

# ORIGINAL

## LIMITED DATA USE AGREEMENT

This Data Use Agreement is between County of El Dorado Health Services Department a political subdivision of the State of California (the "*Covered Entity*"), and Westat Inc., whose principal place of business is 1600 Research Blvd, Rockville, MD 20850 (the "*Data User*").

## RECITALS

**Whereas**, Covered Entity is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder, including the Standards for Privacy of Individually Identifiable Health Information and Security Standards for the Protection of Electronic Protected Health Information at 45 C.F.R. Parts 160 and 164 (collectively "*Privacy and Security Regulations*");

**Whereas**, the Data User performs certain **research** functions (the "*Activities*");

**Whereas**, County of El Dorado Health Services Department (CEDHSD) agrees to disclose a Limited Data Set, as defined herein, to Data User for use by Data User in performance of the Activities;

**Whereas**, Data User agrees to limit its use of the Limited Data Set and protect the Limited Data Set according to terms and conditions of this Agreement and the Health Insurance Portability and Accountability Act (HIPAA) and corresponding Privacy Standards, as may be amended from time to time.

**Now therefore**, in consideration of the mutual agreements, covenants, terms and conditions herein contained, CEDHSD and Data User agree as follows:

### ***I. DEFINITIONS FOR USE IN THIS AGREEMENT***

**"ACCEL"** shall mean the Access El Dorado Initiative, a County-wide collaborative, including representatives from the prominent health organizations in the County, whose purpose is to make County of El Dorado a healthier community by uniting, maximizing, connecting, and focusing health resources.

**"De-identified PHI"** shall mean PHI with certain identifiers blocked or deleted in such a manner that there is no reasonable basis to believe the remaining information can be used to identify an individual as defined by 45 CFR §514(a).

**"Designated Record Set"** shall mean a group of records maintained by or for CEDHSD that is (i) the medical records and billing records about patients maintained by or for CEDHSD; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used, in whole or in part, by or for CEDHSD to make decisions about patients. As used herein the term "Record" means any item, collection, or grouping of information that includes PHI and is maintained, collected, used or disseminated by or for CEDHSD.

“**Disclose**” and “**Disclosure**” mean, with respect to PHI, the release, transfer, provision of access to, or divulging in any other manner of PHI outside Data user’s internal operations. “Internal operations” shall include Data User’s employees, agents, and subcontractors as part of the processes described in this Agreement.

“**Electronic Protected Health Information**” means PHI that is transmitted by electronic media (as defined by the Privacy and Security Regulations) or is maintained in electronic media. Electronic PHI may be transmitted and maintained on devices such as cell phones, PDAs, text pagers, and USB static discs.

“**Limited Data Set**” shall mean PHI which excludes direct identifiers as defined by 45 CFR §514(e) including but not limited to individuals or the relatives, employers, or household members.

“**Privacy Standards**” shall mean the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

“**Protected Health Information**” (PHI) shall mean any information whether oral or recorded in any form or medium, that (i) relates to the past, present or future physical or mental health or condition of a patient; the provision of health care to a patient, or the past, present or future payment for the provision of health care to a patient; (ii) identifies the patient (or for which there is a reasonable basis for believing that the information can be used to identify the patient); and (iii) is received by Data User from or on behalf of CEDHSD, or is created by Data User, or is made accessible to Data User by CEDHSD. For instance, PHI includes information contained in a patient’s medical records and billing records. PHI includes without limitation, electronic PHI.

“**Secretary**” shall mean the Secretary of the U.S. Department of Health and Human Services (“HHS”) and any other agency, officer, or employee of HHS to whom the authority to enforce HIPAA and its implementing regulations has been delegated.

“**Use**” or “**Uses**” mean, with respect to PHI, the sharing, employment, application, utilization, examination or analysis of such information within Data User’s internal operations.

## ***II. DISCLOSURE OF LIMITED DATA SET TO DATA USER***

**2.1 Activities.** Data User performs the following Activities: A data research associate (DRA), hired by Westat, will review data in iReach, the case management software used by ACCEL, as well as information captured in CEDHSD record systems concerning service utilization at the CEDHSD facility by ACCEL clients. While some diagnosis information will be collected for the study, the amount of clinical detail is very limited. All data will be de-identified before submitting to a web-based information portal designed by the Matrix Group International (Matrix), a subcontractor of the Westat Corporation. Matrix will then transmit the de-identified data to Westat researchers.

**2.2 Limited Data Set.** Data User agrees to use, and CEDHSD agrees to disclose, the following PHI to Data User for use by the Data User in the performance of the Activities (the “**Limited Data Set**”): Patient pseudo ID, dates associated with program enrollment, care plan development, medical or social service referrals and completion of appointments. Data will also include whether or not the patient is assigned to a medical home, and if primary care provider appointments are kept. Patient characteristics will be identified such as age, gender, race, English-speaking or not, insurance status and employment status. Patient eligibility for referrals will be

identified such as acute care, primary care, specialty care, mental/behavioral health care, substance abuse treatment services, dental or eye care, or provision of durable medical equipment. If referrals are not made, reasons for the unsuccessful referral will be identified. Social service referrals will be identified by type of referral such as clothing, food, employment, housing, utility assistance, protective services, insurance, transportation or other referrals. Patient's successful acquisition of services or completed referrals will be included. Regarding patients who have utilized the Emergency Department (ED) and been referred to ACCEL, the date of ED discharge will be used, the date of referral to ACCEL; if referral is not scheduled, the reason for unsuccessful referral. After enrollment in ACCEL, Emergency Department visits will be noted as well as the chief complaint for that visit. Hospitalization post pathways completion will be tracked. For patients hospitalized after completion of pathways of care, the dates of hospital admission, hospital discharge, principle diagnosis, and cost of visit will be tracked. In addition, a Westat field employee (the DRA) will have access to PHI for purposes of assessing patient eligibility for inclusion in the study. The field employee will maintain all PHI locally for tracking and de-duplication purposes. However, any patient identifiers will be removed from the dataset as it is uploaded to the central research database so no identifiers will be available to Westat staff at its main office in Maryland, or Westat's subcontractor Matrix.

**2.3 Client Surveys.** In addition to the analysis of the Limited Data Set described in section 2.2, the DRA will select ACCEL clients to participate in a survey of their experiences of care coordination. The survey will be conducted by the DRA by telephone, in person, or by mail, which ever is most convenient. The survey methods will be approved by the Westat Institutional Review Board to ensure the protection of human subjects. The questions are considered low risk and do not touch on sensitive topics. Client participation in the survey will be voluntary, and the DRA will remove any personal identifiers before uploading the data to the central research database maintained by Matrix and Westat researchers. Matrix, ACCEL, and Westat research staff will have no access to identifiable survey response data.

### ***III. OBLIGATIONS OF DATA USER***

**3.1 Use of Limited Data Set.** The Data User may use and disclose the Limited Data Set only as permitted under the terms of this Agreement or required by law. Data User shall limit the use or receipt of the Limited Data Set to the following individuals or classes of individuals who need the Limited Data Set for the performance of the Activities: The local Data Research Associate (DRA), a Westat employee who will have initial access to the data in iReach, the case management software housed on a server which resides at Marshall Medical Center on behalf of ACCEL. The local DRA will use the web-based information portal that is designed by Matrix to upload the de-identified data. Matrix will then process the data for the Westat Corporation's Research Associates for analysis. Others with access to the data include the Principal Investigators of the study at Westat Corporation.

**3.2 Minimum Necessary Information.** The Data User represents that, to the extent the Data User requests that CEDHSD disclose PHI to the Data User as described in Section 2.2, such a request is only for the minimum necessary PHI for the accomplishment of the Data User's purpose.

**3.3 Safeguards Against Misuse of Information.** The Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set in any manner other than as permitted under this Agreement. Data User warrants that it shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic PHI that it creates, receives,

maintains, or transmits on behalf of CEDHSD as required by the Privacy and Security Regulations.

**3.4 Mitigation.** Data User shall mitigate, to the extent practicable, any harmful effect that is known to Data User of a use or disclosure of PHI by Data User in violation of the requirements of this Agreement.

**3.5 Reporting of Disclosure of Protected Health Information.** The Data User shall, report to CEDHSD any use or disclosure of the Limited Data Set in violation of the Agreement made by the Data User, its officers, directors, employees, contractors, or agents or by a third party to which the Vendor disclosed the Limited Data Set. Data User shall report to CEDHSD any security incident of which he/she becomes aware. For purposes of this Agreement, "Security Incident" means the attempted or successful unauthorized access use or disclosure, modification, or destruction of information or interference with the system operations in an information system. Data User shall provide in such notice the remedial or other actions undertaken to correct the unauthorized use or disclosure. In initial report shall be made by telephone call to the County of El Dorado Compliance Officer, Allyn Bulzomi (530-621-5572), within five (5) days from the time Data User becomes aware of an actual or apparent non-permitted Use or Disclosure, followed by a full written report to the ACCEL Program Manager no later than ten (10) business days from the date Data User becomes aware of the non-permitted Use or Disclosure. Data User shall provide in such notice the remedial or other actions undertaken to correct the unauthorized use or disclosure.

**3.6 Use of Subcontractors and Agents.** The Data User shall require each of its agents or subcontractors that receive access to the Limited Data Set, to execute a written Agreement obligating the agent or subcontractor to Data User, pursuant to which agreement such agent or subcontractor agrees to be bound by the same restrictions, terms and conditions that apply to the Data User pursuant to this Agreement with respect to the Limited Data Set.

**3.7 Location and Access to Limited Data Set.** Limited Data Set shall at all times be kept and located at Westat Corporation, 1600 Research Blvd., Rockville, MD 20850, or Matrix 2711 Jefferson Davis Highway, Suite 1200 Arlington, VA 22202-4015, and shall not be removed, transferred, or relocated to any other location without the prior written consent of the Covered Entity. Within five days of a request by CEDHSD for access to PHI that is contained in a Designated Record Set, the Data User shall make available to CEDHSD such PHI. If an individual requests access to PHI directly from the Data User, the Data User shall within two (2) days forward such request to CEDHSD. CEDHSD will respond to individual requests for access to PHI.

**3.8 HIPAA Compliance.** By signing this Agreement, Data User agrees to comply with Exhibit A, Business Associate Agreement, attached hereto and incorporated by reference herein.

**3.9 Availability of Protected Health Information for Amendment.** Within ten (10) days of receipt of a request from CEDHSD for the amendment of a patient's PHI contained in a Designated Record Set, the Data User shall provide such information to CEDHSD for amendment and incorporate any such amendments in the PHI as required by the Privacy and Security Regulations.

**3.10 Accounting of Disclosures.** Upon CEDHSD request, Data User shall provide to CEDHSD an accounting of each Disclosure of PHI made by Data User or its employees, agents,

representatives or subcontractors. Any accounting provided by Data User under this section shall include: (a) the date of the Disclosure; (b) the name, and address if known, of the entity or person who received the PHI; (c) a brief description of the PHI disclosed; and (d) a brief statement of the purpose of the Disclosure. For each Disclosure that could require an accounting under this section, Data User shall document the information specified in (a) through (d), above, and shall securely retain this documentation for six (6) years from the date of the Disclosure.

**3.11 Indemnification. To the extent not covered by insurance as described in Section 3.12,** the Data User shall defend, indemnify, and hold the CEDHSD harmless against and from any and all claims, suits, losses, damages and liability for damages of every name, kind and description, including attorneys fees and costs incurred, brought for, or on account of, injuries to or death of any person, including but not limited to workers, CEDHSD employees, and the public, or damage to property, or any economic or consequential losses, which are claimed to or in any way arise out of or are connected with the DATA USER's services, operations, or performance hereunder, regardless of the existence or degree of fault or negligence on the part of the CEDHSD, the Data User, subcontractor(s) and employee(s) of any of these, except for the sole, or active negligence of the CEDHSD, its officers and employees, or as expressly prescribed by statute. This duty of Data User to indemnify and save CEDHSD harmless includes the duties to defend set forth in California Civil Code Section 2778.

**3.12 Insurance.** Data User shall provide proof of a policy of insurance satisfactory to the County of El Dorado Risk Manager and documentation evidencing that Data User maintains insurance that meets the following requirements:

- Full Workers' Compensation and Employers' Liability Insurance covering all employees of Data User as required by law in the State of California; and
- Commercial General Liability Insurance of not less than \$1,000,000 combined single limit per occurrence for bodily injury and property damage;
- Automobile Liability Insurance of not less than \$1,000,000 is required in the event motor vehicles are used by the Data User in the performance of the Agreement.

3.12.1 Data User shall furnish a certificate of insurance satisfactory to the County of El Dorado Risk Manager as evidence that the insurance required above is being maintained.

3.12.2 The insurance will be issued by an insurance company acceptable to Risk Management, or be provided through partial or total self-insurance likewise acceptable to Risk Management.

3.12.3 Data User agrees that the insurance required above shall be in effect at all times during the term of this Agreement. In the event said insurance coverage expires at any time or times during the term of this Agreement, Data User agrees to provide, in a timely manner, a new certificate of insurance evidencing insurance coverage as provided for herein for not less than the remainder of the term of the Agreement, or for a period of not less than one (1) year. New certificates of insurance are subject to the approval of Risk Management and Data User agrees that no work or services shall be performed prior to the giving of such approval. In the event the Data User fails to keep in effect at all times insurance coverage as

herein provided, CEDHSD may, in addition to any other remedies it may have, terminate this Agreement upon the occurrence of such event.

3.12.4 The certificate of insurance must include the following provisions stating that:

- The insurer will not cancel the insured's coverage without notice delivered to Data User, the named insured, in accordance with the policy provisions and Data User will promptly provide notice to CEDHSD, and;
- The County of El Dorado, its officers, officials, employees, and volunteers are included as additional insured, but only insofar as the operations under this Agreement are concerned. This provision shall apply to the general liability policy.

3.12.5 The Data User's insurance coverage shall be primary insurance as respects the CEDHSD, its officers, officials, employees and volunteers. Any insurance or self-insurance maintained by the CEDHSD, its officers, officials, employees or volunteers shall be excess of the Data User's insurance and shall not contribute with it.

3.12.6 Any deductibles or self-insured retentions must be declared to and approved by the CEDHSD, either: the insurer shall reduce or eliminate such deductibles or self-insured retentions as respects the CEDHSD, its officers, officials, employees, and volunteers; or the Data User shall procure a bond guaranteeing payment of losses and related investigations, claim administration and defense expenses.

3.12.7 Any failure of Data User to comply with the reporting provisions of the policies shall not adversely affect the CEDHSD, its officers, officials, employees or volunteers.

3.12.8 The insurance companies shall have no recourse against the County of El Dorado, its officers and employees or any of them for payment of any premiums or assessments under any policy issued by any insurance company.

3.12.9 Data User's obligations shall not be limited by the foregoing insurance requirements and shall survive expiration of this Agreement.

3.12.10 In the event Data User cannot provide an occurrence policy, Data User shall provide insurance covering claims made as a result of performance of this Agreement for not less than three (3) years following completion of performance of this Agreement.

3.12.11 Certificate of insurance shall meet such additional standards as may be determined by the contracting County Department either independently or in consultation with Risk Management, as essential for the protection of the County.

**3.13 Notice of Request for Data.** The Data User agrees to notify CEDHSD within five (5) business days of the Data User's receipt of any request or subpoena for PHI. To the extent that CEDHSD decides to assume responsibility for challenging the validity of such request, the Data User shall cooperate fully with CEDHSD in such challenge.

**3.14 Injunctive Relief.** Notwithstanding any rights or remedies provided for in the Agreement, CEDHSD retains all rights to seek injunctive relief to prevent or stop the

unauthorized access to, or use or disclosure of PHI by Data User or any agent, subcontractor or third party that received PHI from Data User.

**3.15 Property Rights.** The PHI shall be and remain the property of CEDHSD. Data User agrees that it acquires no title or rights to the PHI, including any and all forms thereof developed by Data User, such de-identified information, as a result of this Agreement.

#### ***IV. TERMINATION***

**4.1 Termination Upon Breach of Provisions Applicable to Protected Health Information.** CEDHSD may terminate this Agreement upon five (5) days written notice to the Data User in the event that the Data User breaches any provision contained in this Agreement.

**4.2 Return or Destruction of Protected Health Information upon Termination.** Upon termination of this Agreement, Data User shall return or destroy all PHI in its possession. In the event that Data User determines that returning or destroying the PHI is infeasible, Data User shall provide to CEDHSD notification of the conditions that make return or destruction infeasible. Data User may retain PHI provided that Data User agrees to extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for as long as Data User maintains such PHI.

**4.3 CEDHSD Right of Cure.** At the expense of the Data User, CEDHSD shall have the right to cure any breach of the Data User's obligations under this Agreement. CEDHSD shall give the Data User notice of its election to cure any such breach and the Data User shall cooperate fully in the efforts by CEDHSD to cure the Data User's breach.

#### ***V. GENERAL PROVISIONS***

**5.1 Term.** The term of this Agreement shall be effective upon final signature through December 31, 2011.

**5.2 Compensation.** There shall be no remuneration associated with this Agreement.

**5.3 Effect.** The terms and provisions of this Agreement shall supercede any other conflicting or inconsistent agreements between CEDHSD and Data User, including all exhibits or other attachments thereto and all documents incorporated therein by reference. Without limitation of the foregoing, any limitation or exclusion of damages provisions shall not be applicable to this Agreement.

**5.4 New Statutory and Legislative Requirements.** The Parties agree that any part of this Agreement that is revoked or amended by legislative action or invalidated by judicial decision shall cease to be effective on the date of revocation, amendment or invalidation, without change to the remainder of the Agreement wheresoever possible. The Parties agree to amend this Agreement as necessary to maintain compliance with current legislative, regulatory and judicial requirements to meet the spirit and purpose of enhanced confidentiality of individually identifiable health information. In the event the Parties are unable to agree on amendments to maintain compliance, either party may terminate this Agreement immediately subject to the provisions of Article IV.

**5.5 Choice of Law.** This Agreement shall be governed by and construed in accordance with the laws of California.

**5.6 Notice to Parties.** All notices to be given by the parties hereto shall be in writing and served by depositing same in the United States Post Office, postage prepaid and return receipt requested. Notices to CEDHSD shall be addressed as follows:

**COUNTY OF EL DORADO  
HEALTH SERVICES DEPARTMENT  
931 SPRING STREET  
PLACERVILLE, CA 95667  
ATTN: NEDA WEST, DIRECTOR**

or to such other location as the CEDHSD directs in writing.

Notices to DATA USER shall be addressed as follows:

**WESTAT, INC.  
1600 RESEARCH BLVD  
ROCKVILLE, MD 20850  
ATTN: W. SHERMAN EDWARDS, VICE PRESIDENT**

or to such other location as the DATA USER directs in writing.

**5.7 Article Headings.** The article headings used herein are for reference and convenience only, and shall not enter into the interpretation of this Agreement.

**5.8 No Third-Party Beneficiaries.** There are no third-party beneficiaries to this Agreement.

**5.9 Attorneys' Fees.** Except as otherwise specified in this Agreement, each party shall bear its own legal expenses and any other costs incurred in the action or proceeding.

**5.10 Interpretation.** Any ambiguity in this Agreement shall be resolved to permit CEDHSD and Data User to comply with the Privacy and Security Regulations.

**6.0 Administrator.** The County Officer or employee with responsibility for administering this Agreement is Sharon Elliott, Assistant Director of Public Health, or successor.

DEPARTMENT HEAD CONCURRENCE

  
\_\_\_\_\_  
Neda West, Director  
Health Services Department

5-26-11  
Date

//  
//  
//  
//



IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the final signature below.

**Data User:**

Westat Inc.

By: W. Sherman Edwards

Title: Vice President

Signed: W. Sherman Edwards

Date: 5/24/11

**Covered Entity:**

County of El Dorado

By: Ray Nutting

Title: Chair, Board of Supervisors

Signed: \_\_\_\_\_

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

**Data User:**

Westat Inc.

By: Veronica Nicua

Title: Vice President

Signed: Veronica J. Nicua

Date: 5/24/11

*Attest:*

*Suzanne Allen de Sanchez,  
Clerk of the Board of Supervisors*

Signed: \_\_\_\_\_

Deputy

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

James F. Hill  
1876