

North Carolina Department of Health and Human Services Data Use Agreement

1. Preamble

This Data Use Agreement (“DUA”) is entered as of [Click here to enter text.](#) (the “Effective Date”) by and between the North Carolina Department of Health and Human Services (“NCDHHS”) and [Click here to enter text.](#) (“Data Recipient”), each hereinafter individually referred to as a “Party” and collectively as the “Parties.”

This DUA addresses the conditions under which NCDHHS will disclose, and the Data Recipient may use, data for approved purposes as specified in this DUA. The terms of this DUA can be changed only by a written amendment, signed by the Parties.

2. Definitions

- a. De-identified Data: Data that has been modified by removing personally-identifiable information to prevent the identification of the individuals to whom the data pertain. Standards for data deidentification may vary based on the source of the data and the laws, regulations, and/or policies that may apply to the data.
- b. Data Integration Staff: The individuals within the NCDHHS Data Office and NCDHHS Information Technology Division (“ITD”) who have responsibility for the handling and securing Confidential Data from the Parties for approved uses. The Data Integration Staff will consult with Party staff, clean data, link data, and prepare data for approved use.
- c. Data Owner: One or more individuals, or their designee, with signatory authority to legally bind a Party and who is empowered to authorize the release of data owned by the Party for a specific Project.
- d. Data Sharing Agreement (DSA): An agreement between each Party, the Data Office, and ITD that documents the specific terms and conditions for intradepartmental data sharing of Confidential Data. The DSA will include a description of the lawful purpose of the data sharing and will include how data is transferred and secured for Data Recipients and refer to this IMOU as needed.
- e. Data Recipient: The individual or entity that makes a request for data intended for NCDHHS operational and business intelligence purposes.
- f. Data Source: A discrete data set or data system owned by a Party. Each Data Source shall have its own Data Owner.
- g. HIPAA: The Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended, and its implementing regulations.
- h. IRB: institutional review board.
- i. Legal Counsel: As defined by the NCDHHS Office of General Counsel.

3. Financial Understanding

For specified requests from external parties, services of Data Integration Staff may be supported through a cost-based model, to the extent permitted by law and policy. If applicable, the fee will only be charged to Data Recipients who are not staff, employees, or contractors of NCDHHS.

This fee may include the actual costs incurred by Parties to this agreement for their efforts to provide data. The detailed fee structure will be developed by the Chief Data Officer and approved by the Data Governance Council and the Office of General Counsel prior to implementation. If applicable, the fee would be payable to NCDHHS prior to receipt of data.

<If applicable, insert fee here>

4. Approved Data Access and Use

This DUA pertains to Request #: [Click here to enter text.](#) This request was approved by the Data Owner(s) and the approved Data Request Form is attached and incorporated into this DUA as Attachment 1. This DUA pertains only to data elements described in this approved Request Form, attached as Attachment 1 (the “NCDHHS Data”) and to the approved use of the data described in Attachment 1.

The Data Recipient shall be permitted to use the NCDHHS Data solely for the purpose approved by the Data Owner and set out in Attachment 1, and for no other purpose.

5. HIPAA

NCDHHS is a Hybrid Entity as defined in 45 CFR § 164.103 as that term is designated pursuant to 45 CFR § 164.105(a)(2)(iii)(D) and is comprised of entities which are both covered and non-covered components. The Data Recipient may or may not be a covered component as that term is designated pursuant to 45 CFR § 164.105(a)(2)(iii)(D). However, this DUA shall not be construed as creating HIPAA liabilities for NCDHHS, its entities, or the Data Recipient, if HIPAA is not otherwise applicable .

NCDHHS **[Division / Office]** is providing the Data Recipient with an identified data set containing Individually Identifiable Health Information (“IIHI”) that is considered Protected Health Information (“PHI”) as defined in 45 CFR §160.103. The North Carolina Department of Health and Human Services is a Hybrid Entity as defined in 45 CFR § 164.103 and is comprised of both covered and non-covered components that are designated pursuant to 45 CFR § 64.105(a)(2)(iii)(D). The **[Division / Office]** is a Covered Component within NCDHHS. The Data Recipient may be a Covered Entity as defined by HIPAA. The Parties agree to the provisions of this DUA in order to address the requirements of HIPAA and to protect the interests of both Parties.

or

NCDHHS **[Division / Office]** is providing the Data Recipient with a limited data set, which is defined in 45 CFR §164.514(e). The North Carolina Department of Health and Human Services is a Hybrid Entity as defined in 45 CFR § 164.103 and is comprised of both covered and non-covered components that are designated pursuant to 45 CFR § 164.105(a)(2)(iii)(D). The **[Division / Office]** is a Covered Component within NCDHHS. The Data Recipient may be a Covered Entity as defined by HIPAA. The Parties agree to the provisions of this DUA in order to address the requirements of HIPAA and to protect the interests of both Parties.

or

NCDHHS [Division / Office] is providing the Data Recipient with a deidentified data set, which is defined in 45 CFR §164.514(a-b). The North Carolina Department of Health and Human Services is a Hybrid Entity as defined in 45 CFR § 164.103 and is comprised of both covered and non-covered components that are designated pursuant to 45 CFR § 164.105(a)(2)(iii)(D). The [Division / Office] is a Covered Component within NCDHHS. The Data Recipient may be a Covered Entity as defined by HIPAA. However, this DUA shall not be construed as creating HIPAA liabilities for NCDHHS or the Data Recipient if HIPAA is not applicable to the data use and disclosure provided for under this DUA.

or

NCDHHS [Division / Office] is providing the Data Recipient with a data set containing Individually Identifiable Health Information (“IIHI”) with potential to be considered Protected Health Information (“PHI”), which are defined in 45 CFR §160.103 and §164.501. The North Carolina Department of Health and Human Services is a Hybrid Entity as defined in 45 CFR § 164.103 and is comprised of both covered and non-covered components that are designated pursuant to 45 CFR § 164.105(a)(2)(iii)(D). The [Division / Office] is not a Covered Component within NCDHHS. The Data Recipient may be a Covered Entity as defined by HIPAA. However, this DUA shall not be construed as creating HIPAA liabilities for NCDHHS or the Data Recipient if HIPAA is not applicable to the data use and disclosure provided for under this DUA.

or

NCDHHS [Division / Office] is providing the Data Recipient with a deidentified data set, which is defined in 45 CFR §164.514(a-b). The North Carolina Department of Health and Human Services, Division of Public Health is a Hybrid Entity as defined in 45 CFR § 164.103 and is comprised of both covered and non-covered components that are designated pursuant to 45 CFR § 164.105(a)(2)(iii)(D). The [Division / Office] is not a Covered Component within NCDHHS. The Data Recipient may be a Covered Entity as defined by the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended, or its implementing regulations (hereinafter referred to as “HIPAA”). However, this DUA shall not be construed as creating HIPAA liabilities for NCDHHS or the Data Recipient if HIPAA is not applicable to the data use and disclosure provided for under this DUA.

6. Data Ownership and Accuracy

The NCDHHS Data provided to Data Recipient under this DUA shall remain the property of NCDHHS. Data Recipient acknowledges that Data Recipient has no ownership rights with respect to the NCDHHS Data and that the Data Recipient may only receive and use the data for the approved purposes.

NCDHHS makes no warranties as to the accuracy and quality of the NCDHHS Data, and Data Recipient accepts the NCDHHS Data as-is. NCDHHS may be unable to commit resources to explain or validate complex matching and cross-referencing programs for the Data Recipient. The quality and accuracy of any data that has been manipulated or reprocessed by the Data Recipient is the responsibility of the Data Recipient.

7. Data Transfer

The NCDHHS data will be transferred to the Data Recipient through a method approved by NCDHHS. The Data Recipient will adhere with industry encryption standard criteria as defined by the National Institute of Standards and Technology (NIST) and, as applicable, HIPAA Security Standards to encrypt all confidential information including protected health information (PHI) and personally identifiable information (PII) while in transit to ensure data confidentiality and security.

8. Safeguarding Data

Security Controls: The Data Recipient shall implement internal data security measures, firewalls, and other security methods utilizing appropriate hardware and software necessary to monitor, maintain, and ensure data integrity in accordance with all applicable federal regulations, state regulations, privacy and security polices, and local laws. The Data Recipient will maintain all security safeguards throughout the term of this DUA. In addition, the Data Recipient agrees to maintain compliance with the following:

NCDHHS Privacy Manual and Security Manual, both located online at:

<https://policies.ncdhhs.gov/departmental/policies-manuals/section-viii-privacy-and-security>

NC Statewide Information Security Manual, located online at: <https://it.nc.gov/statewide-information-security-policies>

Data Security: The Data Recipient shall implement internal data security measures, environmental safeguards, firewalls, access controls, and other security methods utilizing appropriate hardware and software necessary to monitor, maintain, and ensure data integrity in accordance with all applicable federal regulations, state regulations, local laws, and NCDHHS privacy and security policies. NCDHHS data may not be shared further without prior written consent from NCDHHS. In the event that the Data Recipient obtains written consent by NCDHHS to enter into a third-party agreement to share NCDHHS data received under this DUA, the Data Recipient shall ensure that such agreement contains provisions reflecting obligations of data confidentiality and data security as stringent as those set forth in the DUA.

Data Use or Disclosure. Data Recipient shall not use the NCDHHS data for any purpose beyond that specified in Attachment 1. Except as permitted by this DUA, Data Recipient shall not use the NCDHHS data in an attempt to track individuals, link to an individual's data from other data sources, determine real or likely identities, or contact any individual who is the subject of the NCDHHS data.

Cell Suppression Policy. <inserted from Data Sharing Agreement, or use language below>

The Data Recipient agrees that any use of NCDHHS data in the creation of any dissemination materials (manuscript, dashboard, table, chart, study, report, presentation, etc.) that contain or were generated using the NCDHHS data must adhere to the cell size suppression policy described herein. This policy stipulates that no cell (e.g., grouping of individuals, patients, clients) with less than Click here to enter text. observations may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in a cell displaying less than Click here to enter text. observations. Individual level records may not be published in any form, electronic or printed. Reports and analytics must use complementary cell suppression techniques to ensure that cells with fewer than Click here to enter text. are suppressed. Observations cannot be identified by manipulating data in adjacent rows, columns or other manipulations of any combination of dissemination materials generated through this data request.

9. Authorized Personnel

The NCDHHS data will not be provided to the Data Recipient until execution of this DUA by both Parties. The following named individuals who are under the Data Recipient’s control, and only these individuals, (“Authorized Personnel”) will have access to the NCDHHS data. The Data Recipient is responsible for the individuals under its control who access the data. The Data Recipient will submit a Project Change Request to the NCDHHS Data Office when an individual leaves the project. The Data Recipient will obtain written approval from the NCDHHS Data Office for additions to this list prior to granting additional individuals access to NCDHHS Data.

Name	Role	Organization

(add rows as needed)

10. Unauthorized Access, Use, or Disclosure

Data Recipient shall take all steps necessary to identify any use or disclosure of NCDHHS data not authorized by this DUA. Data Recipient shall report to NCDHHS any use or disclosure of the NCDHHS data that is not provided for in this DUA within twenty-four (24) hours from the date it becomes aware of the disclosure by submitting a report online at <https://security.ncdhhs.gov/>. If the privacy or security incident involves Social Security Administration (SSA) data or Centers for Medicare and Medicaid Services (CMS) data, the Data Recipient shall report the incident within one (1) hour after the incident is first discovered. If the privacy or security incident does not involve SSA or CMS data then this one-hour reporting requirement shall not apply. Data Recipient will take reasonable steps to limit any further such unauthorized use or disclosure of the NCDHHS data. NCDHHS in its sole discretion may require the Data Recipient to:

- Investigate and respond to NCDHHS regarding any alleged disclosure and promptly resolve any problems identified by the investigation.
- Submit a corrective action plan with steps designed to prevent any future unauthorized disclosures.
- Require that all of the NCDHHS data files be returned or, if infeasible, be destroyed immediately.
- Reimburse NCDHHS or otherwise be held responsible for the costs associated with giving affected persons written notice of a privacy or security breach, as required by any applicable federal regulations, state regulations, local laws, or rules, when the privacy or security breach arises out of Data Recipient's performance under this DUA.

11. Project Reporting Requirements

Project Reports. Data Recipients must submit project reports to the NCDHHS Data Office annually for the duration of this DUA. The report shall be a standard form automatically distributed by the NCDHHS Data Office and shall require:

- a. If applicable, documentation of annual institutional review board (IRB) approval of the project
- b. Summary of progress to date
 - How project is informing policy or practice
 - Description of anticipated and unanticipated findings
 - Description of challenges encountered and how they are being resolved
- c. Dissemination materials and key findings to date
- d. Project funding source (if applicable)

Reports of Changes to IRB Study and Approval. If the project described in Attachment 1 for which the NCDHHS Data will be used is subject to the jurisdiction of an IRB then Data Recipient shall be responsible for obtaining any necessary IRB approvals and for promptly notifying NCDHHS of all changes to the study protocol and approval status, including but not limited to renewals of IRB approval, modifications to the study protocol, and suspension or termination of the research.

Change Requests. Data Recipients will initiate, when necessary, a data request change request. All requests (e.g., change in key personnel; an extension of the DUA term; requests to use the NCDHHS data for new sub-projects approved by an IRB under the IRB-approved study protocol referenced in Attachment 1 data) will be reviewed by the Data Office and approved by the Data Owner. Change requests may require an amendment to this DUA.

Publications and Presentations. All publications and/or presentations that contain or have been derived from or generated using the NCDHHS data provided under this DUA must undergo NCDHHS review to ensure that confidentiality is maintained. Presentations and publications containing, derived from, or generated using the NCDHHS data provided under this DUA must be

provided to the NCDHHS Data Office at least thirty (30) days before presenting or submitting for publication.

All NCDHHS data presented in publications and/or presentations shall be presented in aggregate form only and in a way that no individual can be identified.

NCDHHS Attribution and Disclaimer All publicly released materials that contain or were derived from or generated using the NCDHHS data provided under in this DUA shall attribute the source of the data to NCDHHS and include the following disclaimer: **“The findings and conclusions in this [presentation or publication] are those of the author(s) and do not necessarily represent the views of the North Carolina Department of Health and Human Services.”**

12. **Notice.** Notice and other official communications from the Data Recipient to NCDHHS regarding this DUA shall be sent to:

Hayley Young, Director of NCDHHS Data Office
803-413-4694, hayley.young@dhhs.nc.gov

With a copy to:
[Data Owner or Legal Counsel, as necessary]

Notice and other official communications regarding this DUA from NCDHHS to the Data Recipient shall be sent to:

Point of contact: _____
Title: _____
Phone number: _____
Email: _____

13. Data Retention and Destruction

The Data Recipient shall destroy all NCDHHS data no later than thirty (30) days from the date of termination of this DUA. Data destruction shall be carried out in accordance with the methods established in compliance with the minimum standards set out in the Guidelines for Media Sanitization (NIST 800-88) guideline issued by the US Dept of Commerce (<https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-88r1.pdf>). The Data Recipient may request an extension of this DUA as set forth in Paragraph 12 of this DUA. termination of this DUA.

Upon destruction of the NCDHHS data, as required under this DUA, Data Recipient shall send a completed “Certification of Removal of Data Access and/or Destruction of Data” form (Attachment 2 to this DUA) to NCDHHS as set out in the Notice paragraph.

Survival

- i. All terms and conditions set out in this DUA regarding publications and presentations that have been derived from the NCDHHS data shall survive the termination of this DUA.
- ii. All terms and conditions regarding use, disclosure, reporting, and protection of the NCDHHS Data set out in this DUA shall survive the termination of this DUA until all of the data has been returned or destroyed pursuant to the section in Paragraph 14 titled “Effects of Termination.”

14. Term and Termination

Term. The Term of the DUA shall be effective as of the date indicated above and shall terminate three (3) years after the DUA effective date unless the DUA is otherwise terminated as set forth below.

Term Extension. If the Data Recipient requires the NCDHHS Data for a period exceeding the term then a written request for a term extension should be submitted to NCDHHS at least sixty (60) days before the expiration of the Term. If a term extension is granted by NCDHHS, then this DUA must be amended.

Termination Without Cause. Either of the parties may terminate this DUA without cause by providing written notice of the termination to the other party.

Termination for Cause. If Data Recipient commits a material breach of this DUA, including, but not limited to, privacy and data security breaches, then NCDHHS will immediately discontinue disclosure of the NCDHHS data to Data Recipient. If the breach is not cured within thirty (30) days in a manner deemed acceptable by NCDHHS, then this DUA will be terminated for cause and the Effects of Termination shall apply. [Note: if the NCDHHS data is a HIPAA-covered limited data set, then must include language explaining that a matter resolved in an unacceptable manner will lead to discontinued disclosure of the Data *and* reporting the problem to the Secretary of the United States Department of Health and Human Services (see 45 CFR 164.514(e)(4)(iii)(A))].

Effects of Termination.

Within thirty (30) days of the termination of this DUA the Data Recipient shall:

- i. Destroy all of the NCDHHS data received from NCDHHS. Data Recipient shall retain no copies of the NCDHHS data.
- ii. Provide NCDHHS with written confirmation that all of the NCDHHS data has been destroyed by completing the **Certification of Removal of Data Access and/or Destruction of Data** form provided in **Attachment 2**.

15. Choice of Law and Venue.

This DUA shall be governed according to the laws of the State of North Carolina. The proper venue for any legal action pertaining to this DUA shall be in Wake County, North Carolina.

16. Conflicts.

The terms and conditions of this DUA shall override and control any conflicting term or condition of any prior agreement between the Parties pertaining to the NCDHHS data.

17. Requests From Third Parties, Subpoenas, or Other Legal Process. The NCDHHS data provided by NCDHHS to the Data Recipient under this DUA shall be considered the property of NCDHHS. If a subpoena or other legal process in any way concerning the NCDHHS data is served upon Recipient, then Recipient shall notify NCDHHS promptly following receipt of such subpoena or other legal process and shall cooperate with NCDHHS in any lawful effort by NCDHHS to contest the legal validity of such subpoena or other legal process. If the Data Recipient is contacted by a third party for information related to the NCDHHS data or to the terms of this DUA then Data Recipient shall promptly notify NCDHHS of the request and shall not provide any such information to the third party without first receiving written approval from NCDHHS.

By signing this DUA, the Data Recipient agrees to abide by all provisions set out in this DUA.

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1. Signatures

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives.

[SIGNATORY]

Dated: [Click here to enter text.](#)

TITLE,

[DATA RECIPIENT NAME]

[Click here to enter text.](#)

Dated: [Click here to enter text.](#)

[DATA RECIPIENT TITLE AND ORGANIZATION]

Attachment 1: Approved Data Request Form

**Attachment 2: Certification of Removal of Data Access
and/or Destruction of Data**

Date of Project Completion: [Click here to enter text.](#)

Date of Removal of Data Access and/or Data Destruction: [Click here to enter text.](#)

Person Providing Oversight for Removal of Access/Destroying Data: [Click here to enter text.](#)

Title: [Click here to enter text.](#)

Agency: [Click here to enter text.](#)

Phone Number: [Click here to enter text.](#)

E-mail: [Click here to enter text.](#)

Term of Data Use Agreement: [Click here to enter text.](#)

Data Use Agreement Number:

I confirm that, as applicable, all access to NCDHHS data permitted pursuant the above referenced Data Use Agreement has been rescinded and all NCDHHS data received under the above referenced Data Use Agreement has been destroyed, including data held and/or accessed by all Authorized Personnel, as defined under the Data Use Agreement.

By signing below, I confirm that NCDHHS data was destroyed and access to NCDHHS data was rescinded, as applicable, on [Click here to enter text.](#) This destruction was carried out as follows:

1. Information in electronic format was destroyed in compliance with the minimum standards set out in the Guidelines for Media Sanitization (NIST 800-88) guideline issued by the US Dept of Commerce (<https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-88r1.pdf>).
2. Information in hardcopy or printed format was destroyed using a cross-cut shredder or an equivalent destruction method.

Signature:

Name: [Click here to enter text.](#)

Title: [Click here to enter text.](#)