health care operations as defined in the Privacy Rule) and for no other purpose:

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*Use an attachment to list any additional purposes. The attachment must be signed by authorized representatives of User and ACH.*

4. **Conditions of Use.** User and each Authorized Party agree as follows:
- a. Not to use or further disclose the Limited Data Set or any information contained therein other than as permitted by this Agreement or required by applicable law.
  - b. To use appropriate safeguards to prevent use or disclosure of the Limited Data Set or any information contained therein other than as provided for by this Agreement.
  - c. To report to ACH, through the ACH Privacy Officer, any use or disclosure of the Limited Data Set or any part of it not provided for by this Agreement of which User or any Authorized Party becomes aware.
  - d. To ensure that any agents, including subcontractors, to whom User or an Authorized Party provides the Limited Data Set or any part of it agree to the same restrictions and conditions that apply to the User and Authorized Parties under this Agreement.
  - e. Not to use the information contained in the Limited Data Set to identify the individuals whose information is contained in the Limited Data Set, nor to contact them under any circumstances.
  - f. Promptly following the end of the permitted use (as defined in Section 3 above), to return all copies of the Limited Data Set to ACH or destroy them and certify to the destruction; or, if User represents and ACH agrees that neither return nor destruction is feasible, to continue to extend the protections of this Agreement to the Limited Data Set.
5. **Reliance.** User and each Authorized Party acknowledge and agree that ACH has relied upon the promises and covenants made in this Agreement and in disclosing the Limited Data Set hereunder.
6. **Relief.** User and each Authorized Party agree that the breach or threatened breach of this Agreement may cause irreparable harm to ACH and/or individuals, that ACH may not have an adequate remedy at law, and that ACH shall therefore be entitled to injunctive or other equitable relief to enforce this Agreement without obligation to post a bond. In the event ACH becomes aware of any use of the Limited Data Set or any part of it that is not authorized under this Agreement or required by applicable law, ACH may (i) terminate this Agreement upon notice; (ii) disqualify (in whole or in part) the User and/or any Authorized Parties from receiving protected health information in the future; and/or (iii) report the inappropriate use or disclosure to the Secretary of the Department of Health and Human Services. Further sanctions may apply to the User and/or Authorized Parties under 45 C.F.R. parts 160 and 164.

7. **Obligations Following Termination.** Upon expiration or termination of this Agreement for any reason, User and all Authorized Parties shall no longer be entitled to receive or use information contained in the Limited Data Set.
8. **Expiration of Agreement.** Except as otherwise provided in Section 4.f. above, this Agreement shall expire thirty days following satisfaction of the requirements of Section 4.f. above.
9. **Construction and Jurisdiction.** This Agreement shall be governed by and construed in accordance with the laws of the State of Arkansas (excepting any conflict of laws provisions which would serve to defeat application of Arkansas substantive law).

Each of the parties hereto submits to the exclusive jurisdiction of the state and/or federal courts located within the State of Arkansas for any suit, hearing or other legal proceeding of every nature, kind and description whatsoever in the event of any dispute or controversy arising hereunder or relating hereto, or in the event any ruling, finding or other legal determination is required or desired hereunder.

10. **No Assignment.** This Agreement may not be assigned by User or any Authorized Party without the prior written consent of ACH.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.

ARKANSAS CHILDREN'S HOSPITAL

\_\_\_\_\_ (Name of User)

By: \_\_\_\_\_

By: \_\_\_\_\_

Name (Printed): \_\_\_\_\_

Name (Printed): \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Address: \_\_\_\_\_

Address: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_