

Exhibit 3



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 14, 2022

SENT VIA EMAIL

Aaron Siri
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

2nd Letter Subject: Final Response Letter

Dear Mr. Siri:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your November 01, 2021, Freedom of Information Act (FOIA) request on November 01, 2021, seeking:

“All data sets for the study titled “Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19-Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity – Nine States, January – September 2021” published in the Morbidity and Mortality Weekly Report dated October 29, 2021, available at https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e1.htm?s_cid=mm7044e1_w”

The CDC Emergency Operations Center (EOC) relayed the following assessment:

No data sets can be provided based on the data use agreement [attached as a courtesy to you]. Specifically see page 3, section g, which includes the following statement regarding third parties:

“Third-Party Access. Recipient must not (nor permit others to) copy, sell, rent, license, lease, or loan the Data covered by this Agreement to any other person or entity. No other access shall be granted to a third-party except as expressly permitted under this Agreement or required by law. The Centers for Disease Control and Prevention is a third party and has been permitted access under this Agreement”

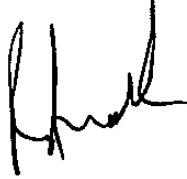
Also, the EOC suggested you review the publicly available data sharing agreement for a study from the VISION Network published in NEJM, the PI (CDC staff) states that “CDC will share aggregate data once study objectives are complete and consistent with data use agreements with partner institutions” https://www.nejm.org/doi/suppl/10.1056/NEJMoa2110362/suppl_file/nejmoa2110362_data-sharing.pdf.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

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If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at <https://requests.publiclink.hhs.gov/app/index.aspx?aspxerrorpath=/App/Index.aspx>. or via e-mail at FOIARequest@psc.hhs.gov or via mail at Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. Please mark both your appeal letter and envelope “FOIA Appeal.” Your appeal must be postmarked or electronically transmitted by July 13, 2022.

Sincerely,

A handwritten signature in black ink, appearing to read 'Roger Andoh', written in a cursive style.

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

Enclosures

#22-00235-FOIA

**DATA USE AGREEMENT
LIMITED DATA SET**

THIS DATA USE AGREEMENT (the “Agreement”) is entered as of the last date of the signatures below (the “Effective Date”) by and between Children’s Hospital Colorado (“CHCO”), a Colorado not for profit corporation having an address at 13123 East 16th Avenue, Aurora, CO 80045 (“PROVIDER”) and Westat, Inc. a State of a Delaware corporation with its principal place of business at 1600 Research Boulevard, Rockville, Maryland 20850 (“RECIPIENT”), and (Recipient and Provider are individually referred to as a “Party”, and collectively referred to as “Parties”).

RECITALS

WHEREAS, the purpose of this Agreement is to satisfy certain obligations of the Parties under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its implementing regulations (45 C.F.R. Parts 160-64) to ensure the integrity and confidentiality of Protected Health Information exchanged in the form of a Limited Data Set (“LDS”).

WHEREAS, PROVIDER will provide certain Protected Health Information in the form of a Limited Data Set to RECIPIENT described herein across a secured network for the purposes of the performance of the research study entitled “**Virtual Network : Investigating the Risk of Influenza - Associated Outcomes and Influenza Vaccine Effectiveness Using Integrated Medical and Public Health Records (VISION) COMIRB 20-0891**” (the “STUDY” as described in the protocol incorporated herein by reference the “PROTOCOL”)

NOW THEREFORE, in consideration of the foregoing and the mutual promises contained herein, and of the mutual benefit to be derived hereunder, the Parties hereto agree as follows:

AGREEMENT

1. **Definitions.** For the purposes of this Agreement, the following terms shall have the meaning ascribed to them below. Terms used but not defined herein shall have the same meaning as in the HIPAA Regulations.
 - a. **Applicable Law** shall mean all applicable statutes and regulations of the state(s) or jurisdiction(s) in which the PROVIDER operates as well as all applicable Federal statutes, regulations, standards and policy requirements.
 - b. **Data** must have the elements described in **Exhibit A** attached and incorporated herein.
 - c. **HIPAA Regulations** shall mean the Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R.§ Parts 160 and 164) promulgated by the U.S. Department of Health and Human Services under the Health Insurance Portability and Accountability Act of 1996 as in effect on the Effective Date of this Agreement and as may be amended, modified or renumbered.
 - d. **Individually Identifiable Health Information** shall have the meaning set forth at 45 C.F.R § 160.103.
 - e. **Limited Data Set** will mean the data provided by the PROVIDER to the RECIPIENT that does not include the following direct identifiers of an individual, or of relatives, employers, or household member(s) of an individual:
 - i. Names;

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- ii. Postal address information (other than town or city, State, and zip code or other geocode);
 - iii. Telephone number;
 - iv. Fax numbers;
 - v. Electronic mail addresses;
 - vi. Certificate and social security numbers;
 - vii. Medical record numbers; health plan beneficiary numbers;
 - viii. Accounting numbers;
 - ix. Certificate/License numbers;
 - x. Vehicle identifiers and serial numbers, including license plate number;
 - xi. Device identifiers and serial numbers;
 - xii. Web universal resource locators (URLs);
 - xiii. Internet protocol (IP) address numbers;
 - xiv. Biometric identifiers, including finger and voice prints; and,
 - xv. Full face photographic images and any comparable images
- f. **Notice or Notification** shall mean a written communication, unless otherwise specified in this Agreement, sent to the appropriate representative at the address listed in Section 9 herein.
- g. **Permitted Purposes** shall mean uses and disclosures related to the performance of the Study and Recipient's administrative usage.
- h. **Protected Health Information** or **PHI** shall have the meaning set forth at 45 C.F.R. §160.103 of the HIPAA Regulations.
2. **Incorporation of Recitals.** The Recitals set forth above are hereby incorporated into this Agreement in their entirety and shall be given full force and effect as if set forth in the body of this Agreement.
3. **Provider Obligations.**
- a. Provider shall provide Data to Recipient and its authorized users in the requisite format as set forth in **Exhibit A**, and in accordance with the n accordance with the HIPAA Regulations. Recipient may use Data for Permitted Purposes as described below.
 - b. All fees associated with this Agreement must be identified in an Exhibit and incorporated into this Agreement by reference.
4. **Recipient Obligations and Functions.**
- a. Recipient is permitted to utilize the Data to conduct the Study according to the Protocol.
 - b. **Use and Disclosure.** Recipient may use and disclose the Data as necessary to conduct the Study, and/or as required by law. Parties specifically acknowledge that data **per the IRB approved data dictionary for this project** will be disclosed to the Center for Disease Control and Prevention. Recipient acknowledges this Agreement does not authorize or permit use or further disclosure of the information in excess of disclosure contemplated by this Agreement, that would violate any Applicable Law. Recipient must ensure Recipient and its directors, officers, employees, contractors, and agents do not use or disclose the Data in any manner that would constitute a violation of the HIPAA

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Regulations if used by the Provider.

- c. **Safeguards.** Recipient must use appropriate safeguards to prevent use or disclosure of the information other than as provided by this Agreement.
- d. **Reporting Required.** Recipient must report to Provider's Privacy Officer any use or disclosure of the Data not provided for by this Agreement of which it becomes aware, including uses or disclosures by Recipient, its employees, subcontractors, and/or agents. Recipient shall reimburse Provider for all costs, expenses (including reasonable attorney's fees), damages, and other losses resulting from any unauthorized use or disclosure involving the Data, including, without limitation: fines or settlement amounts owed to a state or federal government agency or other mitigation steps taken by Provider to comply with HIPAA or state law.
- e. **Subcontractors.** Recipient must ensure any agents, including subcontractors, to whom it provides Data agree to the same restrictions and conditions that apply to Recipient with respect to the Data.
- f. **No Contact.** Recipient will not: (1) re-identify the information; (2) attempt to link the Data with personally identifiable records from any other sources; and, (3) attempt to contact any of the individuals (patients, patient's family members, employers, or household members) identified or otherwise included in the Data.
- g. **Third-Party Access.** Recipient must not (nor permit others to) copy, sell, rent, license, lease, or loan the Data covered by this Agreement to any other person or entity. No other access shall be granted to a third-party except as expressly permitted under this Agreement or required by law. The Center for Disease Control and Prevention is a third party and has been permitted access under this Agreement
- h. **Ownership.** Recipient acknowledges, as between Recipient and Provider, the Data furnished to Recipient by Provider must be and remain the sole property of the Provider. Provider hereby grants to Centers for Disease Control and Prevention (CDC) a world-wide, royalty-free, non-exclusive, and irrevocable license to practice any Inventions developed under this Agreement.
- i. **Notice of Request for Data.** Recipient agrees to notify Provider within ten (10) business days of Recipient's receipt of all requests or subpoenas for the Data. To the extent Provider decides to assume the responsibility for challenging the validity of such request or subpoena, the Recipient must cooperate fully with the Provider.
- j. **Minimum Necessary Information.** To the extent required by the "minimum necessary" requirements of HIPAA, Provider will provide, use and disclose the minimum amount of Data necessary to accomplish the purpose of the request, use and/or disclosure.

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5. Security.

- a. **General.** Recipient must be responsible for maintaining a secure environment and must use appropriate safeguards to prevent use or disclosure of Data other than as permitted by this Agreement, including but not limited to appropriate administrative, physical, and technical safeguards that protect the confidentiality, integrity, and availability of the Data.
- b. **Malicious Software.** Recipient must ensure it employs security controls which meet applicable industry and/or Federal standards so the information and Data will not introduce any viruses, worms, unauthorized cookies, Trojans, malicious software, “malware,” or other program, routine, subroutine, or data designed to disrupt the proper operation of, or any part thereof, of any hardware or software used by Recipient in connection therewith, or which, upon the occurrence of a certain event, the passage of time, or the taking of or failure to take any action, will cause any part thereof or any hardware, software or data used by Recipient in connection therewith, to be improperly accessed, destroyed, damaged, or otherwise made inoperable.

- 6. Change in Law.** Upon enactment or amendment of any law or regulation affecting the use or disclosure of Data, or the publication of any decision of a court of the United States or of the State of Colorado, relating to any such law, the publication of any interpretive policy or opinion of any governmental agency charged with the enforcement of any such law or regulation, or the opinion of counsel, the Parties may, amend this Agreement in such manner as the Parties determine necessary to comply with such law or regulation. If the Parties are unable to agree on an amendment to the Agreement within thirty (30) day thereafter, either Party may terminate this Agreement upon written notice to the other.

- 7. Amendments.** The terms of this Agreement may not be waived, altered, modified, or amended except by a written agreement executed by all Parties.

- 8. Notices.** Unless otherwise specified in writing, any notice or submission required to be given to a party under this Agreement must be made in writing to the party’s authorized representative, indicated below, at the address provided above. Notice must be delivered by first class mail, postage prepaid, and return receipt requested, or by overnight courier capable of confirming delivery, and must be deemed sufficiently given when received by the party to be notified.

If to Recipient: Westat, Inc.

1600 Research Boulevard
Rockville, Maryland 20850
Attn: Kristina Lewis

If to Provider: Children’s Hospital Colorado
Research Contracting
13123 East 16th Avenue
Aurora, Colorado 80045
Attn: Research Agreements

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9. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of Colorado without regard to its conflict of laws provisions. Recipient acknowledges that Provider operates solely within the United States (US), is not subject to the jurisdiction or regulatory authorities of any other country, and any reference to laws any regulatory compliance refers solely to laws of the US jurisdictions and US regulatory agencies.
10. **Severability.** This Agreement is divisible and separable so if any provision or provisions hereof must be held to be invalid, such holding must not impair the remaining provisions hereof. If any provision of this Agreement is held to be too broad to be enforced, such provision must be construed to create an obligation to the full extent allowable by law.
11. **Waiver.** The failure by any Party to enforce, and at any time, all provisions of this Agreement and/or to require at any time performance by another Party of any of the provisions hereof shall in no way be construed to be a waiver of such provisions, to affect either the validity of this Agreement, or any part hereof, or the right of any party thereafter to enforce each and every provision in accordance with the terms of this Agreement.
12. **Entire Agreement.** This Agreement embodies the entire understanding between the parties and supersedes and replaces all prior understandings, arrangements, and/or agreements, whether written or oral, relating to the PROPRIETARY INFORMATION. Further, the parties agree: (1) Amendments or modifications to this Agreement must be in writing, approved and executed by an appropriate officer of each party; and, (2) this Agreement will be binding upon and inure to benefit of the parties hereto and their respective successors and assigns.
13. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which shall together constitute one agreement.
14. **Breach Liability.** The Recipient agrees to defend, indemnify and hold harmless the Provider from any claims or causes of action that might be brought about against the Provider and/or the Provider's directors, officers, employees and/or agents by a third-party because of Recipient's breach of any HIPAA obligations or other regulatory obligations.
15. **Relationship of the Parties.** The Parties are independent contracting entities. Nothing in this Agreement shall be construed to create a partnership, agency relationship, or joint venture among the Parties. No Party will have any authority to bind or make commitments on behalf of another party for any purpose, nor shall any such Party hold itself out as having such authority. No Party will be held liable for the acts or omissions of another Party.

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16. Term and Termination.

- a. The term of this Agreement shall commence upon the Effective Date and will terminate when all Data provided by Provider to Recipient is destroyed or returned to Provider. The parties acknowledge that any Data provided to the CDC will not be destroyed.
- b. Upon the expiration or sooner termination of this Agreement for any reason, including, but not limited to Recipient's decision to cease use of the Data, Recipient shall promptly destroy or return all Data (including copies or derivative versions thereof) to Provider. If the destruction or return of Data is not feasible (for example, due to the structure of a database), the Recipient shall advise Provider as to the reason return is infeasible, extend the protections of this Agreement to such Data and limit, consistent with the HIPAA Regulations, further use and disclosure of the Data only to the purposes that make the return or destruction infeasible, for so long as Recipient maintains such Data.
- c. Upon Provider's knowledge of a material breach by Recipient, Provider will have the right to immediately terminate this Agreement, or, in Provider's sole discretion, allow Recipient thirty (30) days to cure such breach, Provider, at its sole discretion, may: (i) terminate this Agreement upon written notice to Recipient; (ii) request Recipient, to the satisfaction of Provider, take appropriate steps to cure such breach. If Recipient fails to cure such breach to Provider's satisfaction or in the time prescribed by Provider, Provider may terminate this Agreement and report the breach to the Secretary of the Department of Health and Human Services (HHS) or its designee; or, (iii) hold Recipient liable for violations, negligence and all claims related to the breach.
- d. Recipient's obligation to protect the privacy of the Data is continuous and survives any termination, cancellation, expiration, or other conclusion of this Agreement with respect to any portion of the Data Recipient maintains after such termination, cancellation, expiration, or other conclusion of this Agreement.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK-SIGNATURE PAGE TO FOLLOW

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IN WITNESS WHEREOF, the Parties have executed this Agreement on the dates listed below to be effective as of the “Effective Date”.

PROVIDER	RECIPIENT
Signature: _____	Signature: <small>DocuSigned by:</small> <u>Patricia Shifflett</u> <small>94EBCEF56D6E40E...</small>
Printed Name: Erin Sandene	Printed Name: <u>Patricia Shifflett</u>
Title: Director of Research Operations and Administration	Title: <u>vice President</u>
<i>Understood and acknowledged</i> Provider Primary Investigator (“PI”)	<i>Understood and acknowledged</i> Recipient Primary Investigator (“PI”)
Signature: _____	Signature: <small>DocuSigned by:</small> <u>Sarah Ball</u> <small>66B60703664144A...</small>
Printed Name: Tong Oan, MD	Printed Name: <u>Sarah Ball</u>
Title: _____	Title: <u>Associate Director</u>
Date: _____	Date: <u>6/17/2020</u>

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**Exhibit A
Data Description**

VISION DATA ELEMENTS CODE BOOK