

**DATA USE AGREEMENT FORM
NATIONAL INSTITUTE ON AGING**

DUA No.

A research group/organization (“**Project**”) requesting access to confidential data from the Centers for Medicare & Medicaid Services (“**CMS**”) through a “**NIA-Approved IT System**” must execute this Agreement with the National Institute on Aging (“**NIA**”) before its members can obtain access to these data.

This Data Use Agreement (“**DUA**”) or “**Agreement**” consists of:

- (i) This Cover Page;
- (ii) “**DUA Terms and Conditions**” comprises Sections 1-8 of this Agreement.
- (iii) “**DUA Information Form and Signature Page**” comprises Sections 9-13 of this Agreement; and
- (iv) “**Data Documentation**” comprises Section 14-16 of this Agreement along with its three (3) associated attachments: “**Attachment A**”, “**Attachment B**”, and “**Attachment C**”.

This **DUA** is made and entered into by the Project and its associated “**Requestor Organization**” identified on the first page of the DUA Information Form and Signature Page below, as of the date recorded in this form (“**Effective Date**”).

INSTRUCTIONS

- (1) Carefully read DUA Terms and Conditions (Sections 1-8) and the Data Documentation Attachments A, B, and C.
- (2) The Principal Investigator, Requestor Organization Representative, and Data Custodian must complete the DUA Information Form (Sections 9-10).
- (3) The Principal Investigator, Requestor Organization Representative, and Data Custodian must sign the Signature Page through DocuSign (Sections 11).

BY COMPLETING THE INFORMATION FORM AND SIGNING THE SIGNATURE PAGE BELOW, YOU (A) ACCEPT THIS AGREEMENT AND AGREE THAT PROJECT AND REQUESTOR ORGANIZATION ARE LEGALLY BOUND BY ITS TERMS AND (B) REPRESENT AND WARRANT THAT IF YOU ARE A CORPORATION, GOVERNMENTAL ORGANIZATION, OR OTHER LEGAL ENTITY, YOU HAVE THE RIGHT, POWER, AND AUTHORITY TO ENTER INTO THIS AGREEMENT ON BEHALF OF PROJECT AND BIND PROJECT TO ITS TERMS.

DUA TERMS AND CONDITIONS

The following sections of this Agreement specify the terms and conditions under which the Project and Requestor Organization will obtain, use, reuse, and disclose the CMS data file(s) specified in the Data Documentation portion of the Agreement below, including and/or any derivative file(s) that contain direct individual identifiers or elements that can be used with other information to identify individuals.

1. Definitions

- 1.1 **“Data Custodian”** means the person responsible for the observance of all conditions of use and for the establishment and maintenance of security arrangements as specified in this Agreement.
- 1.2 **“Data Documentation”** means the documents comprising Attachments A, B and C, which includes specification of the requested CMS data, and organizational approvals of study and data use.
- 1.3 **“DUA”** means a data use agreement.
- 1.4 **“MedRIC”** refers to the NIA contractor assisting Projects in acquiring DUAs and processing these DUAs.
- 1.5 **“NIA Representative”** means the NIA staff member authorized to enter into this Agreement on behalf of NIA.
- 1.6 **“NIA-Approved IT System”** means any IT/data environment (e.g., an Enclave) that NIA has designated as satisfying a government moderate-level Federal Information Security Modernization Act (FISMA) or Federal Risk and Authorization Management Program (FedRAMP) system with a government-issued Authority to Operate (ATO) approved for distributing confidential data files to researchers with fully executed NIA DUAs.
- 1.7 **“Principal Investigator”** or **“PI”** refers to the primary individual participating in a research Project (as a member of such Project) deemed responsible for the preparation, conduct, and administration of a research grant, contract, cooperative agreement, training, or public service project, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. PI shall be deemed to include any other title or designation given for this primary individual, such as “Co-PIs” and “Project Director” (or similar title/position).
- 1.8 **“Project”** means a research group or organization, comprised of a team of Users, with a valid NIA DUA granted access to a NIA-Approved IT System to conduct the research and data analyses authorized under this DUA and other applicable agreements.

- 1.9** “**Requestor Organization**” means the organization legally representing the Project and Data Custodian in this request and authorized to bind the Project and Data Custodian to this Agreement.
- 1.10** “**Requestor Organization Representative**” means the person authorized to enter into this Agreement on behalf of the Project Organization.
- 1.11** “**Retention Date**” means the end date for NIA data authorization.
- 1.12** “**Sensitive Information**” includes any information in the following categories: (i) personal identifiable information (“**PII**”) as defined in 2 CFR § 200.79; (ii) protected health information (“**PHI**”) as defined in 45 CFR 160.103; (iii) any data a Party knows or reasonably should know (in light of the nature of the information or the circumstances of its disclosure) is protected under 45 CFR 46 (“Protection of Human Research Subjects”); and (iv) any information identified as or that would be considered “sensitive” and/or “restricted” (or words of similar import) pursuant to the terms of a Project’s DUA or under applicable law. These categories may be amended from time to time or altered by applicable law.

2. Purpose and Roles

- 2.1** NIA agrees to provide the Project’s Data Custodian with data specified in Data Documentation.
- 2.2** In exchange, the Project, Requestor Organization, and Data Custodian agree to:
- 2.2.1** use the data only for the purposes specified in Data Documentation and specified within the funding agency Statement of Work (“SOW”);
 - 2.2.2** ensure the confidentiality, integrity, and security of the data by complying with the terms of this Agreement and applicable law, including the FISMA, the Privacy Act, and the Health Insurance Portability and Accountability Act (HIPAA); and
 - 2.2.3** pay any applicable data fees.

3. Data Ownership

- 3.1** The parties agree that CMS retains all ownership rights to CMS data file(s) referred to in this Agreement.
- 3.2** The parties also agree that the Project and Requestor Organization do not obtain any right, title, or interest in any of the data furnished by NIA.

4. Data Usage, Access, and Retention

- 4.1** The Project and Requestor Organization represent that CMS data file(s) authorized in this Agreement will be used solely for the purpose(s) specified in Data Documentation.
- 4.2** The Project and Requestor Organization represents that the facts and statements made in any study protocol, research protocol, or project plan submitted to NIA are complete and accurate.

- 4.2.1** Further, the Requestor Organization represents that said study protocol(s) or project plans, that have been approved by NIA or another appropriate entity as NIA may determine, represents the total use(s) to which the data file(s) specified in Data Documentation will be provided.
- 4.3** The Project and Requestor Organization agree not to disclose, use, or reuse the data covered by this Agreement except as specified in Attachments A, B, and C comprising the Data Documentation of this Agreement. The Project and Requestor Organization further agree not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement, except as NIA shall authorize in writing, or as otherwise required by law.
- 4.4** The Project and Requestor Organization agree that, within the Requestor Organization and the organizations of its agents, access to the data covered by this Agreement shall be limited to the minimum amount of data and the minimum number of individuals necessary to achieve the purpose stated in Data Documentation.
- 4.5** The parties mutually agree that the data files(s) (and/or any derivative file(s)) designated in Data Documentation, including those files that directly identify individuals or that directly identify bidding firms and/or such firms' proprietary, confidential individuals, may be retained by the Project and Requestor Organization until the Retention Date specified in Section 12 below.
- 4.5.1** The Project agrees to notify NIA within 30 calendar days of the completion of the purpose specified in Data Documentation if the purpose is completed before the Retention Date.
- 4.5.2** Upon such notice or applicable Retention Date (whichever occurs sooner), the Project or Requestor Organization agrees to deliver written certification to NIA within 30 calendar days verifying the destruction of all holdings of the Project's data and files encompassed by the Project's NIA DUA. This written certification must include attestation of data destruction from the NIA-Approved IT System hosting the Project's NIA-DUA data.
- 4.5.3** The Project and Requestor Organization agree not to retain CMS data files or any parts thereof, or specific bidding information, after the aforementioned data/file(s) are destroyed unless the NIA Representative designated in Section 13 of this Agreement (or NIA-designated equivalent) grants written authorization. The Project and Requestor Organization acknowledge that the date is not contingent upon action by NIA.

5. Data and System Security

- 5.1** The Project and Data Custodian agree to establish appropriate administrative, technical, and physical safeguards when accessing the NIA-Approved IT System to protect the confidentiality of the data and to prevent unauthorized use or access to it.

- 5.1.1** The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III—Security of Federal Automated Information Systems, which sets forth guidelines for security plans for automated information systems in Federal agencies.
 - 5.1.2** The Project and Data Custodian agrees to access all data in a NIA-Approved IT System.
 - 5.1.3** The Project and Data Custodian acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable, bidder identifiable, or deducible information derived from the file(s) specified in Data Documentation is prohibited.
 - 5.1.4** The Project and Data Custodian agrees that the data must not be physically moved, transmitted, or disclosed in any way from a NIA-Approved IT System without written approval from NIA unless such movement, transmission, or disclosure is required by law.
 - 5.1.5** The Project and Data Custodian agree to grant representatives of NIA or DHHS Office of the Inspector General direct access to the data and files specified in Data Documentation and information derived from these data/file(s) for the purpose of confirming compliance with the terms of this Agreement.
- 5.2** The parties mutually agree that the individual named as Data Custodian on the Information Form below is designated as Custodian of the file(s) and will be the person ultimately responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use.
 - 5.2.1** NIA has designated the default Data Custodian to be the Principal Investigator.
 - 5.2.2** The Data Custodian agrees to notify NIA within fifteen (15) calendar days of any change of custodianship.
 - 5.2.3** The parties mutually agree that NIA may disapprove of the appointment of an alternate data custodian or may require the appointment of a new custodian at any time.

6. Data Sharing and Disclosures

- 6.1** The Project and Requestor Organization agree not to disclose direct findings, listings, or information derived from the file(s) specified in Data Documentation, with or without direct identifiers, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce an individual's identity. Examples of such data elements include, but are not limited to geographic location, age if greater than 89, sex, diagnosis, procedure, admission/discharge date(s), or date of death.

- 6.1.1** The Project and Requestor Organization agree that any use of CMS data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the purpose specified in Data Documentation (regardless of whether the report or other writing expressly refers to such purpose, to NIA, or to the files specified in Data Documentation or any data derived from such files) must adhere to CMS's current cell size suppression policy. This policy stipulates that no cell (e.g., admittances, discharges, patients, services) 10 or less may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell 10 or less.
- 6.1.2** In the case of linking CMS data with other data sources, the minimum cell size may be increased by NIA or another organization providing the other data sources to prevent deducing any individual's identity. This minimum cell size will be specified in writing in the DUA documents authorizing access and use of these other data sources.
- 6.1.3** If you are unsure whether you meet the above criteria, you may submit your written products for NIA review. NIA agrees to provide feedback regarding your data use and/or publication plan 4 to 6 weeks after receipt. NIA may withhold approval for publication only if it determines that the presentation and format of the data/findings may result in the identification of individuals.
- 6.2** By signing this Agreement, the Project and Requestor Organization hereby agree to abide by these rules and, therefore, will not be required to submit any written documents for NIA review.
- 6.3** The Project and Requestor Organization agree that, absent express written authorization from the NIA Representative designated in Section 13 of this Agreement to do so, the Project shall not attempt to link records included in the file(s) specified in Data Documentation to any other individually identifiable source of information. This includes linking the data to other CMS data file(s).
- 6.3.1** Project protocols described in Data Documentation must include a definition of the data to be linked as part of the Project's study. If NIA approves of the Project's request for CMS data, then NIA's approval includes approval of the linkage of CMS data to the other data defined in Data Documentation.
- 6.4** The Project and Requestor Organization understand and agree that they may not reuse original or derivative data file(s) without prior written approval from the NIA Representative designated in Section 13 of this Agreement.

7. Data Breaches and Penalties

- 7.1** The Project and Requestor Organization agree that in the event NIA determines or has a reasonable belief that the Project or Requestor Organization has made or may have made a use, reuse, or disclosure of the aforesaid file(s) that is not authorized by this Agreement or another written authorization from the NIA Representative designated in Information Form below, NIA, at its sole discretion,

may require the Project and Requestor Organization to (a) promptly investigate and report to NIA the Project's and Requestor Organization's determinations regarding any alleged or actual unauthorized use, reuse, or disclosure; (b) promptly resolve any problems identified by the investigation; (c) if requested by NIA, submit a formal response to an allegation of unauthorized use, reuse, or disclosure; (d) if requested by NIA, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses, or disclosures; and (e) if requested by NIA, return data files to NIA or destroy the data files it received from NIA under this Agreement.

7.1.1 The Project and Requestor Organization understands that as a result of NIA's determination or reasonable belief that unauthorized uses, reuses, or disclosures have taken place, NIA may refuse to release further CMS data to the Requestor Organization for a period of time to be determined by NIA.

7.1.2 The Project and Requestor Organization agree to report any breach of personally identifiable information (PII) from the CMS data file(s), loss of these data or disclosure to any unauthorized persons to MedRIC authorities by telephone at (650) 558 – 8310 or by email notification to medric@acumenllc.com within one hour of discovery—as required by government security provisions—and to cooperate fully in the federal security incident process.

7.1.3 While CMS retains all ownership rights to the CMS data file(s), as outlined above, the Requestor Organization shall bear the cost and liability for any breaches of PII from the data file(s) while they are entrusted to the Requestor Organization. Furthermore, if NIA determines that the risk of harm requires notification of affected individual persons of the security breach and/or other remedies, the Requestor Organization agrees to carry out these remedies without cost to NIA.

7.2 The Project and Requestor Organization hereby acknowledge that:

7.2.1 criminal penalties under § 1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding \$10,000 or imprisonment not exceeding five (5) years, or both, may apply to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law;

7.2.2 criminal penalties under the Privacy Act (5 U.S.C. § 552a(i) (3)) may apply if it is determined that the Requestor Organization, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses;

7.2.3 any person found to have violated Sec. (i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than \$5,000; and, finally,

7.2.4 criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the Requestor Organization, or any individual employed or affiliated therewith, has taken or converted to their own use data file(s), or received the file(s) knowing that they were stolen or converted. Under

such circumstances, they shall be fined under Title 18 or imprisoned not more than ten (10) years, or both; but if the value of such property does not exceed the sum of \$1,000, they shall be fined under Title 18 or imprisoned not more than one (1) year, or both.

8. Agreement Term, Modifications, and Termination

- 8.1** The term of this DUA is the Retention Date recorded in Section 12 (DUA Number and Retention Date) below. The Retention Date is typically one (1) year from Signature Date of the NIA Representative recorded in Section 13 below.
- 8.2** This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in Data Documentation.
- 8.3** The terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the Project and Requestor Organization concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the NIA Representative to this Agreement designated in Section 13 below.
- 8.4** The Agreement may be terminated by either party at any time for any reason upon 30 calendar days written notice. Upon notice of termination by Project or Requestor Organization, NIA will cease releasing data from the file(s) to the Project and the Data Custodian under this Agreement and will ensure that authorities of the NIA-Approved IT System hosting the Project's data destroy such data file(s).
- 8.5** Sections 3-13 and Data Documentation shall survive termination of this Agreement.

[INFORMATION FORM AND SIGNATURE PAGE FOLLOWS.]

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DUA INFORMATION FORM AND SIGNATURE PAGE

Project's Principal Investigator, Data Custodian, and duly authorized Requestor Organization Representative ("you") must complete all the form fields below, including the signature fields of this Agreement.

9. Description of Project and Name of Requestor Organization Representing the Project

(Requestor Organization Title)

(Organization Type)

(Address, City, State, Zip)

(Project Title)

(No. Supporting Source (e.g., grant, contract))

(Name of Funding Agency)

(Address, City, State, Zip of Funding Agency)

10. Study Institute Sharing its Data Sources with Project in its Research Activities

(Organization Title)

(Address, City, State, Zip)

(Name of Principal Contact)

(Email Address of Principal Contact)

(Phone of Principal Contact)

11. Project and Requestor Organization Signatures

IN WITNESS WHEREOF, the Project representatives signed below have caused this Agreement to be executed by as authorized representative as of the date last written below (“**Effective Date**”).

Principal Investigator:

(Print Name)

(Email Address)

(Phone)

By: _____
(Signature)

(Date)

Data Custodian:

(Print Name)

(Email Address)

(Phone)

By: _____
(Signature)

(Date)

Requestor Organization Representative:

(Print Name)

(Email Address)

(Phone)

By: _____
(Signature)

(Date)

[INFORMATION BELOW POPULATED BY NIA.]

12. DUA Number and Retention Date

(DUA Number)

(Retention Date)

13. NIA Representative

The parties mutually agree that the following named individual will be designated as the point-of-contact for the Agreement on behalf of NIA. On behalf of NIA, the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

(Print Name)

(Email Address)

(Phone)

By: _____
(Signature)

(Date)

[DATA DOCUMENTATION FOLLOWS.]

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DATA DOCUMENTATION

This last portion of the Agreement consists of Attachments A, B, and C that provide the organizational approvals of study and data use documents and the specification of the CMS data authorized by this DUA.

14. Federal Program Officer (FPO) Letter of Support

14.1 See Attachment A.

15. IRB Letter or Waiver

15.1 See Attachment B.

16. MedRIC Data Request Form

16.1 See Attachment C.

[ATTACHMENTS FOLLOWS.]

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Data Documentation

Attachment A

Federal Program Officer (FPO) Letter of Support

Data Documentation

Attachment B

IRB Letter or Waiver

Data Documentation

Attachment C

MedRIC Data Request Form