Exhibit 4

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CDC FREEDOM OF INFORMATION ACT APPEAL

SUBMITTED VIA EMAIL July 13, 2022

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: Appeal of FOIA Request Case No. 22-00235-FOIA (IR#0601)

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, on November 1, 2021, we submitted a request for records ("**FOIA Request**") from the files of the Centers for Disease Control and Prevention ("**CDC**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). On April 14, 2022, Roger Andoh, CDC/ATSDR FOIA Officer (the "**CDC Officer**") responded to the FOIA Request ("**Final Response**"). ICAN writes now to appeal the Final Response.

A. FOIA Request – 22-00235-FOIA (IR#0601)

On November 1, 2021, ICAN submitted a request to the CDC for the following documents:

> **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 and attached hereto as Exhibit A.**

(**Exhibit 1**.)[1]

[1] All "Exhibits" referenced herein are appended to this letter.

On November 1, 2021, CDC acknowledged the FOIA request and assigned it case number 22-00235-FOIA. (**Exhibit 2**.)

B. CDC's Final Response

On April 14, 2022, CDC responded to ICAN's FOIA request and issued a final response letter. The letter stated in part,

> **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.***

(Emphasis included) (**Exhibit 3**.)

C. Argument

CDC improperly withheld records without invoking any FOIA Exemption, it did not provide ICAN with a proper 'determination' as required under FOIA, and it did not conduct an adequate search for responsive records. For the reasons set forth below, ICAN appeals the Final Response.

1. **CDC Improperly Withheld Records Without Invoking Any FOIA Exemption and Failed to Provide ICAN with a Proper 'Determination' as Required Under FOIA.**

CDC unlawfully withheld records without invoking a FOIA Exemption and did not provide ICAN with an adequate 'determination' as required under FOIA. When the sufficiency of "the release of information under the FOIA" is challenged, "the agency has the burden of showing that requested information comes within a FOIA exemption." *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 904, (D.C. Cir. 1999). An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011).

"[I]n order to make a 'determination' and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and *the reasons for withholding any documents*; and (iii) inform the requester that it can appeal whatever portion of the 'determination' is adverse." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188-89 (D.C. Cir. 2013) (Emphasis added); *see also* 5 U.S.C.§ 552(a)(6)(A)(i) ("notify the person making such request of such determination *and reasons therefor*."). "The statutory requirement that the agency provide 'the reasons' for its 'determination' strongly suggests that the reasons are particularized to the 'determination' — most obviously, the specific exemptions that may apply to certain withheld records." *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d at 186; *see also Khine v. United States Dep't of Homeland Sec.*, 943 F.3d 959, 967-968 (D.C. Cir. 2019) (Court held the agency "satisfied its obligation to 'determine and communicate . . . the reasons for withholding any documents" because they "provided reasons by listing and defining the exemptions that the agency applied to the records" withheld.)

Furthermore, CDC's failure to invoke a FOIA exemption – effectively denying ICAN's request – does not provide the minimal reasoning required to satisfy a proper 'determination' under FOIA. A proper 'determination' requires the agency to provide reasons for withholding any documents. *Citizens for Responsibility & Ethics in Wash,.* at 188-89; *see also* 5 U.S.C.§ 552(a)(6)(A)(i). Such reasonings need to incorporate a FOIA exemption in order to satisfy the agency's obligations under FOIA. *Khine*, 943 F.3d at 967-968. In this instance, CDC's Final Response stated, "no data sets can be provided," effectively denying ICAN's request, but no FOIA Exemption was ever invoked. (**Exhibit 3**.)

In this instance, CDC's Final Response demonstrates the agency withheld records without invoking any FOIA Exemption. Thus, CDC failed to meet its burden to prove that the withheld information falls within the scope of a FOIA exemption. *Pub. Citizen Health Research Grp.*, 185 F.3d at, 904; *American Civil Liberties Union*, 628 F.3d at 619.

Beyond CDC's failure to invoke a FOIA Exemption, the reasoning for its denial of ICAN's request is not justified. CDC's Final Response cites a data use agreement that prohibits the "copy, sell, rent, license, lease, or loan the Data covered by this Agreement to any person or entity" as justification for denying ICAN's request for "all data sets" for the particular study cited in ICAN's request ("**study of interest**"). (**Exhibit 3 & 1**.) CDC provided a copy of the data use agreement it cited in its Final Response. The first paragraph of this agreement identifies the parties of the agreement: Children's Hospital, Colorado – a Colorado not for profit corporation ("Provider") and

Westat, Inc. a State of Delaware corporation ("Recipient"). (**Exhibit 3**.) However, the study of interest – that ICAN wanted "all data sets" for – stated,

> **CDC used data from the VISION Network* to examine hospitalizations in adults with COVID-19–like illness and compared the odds of receiving a positive SARS-CoV-2 test result, and thus having laboratory-confirmed COVID-19, between unvaccinated patients with a previous SARS-CoV-2 infection occurring 90–179 days before COVID-19–like illness hospitalization, and patients who were fully vaccinated with an mRNA COVID-19 vaccine 90–179 days before hospitalization with no previous documented SARS-CoV-2 infection . . . .**
> **To compare the early protection against COVID-19 conferred by SARS-CoV-2 infection and by receipt of mRNA COVID-19 vaccines (i.e., 90–179 days after infection or vaccination), the VISION Network collected data from 187 hospitals across nine states during January–September 2021.**

(**Exhibit 1**.)

At the end of the study of interest, a footnote regarding the VISION Network stated,

> *** Funded by CDC, the VISION Network includes Columbia University Irving Medical Center (New York), HealthPartners (Minnesota and Wisconsin), Intermountain Healthcare (Utah), Kaiser Permanente Northern California (California), Kaiser Permanente Northwest (Oregon and Washington), Regenstrief Institute (Indiana), and University of Colorado (Colorado).**

(**Exhibit 1**.)

The reasoning in CDC's Final Response does not adequately explain how a data use agreement between Children's Hospital, Colorado and Westat, Inc. can justify withholding all other data sets involved within the study of interest.

Lastly, as far as CDC's Final Response does recognize the involvement of the Vision Network, and the responsive data sets it may possess, CDC provides only a limited and conclusory response. In the Final Response CDC stated,

> **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.***

(**Exhibit 3**.)

The link provided above contains a single page and appears to involve a single study. It's unclear from the CDC's statement above whether the particular data sharing agreement provided is an example of one generally, or one directly connected to the study of interest. Moreover, nothing in the Final Response provides any indication that every data set involved in the study of interest is protected by a data use agreement. For example, new data sets may have been created (i.e., by agency actors) from the aggregation or further synthesis of the original data sets, and thus may not be subject to a data use agreement.

Therefore, for all the foregoing reasons, CDC has not provided ICAN with a proper 'determination' as required under FOIA. *Citizens for Responsibility & Ethics in Wash,. At* 188-89; *see also* 5 U.S.C.§ 552(a)(6)(A)(i). ICAN cannot adequately challenge the legitimacy of the denial of its request until CDC provides sufficient reasoning for its denial; including the invocation of a FOIA Exemption. Thus, CDC has improperly withheld records. *Pub. Citizen Health Research Grp.*, 185 F.3d at, 904; *American Civil Liberties Union*, 628 F.3d at 619.

2. The CDC Failed to Conduct an Adequate Search

CDC has failed to conduct an adequate search of the requested records. An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. E.P.A.*, 767 F.2d 569, 571 (9th Cir. 1985) (quoting *Weisberg v. U.S. Dep't. of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984)) (internal quotation marks omitted). "An agency fulfills its obligations under FOIA if it can demonstrate *beyond material doubt* that its search was reasonably calculated to uncover all relevant documents." *Defs. of Wildlife v. United States Border Patrol,* 623 F. Supp. 2d 83, 91 (D.D.C. 2009) (quoting *Valencia-Lucena v. U.S. Coast Guard,* 180 F.3d 321, 325 (D.C. Cir. 1999)) (emphasis added). To satisfy its FOIA obligations, an agency needs to adequately describe the scope and methods of its searches, which can reasonably be expected to uncover the records sought and demonstrate that the places most likely to contain responsive materials were searched. *Davidson v. E.P.A*., 121 F. Supp. 2d 38, 39 (D.D.C. 2000). At minimum, the agency must specify "what records were searched, by whom, and through what process." *Steinberg v. U.S. Dep't of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994).

CDC's search was inadequate because it did not specify what records were searched, by whom, and through what process. *Steinberg*, 23 F.3d 552. Therefore, CDC did not fulfill its obligations under FOIA of demonstrating beyond material doubt that its search was reasonably calculated to uncover all relevant documents. *Valencia-Lucena,* 180 F.3d at 325.

D. <u>Appellate Request</u>

Given the foregoing, ICAN hereby appeals and requests that the documents responsive to the FOIA Requests be produced within 20 days of this appeal. Thank you for your time and

attention to this matter. If you require any additional information, please contact us at **(212) 532-1091** or through email at **foia@sirillp.com**.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Enclosures

Exhibit 1

Siri | Glimstad

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FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL November 1, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

Re: Data Sets for Study Comparing Infection-Induced and Vaccine-Inducted Immunity (IR#0601)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

> **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 and attached hereto as Exhibit A.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of its mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through its website, and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe

any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Gabrielle G. Palmer
Gabrielle G. Palmer, Esq.

Exhibit A

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
October 29, 2021

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

Catherine H. Bozio, PhD[1]; Shaun J. Grannis, MD[2,3]; Allison L. Naleway, PhD[4]; Toan C. Ong, PhD[5]; Kristen A. Butterfield, MPH[6]; Malini B. DeSilva, MD[7]; Karthik Natarajan, PhD[8,9]; Duck-Hye Yang, PhD[6]; Suchitra Rao, MBBS[5]; Nicola P. Klein, MD, PhD[10]; Stephanie A. Irving, MHS[4]; Brian E. Dixon, PhD[2,11]; Kristin Dascomb, MD, PhD[12]; I-Chia Liao MPH[13]; Sue Reynolds, PhD[1]; Charlene McEvoy, MD[7]; Jungmi Han[8]; Sarah E. Reese, PhD[6]; Ned Lewis, MPH[10]; William F. Fadel, PhD[2,11]; Nancy Grisel, MPP[12]; Kempapura Murthy MBBS[13]; Jill Ferdinands, PhD[1]; Anupam B. Kharbanda, MD[14]; Patrick K. Mitchell, ScD[6]; Kristin Goddard, MPH[10]; Peter J. Embi, MD[3,15]; Julie Arndorfer, MPH[12]; Chandni Raiyani, MPH[13]; Palak Patel, MBBS[1]; Elizabeth A. Rowley, DrPH[6]; Bruce Fireman, MA[10]; Nimish R. Valvi, DrPH, MBBS[2]; Eric P. Griggs, MPH[1]; Matthew E. Levy, PhD[6]; Ousseny Zerbo, PhD[10]; Rachael M. Porter, MPH[1]; Rebecca J. Birch, MPH[6]; Lenee Blanton, MPH[1]; Sarah W. Ball, ScD[6]; Andrea Steffens, MPH[1]; Natalie Olson, MPH[1]; Jeremiah Williams, MPH[1]; Monica Dickerson, MPH[1]; Meredith McMorrow, MD[1]; Stephanie J. Schrag, DPhil[1]; Jennifer R. Verani, MD[1]; Alicia M. Fry, MD[1]; Eduardo Azziz-Baumgartner, MD[1]; Michelle Barron, MD[5]; Manjusha Gaglani, MBBS[13]; Mark G. Thompson, PhD[1]; Edward Stenehjem, MD[12]

Previous infection with SARS-CoV-2 (the virus that causes COVID-19) or COVID-19 vaccination can provide immunity and protection from subsequent SARS-CoV-2 infection and illness. CDC used data from the VISION Network* to examine hospitalizations in adults with COVID-19–like illness and compared the odds of receiving a positive SARS-CoV-2 test result, and thus having laboratory-confirmed COVID-19, between unvaccinated patients with a previous SARS-CoV-2 infection occurring 90–179 days before COVID-19–like illness hospitalization, and patients who were fully vaccinated with an mRNA COVID-19 vaccine 90–179 days before hospitalization with no previous documented SARS-CoV-2 infection. Hospitalized adults aged ≥18 years with COVID-19–like illness were included if they had received testing at least twice: once associated with a COVID-19–like illness hospitalization during January–September 2021 and at least once earlier (since February 1, 2020, and ≥14 days before that hospitalization). Among COVID-19–like illness hospitalizations in persons whose previous infection or vaccination occurred 90–179 days earlier, the odds of laboratory-confirmed COVID-19 (adjusted for sociodemographic and health characteristics) among unvaccinated, previously infected adults were higher than the odds among fully vaccinated recipients of an mRNA COVID-19 vaccine with no previous documented infection (adjusted odds ratio [aOR] = 5.49; 95% confidence interval [CI] = 2.75–10.99). These findings suggest that among hospitalized adults with COVID-19–like illness whose previous infection or vaccination occurred 90–179 days earlier, vaccine-induced immunity was more protective than infection-induced immunity against laboratory-confirmed COVID-19. All eligible persons should be vaccinated against COVID-19 as soon as possible, including unvaccinated persons previously infected with SARS-CoV-2.

To compare the early protection against COVID-19 conferred by SARS-CoV-2 infection and by receipt of mRNA COVID-19 vaccines (i.e., 90–179 days after infection or vaccination), the VISION Network collected data from 187 hospitals across nine states during January–September 2021 (*1*). Eligible hospitalizations were defined as those among adults aged ≥18 years who had received SARS-CoV-2 molecular testing (from 14 days before to 72 hours after admission) and had a COVID-19–like illness discharge diagnosis†

* Funded by CDC, the VISION Network includes Columbia University Irving Medical Center (New York), HealthPartners (Minnesota and Wisconsin), Intermountain Healthcare (Utah), Kaiser Permanente Northern California (California), Kaiser Permanente Northwest (Oregon and Washington), Regenstrief Institute (Indiana), and University of Colorado (Colorado).

† Medical events with a discharge code consistent with COVID-19–like illness were included. COVID-19–like illness diagnoses included acute respiratory illness (e.g., COVID-19, respiratory failure, or pneumonia) or related signs or symptoms (cough, fever, dyspnea, vomiting, or diarrhea) using diagnosis codes from the *International Classification of Diseases, Ninth Revision* and *International Classification of Diseases, Tenth Revision*.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

during January–September 2021. Eligible patients had also been tested at least once since February 1, 2020. To limit the analysis to patients with access to SARS-CoV-2 testing before hospitalization, patients who did not receive SARS-CoV-2 testing ≥14 days before hospitalization were excluded.

Two exposure groups were defined based on COVID-19 vaccination status and previous SARS-CoV-2 infection. Vaccination status was documented in electronic health records and immunization registries. Previous infection was ascertained based on SARS-CoV-2 testing from rapid antigen tests or molecular assays (e.g., real-time reverse transcription–polymerase chain reaction) performed before mRNA vaccination and ≥14 days before admission; testing performed after February 2020 was primarily within network partners' medical facilities. Adults were considered unvaccinated with a previous SARS-CoV-2 infection if no COVID-19 vaccine doses were received and if the most recent positive SARS-CoV-2 test result occurred ≥90 days before hospitalization. Adults were considered fully vaccinated with an mRNA COVID-19 vaccine with no previous documented infection if the second dose of Pfizer-BioNTech (BNT162b2) or Moderna (mRNA-1273) mRNA vaccine was received ≥14 days before the index test date[§] and if they had been tested since February 1, 2020, and had no positive test results ≥14 days before hospitalization. Patients were excluded if they had received 1 mRNA vaccine dose only, received the second dose <14 days before index test date, or received the Janssen (Johnson & Johnson [Ad26.COV2]) vaccine (because of sparse data). To reduce the chance that the hospitalization was related to an ongoing SARS-CoV-2 infection, patients were also excluded from the previous infection group if their most recent previous positive test result occurred 14–89 days before hospitalization.[¶]

The outcome of laboratory-confirmed COVID-19 was defined as COVID-19–like illness and a positive SARS-CoV-2 result from molecular testing. Among patients hospitalized with COVID-19–like illness whose previous infection or completion of vaccination occurred 90–179 days earlier, the odds of laboratory-confirmed COVID-19 were compared between previously infected persons and fully vaccinated mRNA COVID-19 vaccine recipients. aORs and 95% CIs were calculated using multivariable logistic regression, adjusted for age, geographic region, calendar time (days from January 1 to hospitalization), and local virus circulation, and weighted based on propensity to be in the vaccinated category (*1*,*2*). Established methods were used to calculate weights to account for differences in sociodemographic and health characteristics between groups (*3*). Separate weights were calculated for each model. aORs were stratified by mRNA vaccine product and age group.

Three secondary analyses were also conducted. First, the impact of whether and how the time interval since previous infection or full vaccination was adjusted was examined. Specifically, any time since either previous infection or completion of vaccination was considered. Then, previously infected patients were limited to those with more recent infections (i.e., 90–225 days before hospitalization [the lowest two tertiles of number of days since infection]), and fully vaccinated patients were limited to those with the longest interval since completion of vaccination (i.e., receipt of second mRNA vaccine dose 45–213 days before hospitalization [the highest two tertiles of number of days since vaccination]). Then, number of days since previous infection or completion of vaccination, rather than calendar time, was adjusted in the model. For the next secondary analysis, aORs for hospitalizations that occurred before and during SARS-CoV-2 B.1.617.2 (Delta) variant predominance (June–September 2021) were compared, beginning on the date the Delta variant accounted for >50% of sequenced isolates in each medical facility's state (*2*). Finally, effect modification was assessed by mRNA vaccine product or by age group; p-values <0.2 were considered indicative of a statistically significant difference in aOR by product or age, similar to previous modeling studies of effect modification (*4*). All analyses were conducted using SAS (version 9.4; SAS Institute) and R (version 4.0.2; R Foundation). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[**]

During January 1–September 2, 2021, a total of 201,269 hospitalizations for COVID-19–like illness were identified; 139,655 (69.4%) patients were hospitalized after COVID-19 vaccines were generally available to persons in their age group within their geographic region. Molecular testing for SARS-CoV-2 was performed for 94,264 (67.5%) patients with COVID-19–like illness hospitalizations. Among these patients, 7,348 (7.8%) had at least one other SARS-CoV-2 test result ≥14 days before hospitalization and met criteria for either of the two exposure categories: 1,020 hospitalizations were among previously infected and unvaccinated persons, and 6,328 were among fully vaccinated and previously uninfected patients (Table 1).

Laboratory-confirmed SARS-CoV-2 infection was identified among 324 (5.1%) of 6,328 fully vaccinated persons and among 89 of 1,020 (8.7%) unvaccinated, previously infected persons. A higher proportion of previously infected than vaccinated patients were aged 18–49 years (31% versus 9%), Black (10% versus 7%), and Hispanic (19% versus 12%).

[§] Index test date was defined as the date of respiratory specimen collection associated with the most recent positive or negative SARS-CoV-2 test result before the hospitalization or the hospitalization date if testing only occurred after admission.

[¶] https://www.cdc.gov/coronavirus/2019-ncov/php/invest-criteria.html

[**] 45 C.F.R. part 46; 21 C.F.R. part 56.

TABLE 1. Characteristics of COVID-19–like illness hospitalizations* among unvaccinated adults with a SARS-CoV-2 infection occurring 90–179 days before the index test date† and among adults who were fully vaccinated§ 90–179 days before the index test date† without a previous documented SARS-CoV-2 infection — nine states,¶ January–September 2021

Characteristic	No. (column %)		Standardized mean or proportion difference**
	Unvaccinated with previous SARS-CoV-2 infection	Fully vaccinated§ without previous documented infection	
All hospitalizations with COVID-19–like illness	**1,020 (100)**	**6,328 (100)**	**NA**
SARS-CoV-2 test result associated with COVID-19–like illness hospitalization			
Positive	89 (9)	324 (5)	0.14
Negative	931 (91)	6,004 (95)	
Sex			
Male	405 (40)	2,905 (46)	0.13
Female	615 (60)	3,423 (54)	
Age group, yrs			
18–49	313 (31)	560 (9)	0.74
50–64	243 (24)	865 (14)	
65–74	207 (20)	1,757 (28)	
75–84	177 (17)	2,018 (32)	
≥85	80 (8)	1,128 (18)	
Race, irrespective of ethnicity			
White	647 (63)	4,356 (69)	0.24
Black	100 (10)	452 (7)	
Other††	71 (7)	686 (11)	
Unknown	202 (20)	834 (13)	
Ethnicity, irrespective of race			
Hispanic	189 (19)	756 (12)	0.20
Non-Hispanic	695 (68)	4,458 (70)	
Unknown	136 (13)	1,114 (18)	
Month of index test date†			
January	11 (1)	0 (—)	2.10
February	41 (4)	0 (—)	
March	114 (11)	0 (—)	
April	245 (24)	6 (0)	
May	294 (29)	235 (4)	
June	184 (18)	1,300 (21)	
July	99 (10)	2,731 (43)	
August	31 (3)	2,049 (32)	
September	1 (0)	7 (0)	

See table footnotes on the next page.

Among COVID-19–like illness hospitalizations in persons whose previous infection or vaccination occurred 90–179 days earlier, the odds of laboratory-confirmed COVID-19 were higher among previously infected, unvaccinated patients than among fully vaccinated patients (aOR = 5.49; 95% CI = 2.75–10.99) (Table 2). In secondary analyses, the aORs that examined the impact of whether and how time since infection or vaccination was adjusted and that stratified hospitalizations before and during Delta variant predominance were all similar to the primary aOR estimate. For product- and age group–specific estimates, sparse data limited the precision of these aORs. However, an assessment of effect modification indicated the aOR of laboratory-confirmed COVID-19 was higher for previously infected patients compared with patients vaccinated with Moderna (aOR = 7.30) than compared with patients vaccinated with Pfizer-BioNTech (aOR = 5.11) during January–September (p = 0.02). Similarly, the interaction term for exposure group by age indicated that the aOR was higher for patients aged ≥65 years (aOR = 19.57) than for those aged 18–64 years (aOR = 2.57) (interaction term, p = 0.05).

Discussion

In this multistate analysis of hospitalizations for COVID-19–like illness among adults aged ≥18 years during January–September 2021 whose previous infection or vaccination occurred 90–179 days earlier, the adjusted odds of laboratory-confirmed COVID-19 were higher among unvaccinated and previously infected patients than among those who were fully vaccinated with 2 doses of an mRNA COVID-19 vaccine without previous documentation of a SARS-CoV-2 infection. Secondary analyses that did not adjust for time since infection or vaccination or adjusted time since infection or vaccination differently as well as before and during Delta variant predominance produced similar results. These findings are consistent with evidence that neutralizing antibody titers after receipt of 2 doses of mRNA COVID-19 vaccine are high (*5*,*6*); however, these findings differ from those of a retrospective records-based

TABLE 1. (*Continued*) Characteristics of COVID-19–like illness hospitalizations* among unvaccinated adults with a SARS-CoV-2 infection occurring 90–179 days before the index test date† and among adults who were fully vaccinated§ 90–179 days before the index test date† without a previous documented SARS-CoV-2 infection — nine states,¶ January–September 2021

Characteristic	No. (column %)		Standardized mean or proportion difference**
	Unvaccinated with previous SARS-CoV-2 infection	Fully vaccinated§ without previous documented infection	
Site			
Columbia University	53 (5)	238 (4)	0.73
HealthPartners	22 (2)	94 (1)	
Intermountain Healthcare	117 (11)	454 (7)	
Kaiser Permanente Northern California	254 (25)	3,614 (57)	
Kaiser Permanente Northwest	30 (3)	250 (4)	
Regenstrief Institute	390 (38)	1,145 (18)	
University of Colorado	154 (15)	533 (8)	
Time since either previous SARS-CoV-2 infection or full mRNA vaccination until COVID-19–like illness index test date, days			
90–119	367 (36)	3,325 (53)	0.42
120–149	353 (35)	2,101 (33)	
150–179	300 (29)	902 (14)	
COVID-19 vaccination status			
Unvaccinated	1,020 (100)	0 (—)	NA
Pfizer-BioNTech (BNT162b2)	0 (—)	3,736 (59)	
Moderna (mRNA-1273)	0 (—)	2,592 (41)	

Abbreviation: NA = not applicable.

* Medical events with a discharge code consistent with COVID-19–like illness were included. COVID-19–like illness diagnoses included acute respiratory illness (e.g., COVID-19, respiratory failure, or pneumonia) or related signs or symptoms (cough, fever, dyspnea, vomiting, or diarrhea) using diagnosis codes from the *International Classification of Diseases, Ninth Revision* and *International Classification of Diseases, Tenth Revision*. Clinician-ordered molecular assays (e.g., real-time reverse transcription–polymerase chain reaction) for SARS-CoV-2 occurring ≤14 days before to <72 hours after hospital admission were included.

† Index test date was defined as the date of respiratory specimen collection associated with the most recent positive or negative SARS-CoV-2 test result before the hospitalization or the hospitalization date if testing only occurred after the admission.

§ Full vaccination was defined as receipt of the second dose of Pfizer-BioNTech or Moderna mRNA vaccine ≥14 days before the index test date.

¶ Partners contributing hospitalizations were in California, Colorado, Indiana, Minnesota and Wisconsin, Oregon and Washington, Utah, and New York.

** In comparing characteristics between unvaccinated adults with a previous infection and fully vaccinated adults without a previous documented infection, a standardized mean or proportion difference >0.2 was considered noteworthy. After balancing characteristics that differed between the two comparison groups, the standardized mean or proportion differences were ≤0.06.

†† Other race includes Asian, Hawaiian or Other Pacific islander, American Indian or Alaskan Native, Other not listed, and multiple races.

cohort study in Israel,†† which did not find higher protection for vaccinated adults compared with those with previous infection during a period of Delta variant circulation. This variation is possibly related to differences in the outcome of interest and restrictions on the timing of vaccination. The Israeli cohort study assessed any positive SARS-CoV-2 test result, whereas this study examined laboratory-confirmed COVID-19 among hospitalized patients. The Israeli cohort study also only examined vaccinations that had occurred 6 months earlier, so the benefit of more recent vaccination was not examined. This report focused on the early protection from infection-induced and vaccine-induced immunity, though it is possible that estimates could be affected by time. Understanding infection-induced and vaccine-induced immunity over time is important, particularly for future studies to consider.

In this study, the benefit of vaccination compared with infection without vaccination appeared to be higher for recipients of Moderna than Pfizer-BioNTech vaccine, which is consistent with a recent study that found higher vaccine effectiveness against COVID-19 hospitalizations for Moderna vaccine recipients than for Pfizer-BioNTech vaccine recipients (*7*). In this study, the protective effect of vaccination also trended higher for adults aged ≥65 years than for those aged 18–64 years. However, considering the limited data by both product type and age, additional research is needed on the relative protection of vaccination versus infection without vaccination across demographic groups and vaccine products, as well as vaccination in previously infected persons.

The findings in this report are subject to at least seven limitations. First, although this analysis was designed to compare two groups with different sources of immunity, patients might have been misclassified. If SARS-CoV-2 testing occurred outside of network partners' medical facilities or if vaccinated persons are less likely to seek testing, some positive SARS-CoV-2 test results might have been missed and thus some patients classified as vaccinated and previously uninfected might also have been infected. In addition, despite the high specificity of COVID-19 vaccination status from these data sources, misclassification is possible. Second, the aOR could not be further stratified by time since infection or vaccination because of sparse data and limited ability to control for residual confounding that could be magnified within shorter intervals. The aOR that did not adjust for time might also be subject to residual confounding,

†† https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1

TABLE 2. Adjusted odds ratios* of laboratory-confirmed COVID-19 among hospitalizations in adults with COVID-19–like illness comparing unvaccinated adults with a SARS-CoV-2 infection occurring 90–179 days before the index test date and adults who were fully vaccinated 90–179 days before the index test date without a previous documented SARS-CoV-2 infection — nine states, January–September 2021

Outcome	Total no.	No. (row %) of SARS-CoV-2 positive test results	Adjusted odds ratio (95% CI)
All adults (aged ≥18 years), any COVID-19 mRNA vaccine			
Any mRNA vaccine			
Fully vaccinated† without previous documented infection	**6,328**	324 (5.1)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	**1,020**	89 (8.7)	5.49 (2.75–10.99)
Any mRNA vaccine, no restriction of time since previous infection or completion of vaccination			
Fully vaccinated† without previous documented infection (range of time since vaccination = 0–213 days before hospitalization)	**18,397**	542 (3.0)	Ref
Unvaccinated with a previous SARS-CoV-2 infection (range of time since previous infection = 90–494 days before hospitalization)	**2,085**	130 (6.2)	2.75 (1.90–3.98)
Any mRNA vaccine, examining the potential influence of time since previous infection or completion of vaccination			
Fully vaccinated† without previous documented infection, limited to those with longest period since vaccination (range of time since vaccination = 45–213 days before hospitalization)	**12,231**	458 (3.7)	Ref
Unvaccinated with a previous SARS-CoV-2 infection, limited to those with more recent infections (range of time since previous infection = 90–225 days before hospitalization)	**1,389**	107 (7.7)	3.98 (2.49–6.35)
Any mRNA vaccine, adjusting for time since previous infection or completion of vaccination in model			
Fully vaccinated† without previous documented infection	**6,328**	324 (5.1)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	**1,020**	89 (8.7)	3.22 (1.68–6.20)
By time relative to SARS-CoV-2 B.1.617.2 (Delta) variant predominance			
Before Delta predominance (January–June 2021)			
Fully vaccinated† without previous documented infection	**1,115**	18 (1.6)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	**831**	70 (8.4)	6.11 (2.83–13.16)
During Delta predominance (June–September 2021)**			
Fully vaccinated† without previous documented infection	**5,213**	306 (5.9)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	**189**	19 (10.1)	7.55 (3.45–16.52)
By mRNA vaccine product§			
Pfizer-BioNTech (BNT162b2)			
Fully vaccinated† without previous documented infection	**3,736**	215 (5.8)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	**1,020**	89 (8.7)	5.11 (2.53–10.29)
Moderna (mRNA-1273)			
Fully vaccinated† without previous documented infection	**2,592**	109 (4.2)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	**1,020**	89 (8.7)	7.30 (3.40–15.60)
By age group, yrs¶			
18–64			
Fully vaccinated† without previous documented infection	**1,425**	71 (5.0)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	**556**	49 (8.8)	2.57 (1.42–4.65)
≥65			
Fully vaccinated† without previous documented infection	**4,903**	253 (5.2)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	**464**	40 (8.6)	19.57 (8.34–45.91)

Abbreviations: CI = confidence interval; ref = referent group.

* Odds ratios were adjusted for age, geographic region, calendar time (days since January 1, 2021), and local virus circulation (percentage of SARS-CoV-2 positive results from testing within the counties surrounding the facility on the date of the hospitalization) and balanced using inverse weights on characteristics that differed between the two groups (calculated separately for each odds ratio model) using facility characteristics, sociodemographic characteristics, and underlying medical conditions. Cardiovascular disease was also adjusted in the main model and in the model for Pfizer-BioNTech. Any likely immunosuppression was also included in the model for Moderna. Neuromuscular and respiratory conditions were also adjusted in the model for adults aged ≥65 years. Number of days since previous infection or completion of vaccination, instead of calendar time, was adjusted in the model within the stated secondary analysis.

† Full vaccination was defined as receipt of the second dose of Pfizer-BioNTech or Moderna mRNA vaccine ≥14 days before the index test date.

§ P-value from assessment of effect modification by mRNA product was 0.02.

¶ P-value for interaction term for exposure group by age group was 0.05.

** SARS-CoV-2 B.1.617.2 (Delta) variant predominance began on the date the Delta variant accounted for >50% of sequenced isolates in each medical facility's state.

https://doi.org/10.15585/mmwr.mm7037e2

particularly related to waning of both types of immunity. Third, selection bias might be possible if vaccination status influences likelihood of testing and if previous infection influences the likelihood of vaccination. Previous work from the VISION network did not identify systematic bias in testing by vaccination status, based on data through May 2021 (*1*). Fourth, residual confounding might exist because the study did not measure or adjust for behavioral differences between the comparison groups that could modify the risk of the outcome. Fifth, these results might not be generalizable to nonhospitalized patients who have different access to medical care or different health care–seeking behaviors, particularly outside of the nine states

covered. Sixth, the statistical model incorporated the use of a weighted propensity score method which is subject to biases in estimates or standard errors if the propensity score model is misspecified. Numerous techniques were used to reduce potential suboptimal specification of the model, including but not limited to including a large set of covariates for machine learning estimation of propensity scores, including covariates in both regression and propensity models, ensuring large sample sizes and checking stability of weights, and conducting secondary analyses to assess robustness of results. Finally, the study assessed COVID-19 mRNA vaccines only; findings should not be generalized to the Janssen vaccine.

In this U.S.-based epidemiologic analysis of patients hospitalized with COVID-19–like illness whose previous infection or vaccination occurred 90–179 days earlier, vaccine-induced immunity was more protective than infection-induced immunity against laboratory-confirmed COVID-19, including during a period of Delta variant predominance. All eligible persons should be vaccinated against COVID-19 as soon as possible, including unvaccinated persons previously infected with SARS-CoV-2.

Summary

What is already known about this topic?

Previous infection with SARS-CoV-2 or COVID-19 vaccination can provide immunity and protection against subsequent SARS-CoV-2 infection and illness.

What is added by this report?

Among COVID-19–like illness hospitalizations among adults aged ≥18 years whose previous infection or vaccination occurred 90–179 days earlier, the adjusted odds of laboratory-confirmed COVID-19 among unvaccinated adults with previous SARS-CoV-2 infection were 5.49-fold higher than the odds among fully vaccinated recipients of an mRNA COVID-19 vaccine who had no previous documented infection (95% confidence interval = 2.75–10.99).

What are the implications for public health practice?

All eligible persons should be vaccinated against COVID-19 as soon as possible, including unvaccinated persons previously infected with SARS-CoV-2.

Acknowledgments

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Exhibit 2

Annalise Beube

From: Centers for Disease Control and Prevention / Agency for Toxic Substances and Disease Registry <foiarequests@cdc.gov>
Sent: Monday, November 1, 2021 1:24 PM
To: S&G Information Request Staff
Subject: Status Update for Request #22-00235-FOIA

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Elizabeth Brehm,

The status of your FOIA request #22-00235-FOIA has been updated to the following status 'Received'. To log into the CDC FOIA Public Access Link click on the Application URL below.

https://foia.cdc.gov/

Sincerely,
FOIA

Exhibit 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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:

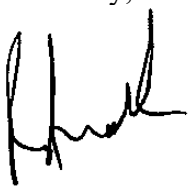
> *No data sets can be provided based on the data use agreement* [attached as a courtesy to you]. *Specifically see page 3, section g, which includes the following statement regarding third parties:*
>
> > *"**Third-Party Access**. Recipient must not (nor permit others to) copy, sell, rent, license, 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.

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,



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 statues and regulations of the state(s) or jurisdiction(s) in which the PROVIDER operates as well as all applicable Federal statues, 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.

DATA USE AGREEMENT
LIMITED DATA SET

16. Term and Termination.

a. The term of this Agreement shall commence upon the Effective Data 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

DATA USE AGREEMENT
LIMITED DATA SET

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: DocuSigned by: Patricia Shifflett 94EBCEF56D6E40E...
Printed Name: Erin Sandene	Printed Name: Patricia Shifflett
Title: Director of Research Operations and Administration	Title: Vice President
Understood and acknowledged **Provider Primary Investigator ("PI")**	*Understood and acknowledged* **Recipient Primary Investigator ("PI')**
Signature: _____	Signature: DocuSigned by: Sarah Ball 66B60703664144A...
Printed Name: Tong Oan, MD	Printed Name: Sarah Ball
Title: _____	Title: Associate Director
Date: _____	Date: 6/17/2020

DATA USE AGREEMENT
LIMITED DATA SET

Exhibit A
Data Description

VISION DATA ELEMENTS CODE BOOK